EXECUTIVE SUMMARY

This publication presents the methods and resources needed to conduct a Cleaner Technologies Substitutes Assessment (CTSA), a methodology for evaluating the comparative risk, performance, cost, and resource conservation of alternatives to chemicals currently used by specific industry sectors. The CTSA methodology was developed by the U.S. Environmental Protection Agency (EPA) Design for the Environment (DfE) Program, the University of Tennessee Center for Clean Products and Clean Technologies, and other partners in voluntary, cooperative, industry-specific pilot projects.

Part I of this publication is an overview of the CTSA process, including the preparatory steps leading up to a CTSA, and the types of data collected and analyses performed in a CTSA. Part II describes the data sets and analyses in more detail.

Businesses operating in the 1990s face a variety of competing demands — maintaining high quality at low cost, staying competitive in a global marketplace, and meeting consumer preferences and regulatory demands for reduced environmental impacts. Designing for the environment is an effective strategy for organizing and managing these challenging demands.

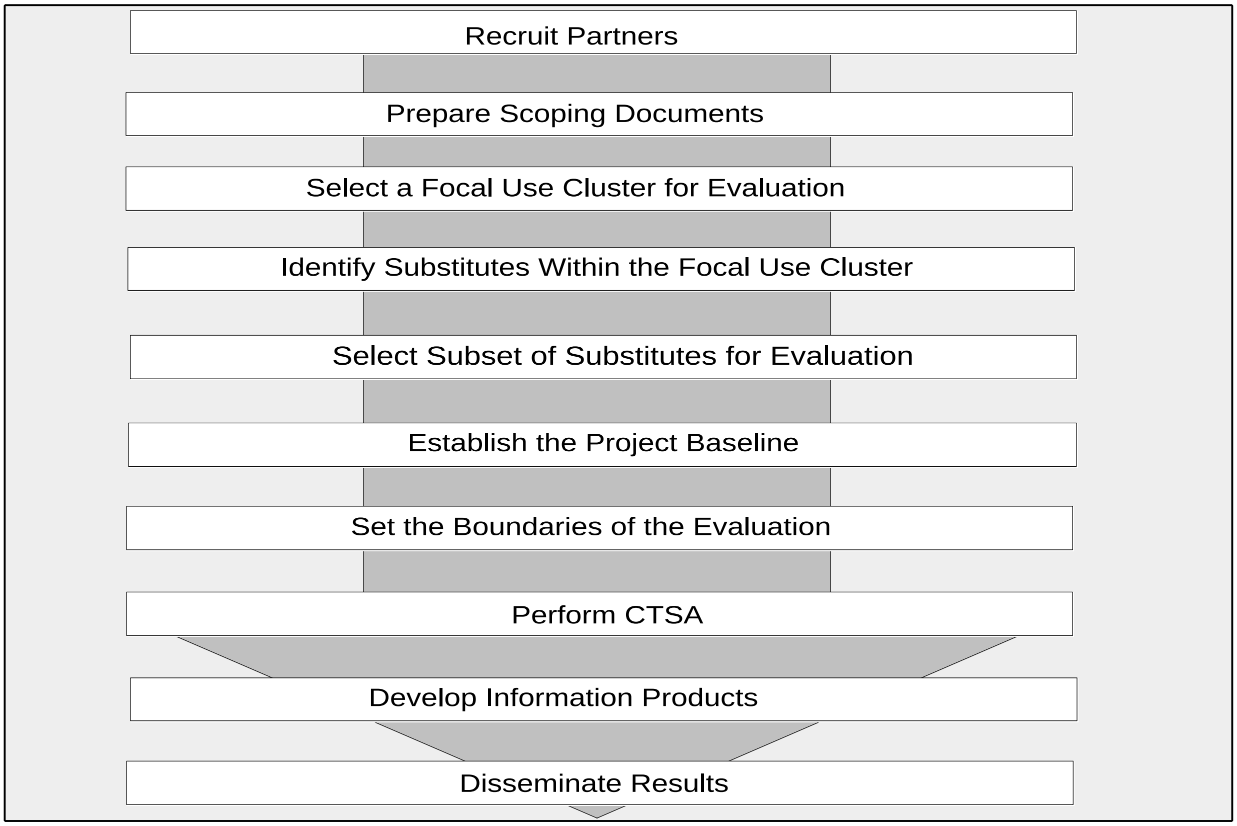
The EPA Office of Pollution Prevention and Toxics created the DfE program in 1991 to help businesses incorporate environmental considerations into the design and redesign of products, processes, and technical and management system. DfE projects include broad institutional efforts aimed at changing general business practices, as well as voluntary, cooperative projects with trade associations and businesses in specific industries.

A typical industry project includes developing a CTSA and a communication and implementation strategy. The CTSA *methodology* has grown out of DfE industry projects, which are cooperative, joint efforts with trade associations, businesses, public-interest groups, and academia to assist businesses in specific industries to select more environmentally-sound products, processes and technologies. A CTSA *document* is the repository for the technical information developed by a particular DfE project, including detailed environmental, economic, and performance information on traditional and alternative chemicals, manufacturing methods and technologies. A CTSA does not recommend alternatives or make value judgements concerning an alternative. Instead, the goal is to provide businesses with information to make environmentally informed choices and design for the environment.

STEPS IN A CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT PROJECT

Figure ES-1 illustrates the basic steps leading up to and following a CTSA. First, DfE project organizers recruit partners from various stakeholder communities to create a project team. Past CTSA project teams have been convened by EPA together with trade associations, industry research organizations, or other concerned representatives of the business community seeking to reduce the environmental impacts of their products and manufacturing processes. A goal of this publication, however, is to provide businesses, public-interest groups, and other stakeholders the information they need to perform comparative evaluations with or without the direct participation of EPA.

FIGURE ES-1: STEPS IN A CTSA PROJECT



Once a project team is assembled, the team members develop an Industry and Use Cluster Profile document and a Regulatory Profile document to help define the project focus. An Industry and Use Cluster Profile gives market data for the industry, describes technological trends, and presents a summary of key industry processes, individual steps within processes, chemicals typically used in each step, and a preliminary list of substitutes for each step. These sets of substitutes make up the *use clusters* for the industry. A *use cluster* is a product- or process-specific application in which a set of chemical products, technologies, or processes can substitute for one another to perform a particular function. A Regulatory Profile identifies the principal federal environmental regulations that may affect the industry under study and the factors that determine which regulations apply to any particular operation. The project team typically selects the use cluster with the greatest opportunities for environmental improvement for the detailed analysis of a CTSA.

Identifying Substitutes

Additional substitutes are identified as a CTSA progresses and more information is gained about the characteristics of the use cluster and of the industry. All stakeholder groups are potential sources of information about additional substitutes. For example, manufacturers and suppliers of chemical products and technologies play an important role in substitutes identification, since they frequently have an up-to-date understanding of current industry trends, and emerging products or technologies. Also, the participation of suppliers in the CTSA process is essential to developing information on chemical product formulations, which is used in the risk characterization

Trade associations frequently track new developments; universities and other research organizations may be involved in applied or basic research on new alternatives. Public-interest groups concerned about human health risk or other environmental impacts may have independently searched for options to prevent pollution. DfE project teams use all of these resources to develop a *substitutes tree*. A *substitutes tree* is a graphical depiction of the substitute or alternative chemical products, technologies, or processes that form the use cluster and their relationship to each other within the functional category defined by the use cluster. In a DfE project, the terms *substitute* and *alternative* are used interchangeably to mean any traditional or novel chemical product, technology, or process that can be used to perform a particular function.

Establishing the Baseline and Boundaries of the Evaluation

Due to time and resource constraints, the project team may select a subset of substitutes for detailed evaluation in a CTSA. Past CTSAs have evaluated a subset of currently available substitutes, including substitutes that have not yet been widely adopted by industry. The project baseline(s) are substitute(s) that are currently industry standard practice or familiar to most of the industry, which come from this subset. With a familiar baseline as the basis for comparison, the comparative data on risk, performance, cost, and conservation developed through the project will be understandable to the majority of industry.

Once the subset of substitutes and baseline(s) are established, the boundaries of the evaluation are set by identifying the life cycle stages and types of environmental impacts (i.e., human health and environmental risk to workers, energy impacts, etc.) of greatest concern. Past CTSAs have focussed on the areas where the project partners can most influence change, in the use and disposal of chemicals at operating facilities. The project team is then ready to perform the detailed data collection and analysis needed to develop a CTSA (see below).

Disseminating Results

Following completion of a CTSA, DfE project partners develop a variety of outreach tools to communicate CTSA results. These may include fact sheets, bulletins, pollution prevention case studies, software, videos, and training materials. CTSA results are disseminated to businesses and other stakeholders to encourage businesses to consider and use cleaner products, processes, and technologies.

DEVELOPING A CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT

A CTSA uses *information modules* to develop as complete and systematic a picture as possible of the comparative risk, competitiveness (i.e., performance, cost, etc.), and resource conservation of the substitutes in a use cluster. An *information module* is a standard analysis or set of data designed to build on or feed into other information modules to form an overall assessment of the substitutes. A CTSA records and presents facts collected in the information modules, but does not make value judgements or advocate particular choices.

Figure ES-2 describes the basic process for developing a CTSA. The technical work typically starts with the collection of basic chemical properties and process information, followed by the collection of risk, competitiveness, and conservation data. At the same time, the project team develops methodologies for data analysis to ensure that all necessary data are collected. The next step is to analyze the collected data to determine the relative human health and environmental risk, competitiveness, and resource conservation of alternatives. Past DfE projects have shown that the choice of an alternative will frequently involve making trade-offs. For example, when compared to the baseline, an alternative may cost slightly more, but have substantially reduced risk. The trade-off issues are evaluated to determine the relative benefits and costs of an alternative from both an individual perspective and a societal perspective. All of this is performed through the completion of 22 information modules, shown as bullets in Figure ES-3.

Table ES-1 presents an overview of each of the information modules listed in Figure ES-3. Part II of this publication describes each of these modules in more detail, including a summary of the step-by-step process for completing a module, and sources of data, analytical models, and previously published guidance helpful in completing a module. Since the CTSA process is applicable to numerous industry sectors, the module descriptions were developed to provide basic information suitable for a wide audience with a broad range of information needs. The descriptions should give a DfE project team a basic understanding of the analytical concepts and methodology for completing a module, but they do not give a complete accounting of all of the assumptions, analytical methods or steps required for some of the more complicated analyses, such as exposure assessment.

For the more complicated analyses, a DfE project team should refer to published guidance, with references provided in the module descriptions. In addition, many of the modules describe analyses or data evaluations that cannot be performed without substantial expertise and experience (e.g., the Human Health Hazards Summary, Environmental Hazards Summary, Exposure Assessment, and Risk Characterization modules). For these and other analyses, users of this publication who do not have the necessary expertise are urged to seek outside assistance.

FIGURE ES-2: STEPS TO DEVELOP A CTSA

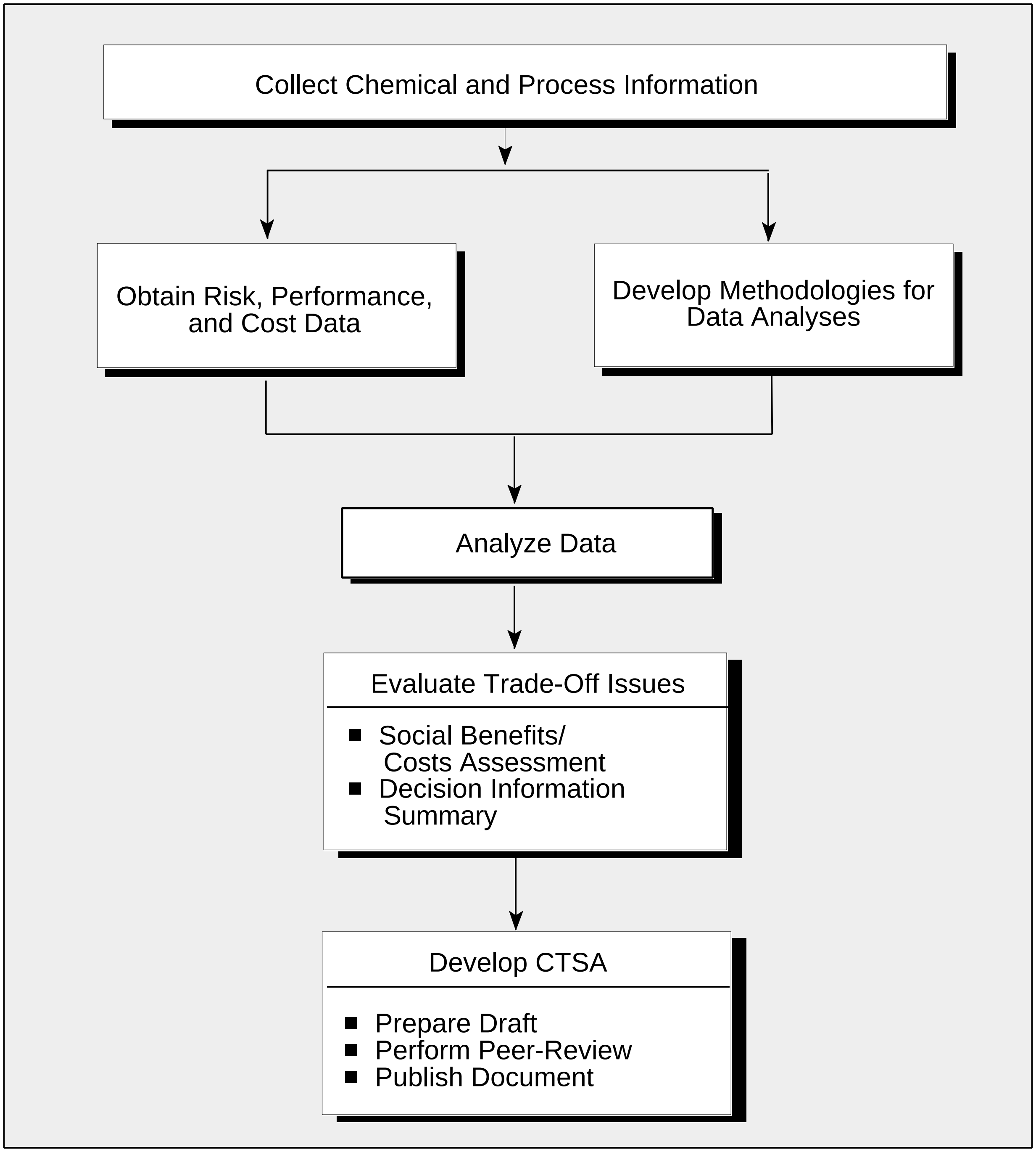


FIGURE ES-3: CTSA INFORMATION FLOWS

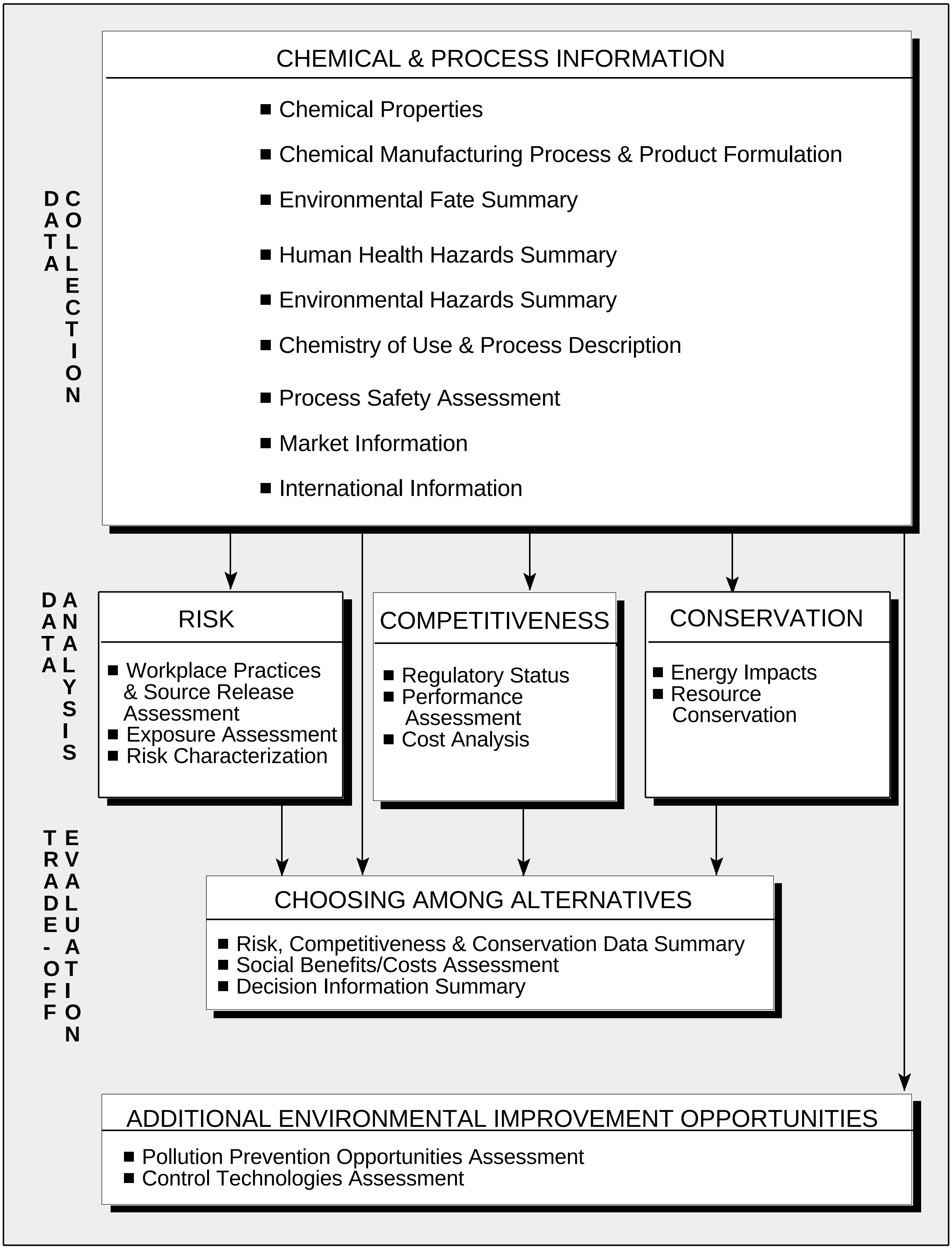


TABLE ES-1: OVERVIEW OF CTSA INFORMATION MODULES		
Component	**Module**	**Overview**
Chemical & Process Information	Chemical Properties	The chemical and physical properties of a substance are characteristics which identify it from other substances. In this module, the physical and chemical characteristics of the chemicals in the use cluster are detailed.
	Chemical Manufacturing Process & Product Formulation	The Chemical Manufacturing Process & Product Formulation module describes: (1) the process for manufacturing the chemicals in the use cluster; and (2) the chemical product formulation process, if applicable. Past CTSAs have qualitatively described these processes. However, if up-stream processes are being quantitatively evaluated in a CTSA a more quantitative description would be needed.
	Environmental Fate Summary	The environmental fate of chemicals describes the processes by which chemicals move and are transformed in the environment. Some of the processes that should be addressed include: persistence in air, water, and soil; reactivity and degradation; migration in groundwater; removal from effluents by standard waste water treatment methods; and bioaccumulation in aquatic or terrestrial organisms.
	Human Health Hazards Summary	Human health hazards assessment is the process of identifying the potential effects that a chemical may have on humans who are exposed to it, and of determining the levels at which these effects may occur. Exposure to a chemical may occur by inhalation, oral, or dermal routes through the production, use, or disposal of the chemical or products containing the chemical. Human health toxicity data are combined with data from the Exposure Assessment module to assess human health risk in the Risk Characterization module.
	Environmental Hazards Summary	Environmental hazards assessment is the process of identifying the adverse effects that a chemical may have on organisms in the environment. Currently, the CTSA process for environmental hazards assessment focuses on aquatic toxicity. This module collects data on measured or predicted toxicity of chemicals to aquatic organisms to characterize potential hazards of chemical discharges to receiving waters. Toxicity data are combined with data from the Exposure Assessment module to assess ecological risk in the Risk Characterization module.
	Chemistry of Use & Process Description	The Chemistry of Use & Process Description module identifies: (1) the chemical/physical properties which contribute to the effectiveness of the chemicals in the use cluster; and (2) the process in which the chemicals are used. A process flow diagram is created that schematically describes the process operations, equipment, and material flows.
	Process Safety Assessment	The Process Safety Assessment module screens potential chemical substitutes to determine if they could potentially pose a safety hazard in the workplace. Process operating characteristics and workplace practices are combined with physical hazard data, precautions for safe handling and use, and other data to determine if a substitute might pose a safety hazard.
	Market Information	The Market Information module contains economic data used to evaluate the importance of the target industry sector to the overall market and conversely, the economic importance of the alternatives to the industry sector. Market information includes chemical/technology cost information, production, and manufacturing volumes, and an analysis of market trends that could affect future supply and demand.
	International Information	The International Information module collects data pertaining to the use or production of alternatives in other parts of the world, the impact of international trade on the selection of alternatives, and the impacts of switching to an alternative on international trade. Primarily, international trade issues are driven by the source and availability of alternatives and possible indirect costs (e.g., taxes, tariffs, etc.) imposed on alternatives.

TABLE ES-1: OVERVIEW OF CTSA INFORMATION MODULES

Component	Module	Overview
Risk	Workplace Practices & Source Release Assessment	The Workplace Practices & Source Release Assessment module identifies: (1) the workplace practices that contribute to environmental releases and worker exposure; and (2) the sources, amounts, and characteristics of environmental releases.
	Exposure Assessment	Exposure assessment is the quantitative or qualitative evaluation of the contact an organism (human or environmental) may have with a chemical or physical agent, which describes the magnitude, frequency, duration, and route of contact.
	Risk Characterization	Risk characterization (also referred to in the CTSA process as risk integration) is the integration of hazard and exposure information to quantitatively or qualitatively assess risk. Risk characterization typically includes a description of the assumptions, scientific judgments, and uncertainties that are part of this process.
Competitiveness	Regulatory Status	The Regulatory Status module determines the statutes and regulations that govern a particular chemical or industrial process.
	Performance Assessment	The Performance Assessment module measures how well a substitute performs to meet the functional requirements of the use cluster. In order to allow a comparative evaluation of the performance of baseline products or processes with the performance of substitutes, performance data are collected for both. This module provides assistance in developing methodologies for obtaining comparative performance data.
	Cost Analysis	The Cost Analysis module identifies the costs associated with the baseline process, as well as suitable substitutes, and calculates comparative costs between the baseline process and the substitutes. As a minimum, the cost analysis should identify the direct costs of the baseline process and the substitutes. If time and resources permit, data are also collected on indirect and future liability costs as well as any less-tangible benefits that occur through the implementation of a substitute.
Conservation	Energy Impacts	Energy consumption, either during the manufacture of a chemical or the use of a substitute product, process, or technology can vary with a selected chemical or process change. This module provides a procedure for evaluating the energy impacts of substitutes in a use cluster.
	Resource Conservation	Resource conservation is the process of selecting and using products, processes, or technologies that minimize the overall consumption of resources while effectively achieving a desired function. This module addresses materials use rates and provides methods for identifying the relative amounts of resources or materials consumed as a consequence of changing from a chemical, process, or technology to a substitute.

TABLE ES-1: OVERVIEW OF CTSA INFORMATION MODULES

Component	Module	Overview
Additional Environmental Improvement Opportunities	Pollution Prevention Opportunities Assessment	Pollution prevention is the process of reducing or preventing pollution at the source through changes in production, operation, and raw materials use. This module provides methods for identifying pollution prevention opportunities that can provide additional benefits beyond the benefits realized if one of the alternatives evaluated in the CTSA is implemented.
	Control Technologies Assessment	Control technologies are methods which can be used to minimize the toxicity and volume of pollutants. This module provides methods for identifying control technologies that may be suitable for on-site treatment and disposal of product or process waste streams.
Choosing Among Alternatives	Risk, Competitiveness & Conservation Data Summary	The Risk, Competitiveness & Conservation Data Summary module organizes data from the risk, competitiveness, and conservation components of a CTSA together with data from the Process Safety Assessment, Market Information, and International Information modules to: (1) identify the trade-off issues associated with any one substitute; and (2) compare the trade-off issues across substitutes. Data summaries are transferred to the Social Benefits/Costs Assessment and to the Decision Information Summary modules for further analysis.
	Social Benefits/ Costs Assessment	Social Benefits/Costs Assessment is the process of qualitatively and systematically evaluating the impacts made on all society by individual decisions. Social benefits/costs assessment includes the benefits and costs to the individual of alternative choices (referred to as private benefits and costs) and the benefits and costs to others who are affected by the choices (referred to as external benefits and costs). Consideration of these effects in decision-making by industry could result in improvements for industry and society as a whole.
	Decision Information Summary	The Decision Information Summary is the final module of a CTSA. It combines the results of the Risk, Competitiveness & Conservation Data Summary with the Social Benefits/Costs Assessment to identify the overall advantages and disadvantages of the baseline and the substitutes from both an individual business perspective and a societal perspective. The actual decision of whether or not to implement an alternative is made by individual decision-makers outside of the CTSA process, who typically consider a number of other factors, such as their individual business circumstances, together with the information presented in a CTSA.

BENEFITS OF A CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT

DfE partnerships developed the CTSA methodology described in this publication to help business decision-makers achieve the tangible benefits that result from using a cleaner product or technology. CTSA results give businesses the information needed to improve their bottom line by evaluating and documenting voluntary changes a business can make to prevent pollution and reduce risk. Pollution prevention often lowers cost by reducing the amount of materials used in production processes, the amount of waste streams that must be treated and disposed, and by improving worker health and safety. In addition, a CTSA provides the necessary information for companies to make informed business decisions that may reduce their regulatory burden or potential liability costs. Also, companies that make voluntary changes to prevent pollution or reduce risk may enjoy increased acceptance and market share from environmentally conscious consumers.

Businesses that participate in voluntary DfE initiatives demonstrate their commitment to continuous environmental improvement. Company employees involved in day-to-day operations ensure the project team understands the process constraints that need to be considered in the design of environmentally preferable options. Stakeholder communities outside the company provide unique perspectives and ideas to broaden the evaluation beyond standard industry concerns.

CTSA results also promote environmental competitiveness. Many companies are discovering that proactive environmental business policies are necessary to remain competitive in today's global marketplace. In addition to the benefits of an improved company image, businesses are finding that they can no longer afford to waste energy or other precious resources or pollute the environment.

Chapter 1

INTRODUCTION

This publication presents the methods and resources needed to conduct a Cleaner Technologies Substitutes Assessment (CTSA), a methodology for evaluating the comparative risk, performance, cost, and resource conservation of alternatives to chemicals currently used by specific industry sectors. The CTSA methodology was developed by the U.S. Environmental Protection Agency (EPA) Design for the Environment (DfE) Program, the University of Tennessee Center for Clean Products and Clean Technologies, and other partners in voluntary, cooperative, industry-specific pilot projects.

This publication is designed for trade associations, businesses, citizen groups, government agencies, or other stakeholders interested in learning about, initiating, or participating in a CTSA. The goal is to provide the CTSA methodology to anyone who can benefit from the increased efficiency and reduced environmental risk that results from using a cleaner product, process, or technology. It presents sources of data, analytical models, and previously published guidance that can be used in a CTSA. A companion publication, Design for the Environment: Building Partnerships for Environmental Improvement *(EPA, 1995a), describes other aspects of DfE industry projects, including how DfE projects are organized and how DfE partnerships disseminate project results.*

The 1990s have ushered in a revolutionary new approach to environmental protection: together with traditional criteria like performance, quality and cost, business leaders are taking the environment into account in the design and redesign of products and processes. This new focus on the environment helps create cleaner products and technologies that minimize environmental impacts throughout their life cycles[1] while fulfilling their function effectively, efficiently, and economically. Businesses are finding that by designing products and processes with the environment in mind, they can reduce the environmental impacts of the products and services our society now enjoys, which improves profitability and the quality of life while strengthening the economy.

An important change has also been taking place in our national strategy for protecting the environment. Through an array of partnership programs, EPA is demonstrating that voluntary goals and commitments achieve real environmental results in a timely and cost-effective way. In addition to traditional, regulatory approaches to environmental protection, EPA is building cooperative partnerships with a variety of groups, including large and small businesses, public-

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[1] As referred to here, the life cycle of a product or process encompasses extraction and processing of raw materials, manufacturing, transportation and distribution, use/re-use/maintenance, recycling, and final disposal.

interest groups, state and local governments, universities, and trade associations. Among others, these collaborative partnerships include the DfE Program, the 33/50 Program, WasteWi$e, Green Lights, Energy Star, the Common Sense Initiative, and Project XL.

The results of these efforts are impressive. Thousands of organizations are working cooperatively with EPA to set and reach environmental goals such as conserving water and energy, and reducing greenhouse gases, toxic emissions, solid waste, indoor air pollution, and pesticide risk. Program partners are making pollution prevention a central consideration in doing business and working cooperatively to provide all stakeholders with effective tools to address environmental issues. And these partners are achieving measurable environmental results often more quickly and with lower costs than would be the case with regulatory approaches. EPA views these partnerships as key to the future success of environmental protection.

WHAT IS EPA'S DESIGN FOR THE ENVIRONMENT PROGRAM?

The DfE Program in EPA's Office of Pollution Prevention and Toxics was created in 1991 to promote the incorporation of environmental considerations into the design and redesign of products, processes, and technical and management systems. By developing and providing businesses with information on designing for the environment, the program aims to encourage pollution prevention and efficient risk reduction in a wide variety of activities. Under the DfE Program, EPA works through voluntary partnerships with industry, professional organizations, state and local governments, other federal agencies, and the public, including environmental and community groups.

The DfE Program aims to turn pollution prevention into both a corporate and environmental asset, by helping businesses incorporate environmental considerations into the product or process design and decision-making process. The program has three goals:

- Encourage voluntary reduction of the use of specific hazardous chemicals by businesses, governments, and other organizations through actual design or redesign of products, processes, and technical and management systems.

- Change the way businesses, governments, and other organizations view and manage for environmental protection by demonstrating the benefits of incorporating environmental considerations into the up-front design and redesign of products, processes, and technical and management systems.

- Develop effective voluntary partnerships with businesses, labor organizations, government agencies, and environmental/community groups to implement DfE projects and other pollution prevention activities.

DfE projects include three distinct project types:

- *Institutional projects* are aimed at changing specific aspects of general business practices in order to remove barriers and provide positive incentives for businesses and other organizations to undertake environmental design and pollution prevention efforts. These include environmental accounting, curriculum development, green chemistry, and insurance projects.

- Cooperative *industry projects* are joint efforts with trade associations, businesses, public-interest groups, and academia to assist businesses in specific industries to select more environmentally-sound products, processes and technologies, especially through provision of easily-accessible information on the comparative risks, performance, and costs of alternatives to currently used chemicals.

- Cooperative *government projects* are joint efforts with government organizations to promote the use of environmentally-preferred products by organizations. The General Services Administration Products Project is one such project to help implement the President's Executive Order 12873: "Federal Acquisition, Recycling and Waste Prevention."

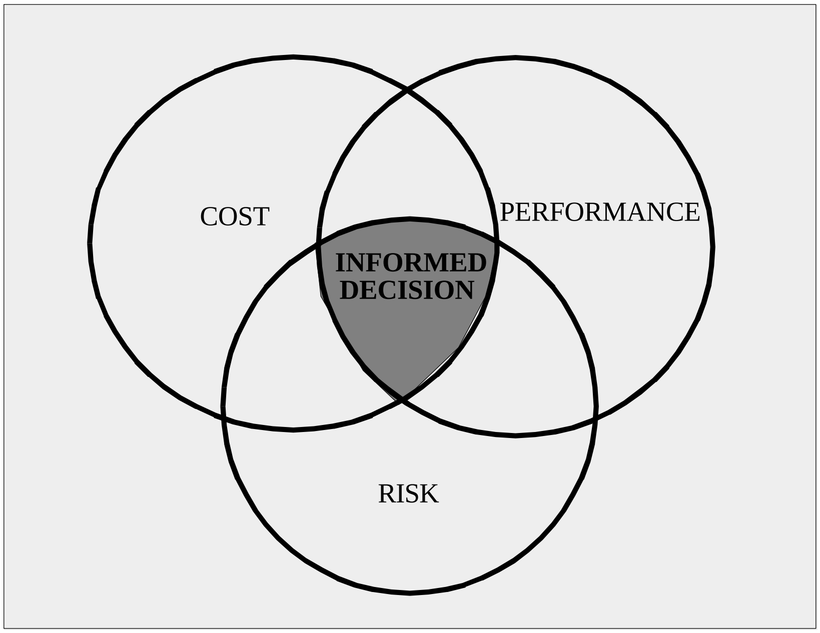
This publication describes methods for performing the technical work of DfE industry projects.

WHAT IS A CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT?

The CTSA *methodology* is a means of systematically evaluating the comparative human health and environmental risk, competitiveness (e.g., performance, cost, etc.) and resource conservation of traditional and alternative chemicals' manufacturing methods and technologies. A CTSA *document* is the repository for the technical information developed by a DfE industry project, including risk, performance, cost, and resource conservation data. Project partners in DfE pilot projects with the printing, dry cleaning, and printed wiring board industries have focussed the project's technical work and the CTSAs for these industry sectors by evaluating a particular group of traditional and nontraditional (i.e., unusual, new, or novel) substitutes or alternatives that can be used to perform a key function within a given industrial process. In DfE terminology, such a project focus area is called a *use cluster*. A use cluster is a product- or process-specific application in which a set of chemical products, technologies, or processes can substitute for one another to perform a particular function.

A CTSA does not recommend alternatives. Instead, the goal is to promote informed business decisions that integrate risk, performance, and cost concerns by providing businesses with easily accessible information (Figure 1-1). The DfE project team uses data from the CTSA to develop fact sheets and summary reports designed to reach individual users and suppliers who may not have the resources to develop the information on their own.

FIGURE 1-1: THE DfE PROCESS PROMOTES INFORMED BUSINESS DECISIONS THAT INTEGRATE RISK, PERFORMANCE, AND COST CONCERNS



WHO PARTICIPATES IN A CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT?

The DfE process catalyzes voluntary environmental improvement through stakeholder partnerships. The technical work of a DfE industry project typically involves participants from various stakeholder communities, including industry (users and suppliers of chemical products, equipment or technologies), government (federal, regional, state, local), public-interest groups (environmental, environmental justice, labor, consumer, etc.), and research and education organizations (non-profit research centers, universities, technical schools, etc.). Each of these stakeholder communities brings unique and valuable resources and perspectives to the project (Figure 1-2). By involving representatives from each of these stakeholder communities, a DfE technical workgroup can accomplish the following:

- Gain the necessary expertise to perform the technical work.
- Ensure the quality, credibility, and utility of the projects technical results.
- Provide a solid foundation for long-term continuous improvement.

Stakeholder partnerships promote consensus options or solutions to address complex environmental problems that are far more effective and productive than those obtained by any group acting alone.

FIGURE 1-2: CONTRIBUTIONS OF DfE PARTNERS

Industry

- Perspective on industry concerns and priorities
- Knowledge of industry infrastructure
- Expertise and data on industry technologies, products, practices, cost and performance
- Access to industry communication channels and networks
- Industry credibility

Government

- Perspective on government and public concerns and priorities
- Risk expertise and data
- Regulatory information
- Public credibility
- Ability to mediate divergent stakeholder interests
- Ability to convene stakeholder groups

Public-Interest Groups

- Perspective on constituents' concerns
- Access to channels and networks for communicating to constituents
- Risk data
- Ideas about alternatives

Research/Education

- Expertise and facilities for:
    - – Research and analysis
    - – Tests and demonstrations
    - – Information/technology transfer
    - – Training resources and expertise
- Public credibility

Source: Design for the Environment: Building Partnerships for Environmental Improvement (EPA, 1995a).

Past CTSA project teams have been convened by EPA together with trade associations, industry research organizations, or other concerned representatives of the business community seeking to reduce the environmental impacts of their products and manufacturing processes. A goal of this publication, however, is to provide businesses, public-interest groups, and other stakeholders the information they need to perform comparative evaluations with or without the direct participation of EPA.

WHY PARTICIPATE IN A CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT?

In the U.S. the problems with chemical pollution became particularly notable at the end of World War II when petroleum supplies were plentiful and the development of new products and technologies flourished. By the 1960s it was apparent that unchecked industrial and municipal discharges were seriously degrading the country's natural resources. The U.S. Congress responded to the increasing environmental degradation by passing the Clean Water Act in 1970, the same year EPA was formed. Smog-filled cities prompted Congress to pass the Clean Air Act the next year. These statutes led to other such statutes (Resource Conservation and Recovery Act [RCRA], Toxic Substances Control Act [TSCA], etc.) and a regulatory system focussed on single environmental medium (air, water, land), end-of-pipe, command-and-control environmental protection.

An unforeseen consequence of command-and-control regulation is that pollutants are often shuffled from one environmental medium to another, with little net environmental improvement. In other cases, regulation has caused industry to substitute materials which in turn may become subject to regulation. While our current regulatory system has reduced risk and improved the environment, it has in some cases been inefficient and unnecessarily costly in achieving environmental goals.

As a result, despite billions of dollars spent on pollution control equipment, in 1992 U.S. industries still released over three billion tons of toxic chemicals to the environment and spent $30 billion on environmental compliance. These persistent problems and costs have led many in industry to make voluntary changes to prevent pollution and to re-evaluate the processes and materials they use and the products they manufacture. DfE partnerships developed the CTSA methodology described in this publication to help business decision-makers achieve the tangible benefits that result from using a cleaner product or technology:

- *CTSA results can improve businesses' bottom line:* A CTSA provides a systematic methodology for evaluating voluntary changes to prevent pollution and reduce risk. Pollution prevention often lowers cost by reducing the amount of materials used in production processes, the amount of waste streams that must be treated and disposed, and by improving worker health and safety. A CTSA provides the necessary information for companies to make informed business decisions that may reduce their regulatory burden or potential liability costs or avoid regulation altogether. Also, companies that make voluntary changes to prevent pollution or reduce risk may enjoy increased acceptance and market share from environmentally conscious consumers.

- *CTSA projects promote effective, efficient change through constructive partnerships:* Businesses that participate in voluntary DfE initiatives demonstrate their commitment to continuous environmental improvement. The result is effective and efficient change founded in the requisite expertise to identify innovative solutions. Company employees involved in day-to-day operations ensure the project team understands the process constraints that need to be considered in the design of environmentally preferable options. Stakeholder communities outside the company provide unique perspectives and ideas to broaden the evaluation beyond standard industry concerns.

  Environmental evaluation and setting priorities for change involve value judgements. No simple metric exists that encompasses the range of environmental issues or addresses the concerns of all stakeholders. By bringing together stakeholders who represent different interest groups, a project team better ensures the credibility and acceptability of CTSA results. Instead of being adversaries, DfE stakeholders work together to find common ground and achieve shared, mutually beneficial goals. This leverages the resources that enable DfE partners to accomplish far more together than would be possible working separately.

- *CTSA results promote environmental competitiveness in a global marketplace:* Companies and businesses throughout the world are not practicing proactive environmental improvement to remain competitive in today's global marketplace. In addition to the benefits of an improved company image, businesses are finding that they can no longer afford to waste energy or other precious resources or pollute the environment.

  For example, the German government has undertaken an aggressive regulatory program to ensure that German industries remain competitive in today's marketplace. Klaus Töpfer, Germany's Environment Minister, recently outlined some of the thinking that lies behind the German "take-back" policies.[2] Töpfer suggests that the markets of the future will be for products that minimize energy use and waste production. Germany is attempting to stimulate industry to develop the technology that will be needed for these future markets by sending economic signals to industry that cause industry to internalize environmental costs (Center for Clean Products, 1995).

  In short, government, industry, and public interest groups alike are recognizing that voluntary changes to reduce risks by preventing pollution are good for business *and* good for the environment.

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[2] "Take-back" regulations would require the manufacturer of certain products to take their products back from the consumer at the end of their useful lives and recycle the materials, preferably into new products.

WHAT IS IN THIS PUBLICATION?

This publication is organized into two parts. Part I contains three chapters that provide an overview of the CTSA process. Following this introduction, Chapter 2 describes the preparatory steps that a DfE project team should perform before embarking on a CTSA. Chapter 3 outlines the types of data and analyses performed in a CTSA.

Part II of this publication describes in detail each of the data sets collected and the analyses conducted in a CTSA, including the following:

- Goals or uses of the data.
- Basic steps to collect the data or complete an analysis.
- Flow of information into and out of each analysis.
- References for data sources, analytical models, and previously published guidance.

Chapter 4 describes in more detail the types of information contained in Part II. Chapter 5 describes the data sets and analyses concerning basic chemical properties and the products or process description. Chapter 6 describes the risk-related analyses. Chapter 7 presents evaluation criteria traditionally related to competitiveness, such as performance and cost. Chapter 8 addresses conservation issues, including energy impacts, and resource conservation. Chapter 9 discusses additional environmental improvement opportunities, including how to conduct a pollution prevention opportunities and control technologies assessment. Chapter 10 describes how all of this information is brought together to evaluate the trade-off issues and provide interpretive decision information summaries that enable businesses to choose among alternatives.

Chapter 2

PREPARING FOR A CTSA

Project partners in a CTSA perform a number of preliminary steps prior to embarking on the detailed analyses of a CTSA. These include recruiting partners, preparing scoping documents, selecting a use cluster for evaluation, and setting the boundaries of the evaluation. These preliminary steps not only ensure the selection of a productive project focus, they also help build relationships among the potential team members and lay the foundation for the culture of collaboration essential to project success.

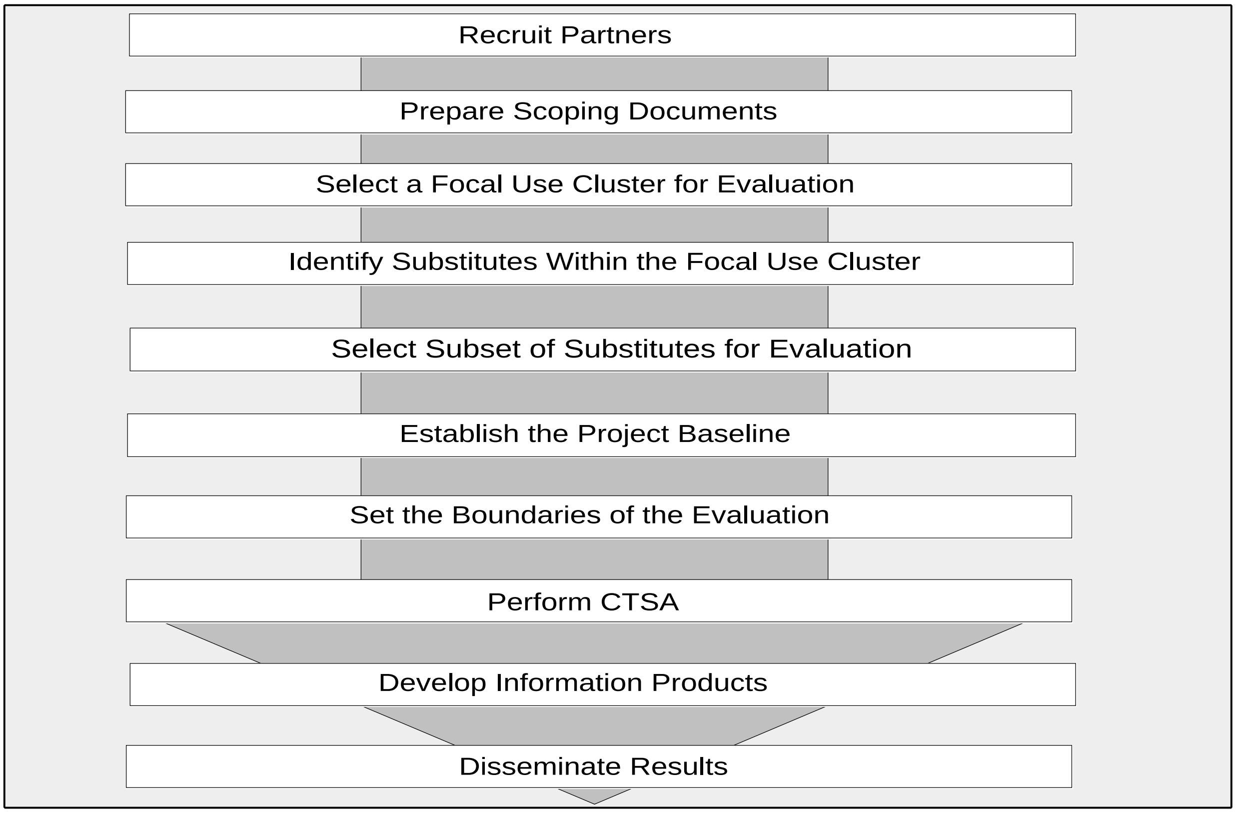
This chapter summarizes the basic steps leading up to a CTSA and the scoping documents which help a DfE project team select a use cluster. It then gives a more detailed overview of each of the preparatory analytical steps. Design for the Environment: Building Partnerships for Environmental Improvement *(EPA, 1995a) addresses each of these steps and describes in more detail how to involve multiple stakeholders in the DfE process and how to disseminate results.*

Figure 2-1 illustrates the basic steps leading up to and following a CTSA. First, DfE project organizers recruit partners from various stakeholder communities to create a project team. Team members then develop an Industry and Use Cluster Profile document and a Regulatory Profile document to help define the project focus. An Industry and Use Cluster Profile gives market data for the industry, describes technological trends, and presents a summary of key industry processes, individual steps within processes, chemicals typically used in each step, and a preliminary list of substitutes for each step. These sets of substitutes make up the use clusters for the industry. A Regulatory Profile identifies the principal federal environmental regulations that may affect the industry under study and the factors that determine which regulations apply to any particular operation. The project team typically selects the use cluster with the greatest opportunities for environmental improvement for the detailed analysis of a CTSA.

Once the use cluster is selected, team members identify substitutes within the use cluster, select a subset of these substitutes for evaluation in a CTSA, and establish the project baseline. The project baseline is typically the industry standard practice, to which other substitutes can be effectively compared. The next step is to set the boundaries of the evaluation by identifying the life cycle stages and types of environmental impacts (e.g., human health and environmental risk to workers, energy impacts, etc.) of greatest concern.

Each of these steps sets the stage for the detailed substitutes assessments that are performed in a CTSA. Following completion of a CTSA, DfE project partners develop a variety of outreach tools to communicate the results of the CTSA. These may include fact sheets, bulletins, pollution prevention case studies, software, videos, and training materials. The final phase of a

FIGURE 2-1: STEPS IN A CTSA PROJECT



DfE project is to disseminate CTSA results to businesses and other stakeholders, who may not have the resources to develop the information on their own. By providing a clear picture of the trade-offs among environmental, economic, and performance concerns, CTSA projects encourage continuous environmental improvement.

PREPARING THE SCOPING DOCUMENTS

The first task for the DfE project team is to conduct research and analysis to identify use clusters within an industry and the use clusters that would provide a productive project focus (EPA, 1995a). Two outcomes of these initial scoping exercises, the Industry and Use Cluster Profile and the Regulatory Profile, provide the foundation for selecting a use cluster and beginning a CTSA. *Printing Industry and Use Cluster Profile* (EPA, 1994a),[1] *Printed Wiring Board Industry and*

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[1] The printing industry is frequently divided into industry sectors, depending on the type of printing process utilized. The five most common printing processes are lithography, letter press, flexography, gravure, and screen printing. The Printing Industry and Use Cluster Profile describes each of these industry sectors. EPA's DfE Program has worked with the screen printing and lithography sectors, and is currently working with the flexography sector.

Use Cluster Profile (EPA, 1995b), *Federal Environmental Regulations Potentially Affecting the Commercial Printing Industry* (EPA, 1994b), and *Federal Environmental Regulations Affecting the Electronics Industry* (EPA, 1995c) are examples of Use Cluster Profile and Regulatory Profile documents prepared during DfE industry projects.

Industry and Use Cluster Profile

The Industry and Use Cluster Profile gives market data for the industry, describes technological trends, and presents a summary of each of the use clusters within the industry. This information helps the project team to select a use cluster for evaluation in the CTSA. It also provides information to other sections of the CTSA, such as the exposure assessment. Table 2-1 lists some of the information typically included in an Industry and Use Cluster Profile and gives examples of how this information may be used in a CTSA.

TABLE 2-1: USES OF INFORMATION FROM AN INDUSTRY AND USE CLUSTER PROFILE

Type of Information	Potential Uses in a CTSA
Geographic distribution of industry by size (number of employees, sales) and function.	Determine the aggregate number of workers exposed, information needed in the exposure assessment.
Key industry processes, individual steps within processes, and chemicals typically used in each step.	Identify traditional chemicals and processes within the focal use cluster; provide the foundation for the source release assessment, exposure scenarios, and exposure pathways.
The set of readily identifiable substitutes for each step, which make up the use clusters.[a]	Preliminary pool of substitutes for evaluation in the CTSA.
Technology trends.	Identify potential substitutes; help select subset of substitutes for evaluation.

a) Well known or already documented substitutes may be presented in the Industry and Use Cluster Profile, but additional substitutes are usually identified as the CTSA process continues.

The first Industry and Use Cluster Profile document prepared by a DfE industry project, *Printing Industry and Use Cluster Profile* (EPA, 1994a), did not contain information on the substitutes in printing industry use clusters. However, as the process for conducting DfE industry projects has evolved, project partners have recognized the added benefit of profiling traditional as well as newer, or more novel alternatives. Thus, the Printed Wiring Board document includes limited information on substitutes. The same is true for Regulatory Profile documents, which now seek to include more information regarding substitutes that are readily identifiable in the early stages of a DfE industry project.

Regulatory Profile

The Regulatory Profile identifies the principal federal environmental regulations that may affect the industry under study and the factors that determine which regulations apply to any particular operation. Such factors might include the size of the operation; the location of a facility (i.e., in an ozone non-attainment area); the types of chemical products it uses; and the types, quantity, and toxicity of the emissions and waste streams it generates. For the purposes of a CTSA, the Regulatory Profile helps focus the selection of alternatives by:

- Providing project participants with consistent information on the regulatory requirements affecting an industry.
- Determining if implementing a substitute would reduce the overall regulatory burden of a facility.[2]
- Determining if implementing a substitute would shift the environmental impact across environmental media, such as from air to water, or from water to land.[3]
- Identifying impending chemical or technology bans, phase-outs or other regulatory actions that could affect the market availability and use of affected substitutes.

The Regulatory Profile also serves as a data source for the regulatory status section of the CTSA which evaluates in more detail the regulatory status of each of the potential substitutes selected for quantitative assessment in a CTSA.

SELECTING THE PROJECT FOCUS

Each use cluster constitutes an area where the relative human health and environmental risk, performance, cost, and resource conservation of alternatives can be compared. For example, Figure 2-2 illustrates the basic functional steps in printed wiring board (PWB) fabrication. Each step can be performed using a discrete set of products, processes, or technologies that can substitute for one another to perform the desired function. And each of these sets of substitutes comprise a discrete use cluster.[4]

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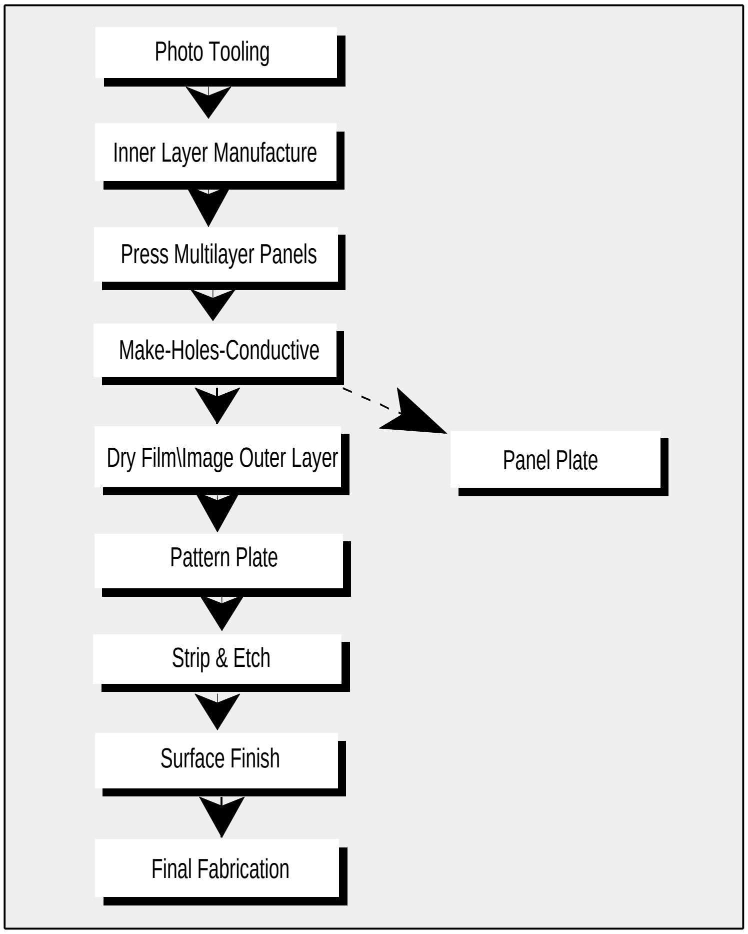
[2] To date, Regulatory Profile documents have not explicitly analyzed the regulatory effects of implementing a substitute, but the regulatory status data can be used by DfE project partners to determine what the effects might be.

[3] Since a principal objective of the overall DfE process is to identify and evaluate substitutes that have the greatest potential for reducing overall environmental impacts, attention is focussed on finding alternatives that prevent pollution instead of simply shifting pollutants from one environmental medium to another.

[4] Some of the steps in Figure 2-2 can be broken down further to more narrowly define the use clusters.

FIGURE 2-2: BASIC FUNCTIONAL STEPS IN PRINTING WIRING BOARD FABRICATION



For practical reasons, DfE project partners usually select one use cluster as the focal point for the project's technical work. The PWB Project partners selected the making-holes-conductive (MHC) use cluster, which is the process of depositing a conductive surface in the barrels of drilled though-holes prior to electroplating. When the technical analysis of a use cluster is complete, the project team can decide whether to extend the project to investigate other use clusters.

Factors to consider when selecting a use cluster for evaluation include the following:

- *The degree of risk associated with current practice in the use cluster:* Use clusters that involve greater exposure to highly toxic chemicals may pose greater human health and environmental risk and offer greater potential for improvement. EPA uses a relative risk ranking methodology to screen the relative health and environmental effects of different use clusters. The Use Clusters Scoring System ranks use clusters into broad concern categories (high, medium, or low) based on use volumes, total environmental releases of chemicals, health and environmental hazards, exposure potential and other factors (EPA, 1993a).

- *The degree of interest that industry and other stakeholders have in the use cluster:* DfE project teams typically represent different stakeholder communities with differing values. Understanding the interests of each of the partners is important to building consensus. The level of interest in the use cluster of each of the partners will also be an important factor motivating their participation. For example, the cooperation of suppliers in providing information on or samples of their products has proven to be essential to the success of past projects.

- *The availability of potentially cleaner substitutes:* The purpose of a CTSA is to evaluate the trade-offs among substitutes of human health and environmental risk, performance, cost, and other environmental effects. Viable substitutes within a use cluster that are in use or ready to be demonstrated are necessary for a CTSA to have the best potential for real environmental gains in the near-term. Processes or technologies that perform a similar function in other industries may also be viable substitutes. The DfE project team may elect to include new technologies that are still in the research and development stage, even though tangible environmental improvements from the use of these technologies may be less immediate.[5]

- *The degree to which a use cluster is tied to other process steps outside of the use cluster:* In some cases, implementing a substitute product, process, or technology might require changes in process steps outside of the use cluster. If so, the project team may need to evaluate these other changes as well to ensure that selection of a substitute does not adversely affect performance or cost outside of the use cluster or shift the environmental impacts from one part of the process to another. Project teams need to consider the time and resources they have available for the evaluation as well as the potential improvement opportunities of these more complex use clusters.

- *The status of other ongoing projects related to a use cluster:* If other projects are already evaluating a use cluster the project team should determine if a CTSA will add valuable information to information already being developed. In some cases, it may be possible to coordinate the work of a DfE project team with other efforts that are not considering the full range of issues evaluated in a CTSA.

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[5] This is not to discourage the application of environmental principles in research and development activities. It is simply to note that it may take longer to realize the environmental benefits. If today's trends continue, technologies of the future will undoubtedly be designed to minimize environmental impacts, and this methodology can be used to inform that design process.

Design for the Environment: Building Partnerships for Environmental Improvement (EPA, 1995a) also discusses factors for selecting a focal use cluster and how to solicit input from stakeholder sectors.

IDENTIFYING SUBSTITUTES WITHIN THE USE CLUSTER

The Use Cluster and Industry Profile, with its preliminary list of chemicals, processes and technologies employed in each use cluster, provides the initial pool of substitutes for evaluation in a CTSA. The identification of substitutes is not limited to this preliminary stage of a CTSA, however. Additional substitutes are identified as a CTSA progresses and more information is gained about the characteristics of the use cluster and of the industry.

The project team begins to identify additional substitutes after the focal use cluster is selected. All stakeholder groups are potential sources of information about additional substitutes. Manufacturers and suppliers of chemical products and technologies play an important role in substitute identification, since they frequently have an up-to-date understanding of current industry trends, and emerging products or technologies. Also, the participation of suppliers in the CTSA process is essential to developing generic chemical product formulations which may be used in the risk characterization if necessary to protect proprietary formulation information (see page 2-18 for a discussion of generic chemical product formulations).

At the same time, trade associations may be tracking new developments; their laboratories and research facilities may be currently developing alternatives. Universities and other research organizations also may be involved in applied or basic research on new alternatives. Public-interest groups concerned about human health risk or other environmental impacts may have independently searched for options to prevent pollution. International organizations may have information on alternatives used abroad. DfE project teams use all of these resources to develop a substitutes tree.

The Substitutes Tree

A substitutes tree is a graphical depiction of the substitute or alternative chemical products, technologies, or processes that form the use cluster and their relationship to each other within the functional category defined by the use cluster. In a DfE project, the terms "substitute" and "alternative" are used interchangeably to mean any traditional or novel chemical product, technology, or process that can be used to perform a particular function.[6] The substitutes tree developed for the DfE Dry Cleaning Project is illustrative of the thought processes that are employed in identifying substitutes.

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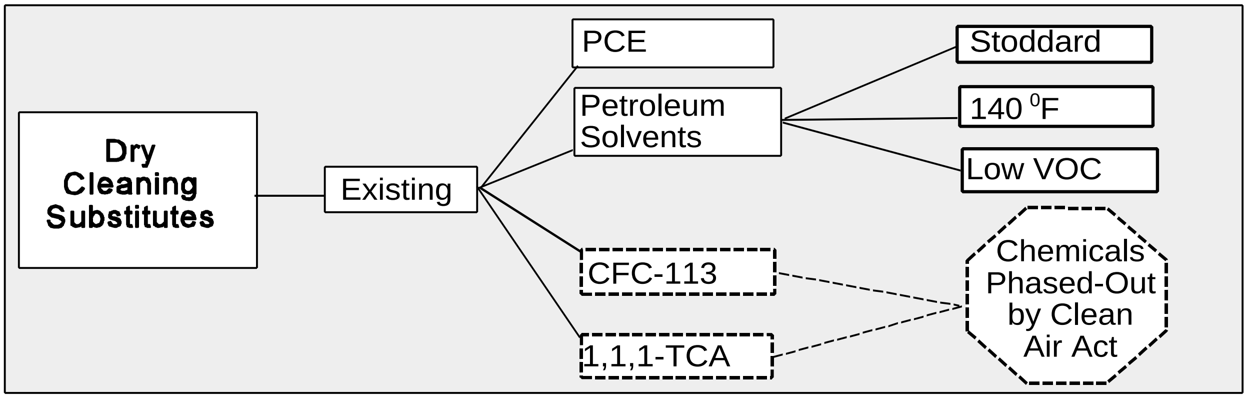
[6] In the context of a CTSA, the term "alternative" does not necessarily connotate a new or novel substitute. Instead it is used to denote the concept of having a choice, either between a traditional product, process, or technology, or a new or novel product, process, or technology. In this manner, the terms "alternative" and "substitute" are synonymous: either of them represents a choice that can be made between products, processes, or technologies that can be used to perform a particular function.

The Dry Cleaning Project evolved from several years of work by EPA with the dry cleaning industry to examine ways to reduce exposure to perchloroethylene (PCE). PCE, a suspected carcinogen, is the chemical solvent most frequently used to dry clean clothes (EPA, 1995a).[7] The dry cleaning process was originally developed to clean water-sensitive fabrics. If the function of dry cleaning is defined as solvent-based cleaning, a number of chemical substitutes can be readily identified that are currently used in dry cleaning facilities (Figure 2-3). When identifying alternatives in a use cluster, however, the project team must be careful to not define the function too narrowly or too broadly. The following discussion illustrates the limitations that would have been imposed on the dry cleaning project if the function had been defined as solvent-based cleaning.

FIGURE 2-3: TRADITIONAL DRY CLEANING CHEMICALS



Recall that a goal of a CTSA is to evaluate both traditional and novel chemicals, processes, or technologies that can substitute for one another to perform a particular function. The substitutes tree shown in Figure 2-3 is too narrow in its scope since it only illustrates traditional chemicals. Figure 2-4 shows the substitutes tree expanded to include newly available professional dry cleaning technologies, and dry cleaning chemicals and technologies that are currently under development. This also proved to be too narrowly defined.

Each of these substitutes or alternatives are *dry* cleaning processes, which is how the use cluster has been defined in Figure 2-4. In the Dry Cleaning Project, however, the project gained momentum when an alternative process called multi-process wet cleaning came to the attention of the project partners. This process primarily uses controlled application of heat, steam, and soap to clean garments, including garments made from water-sensitive fabrics. If the function of the use cluster is redefined as professional garment cleaning (excluding water-washable garments that are usually home-laundered), which is the ultimate function that dry cleaners provide and the service that consumers seek, a whole new array of potential alternatives can be identified.

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[7] The dry cleaning process typically involves a solvent-wash step and a tumble drying step. The process is similar to residential laundering processes — except that a chemical solvent is the primary cleaning agent instead of water and detergent.

FIGURE 2-4: EXISTING AND EMERGING DRY CLEANING ALTERNATIVES

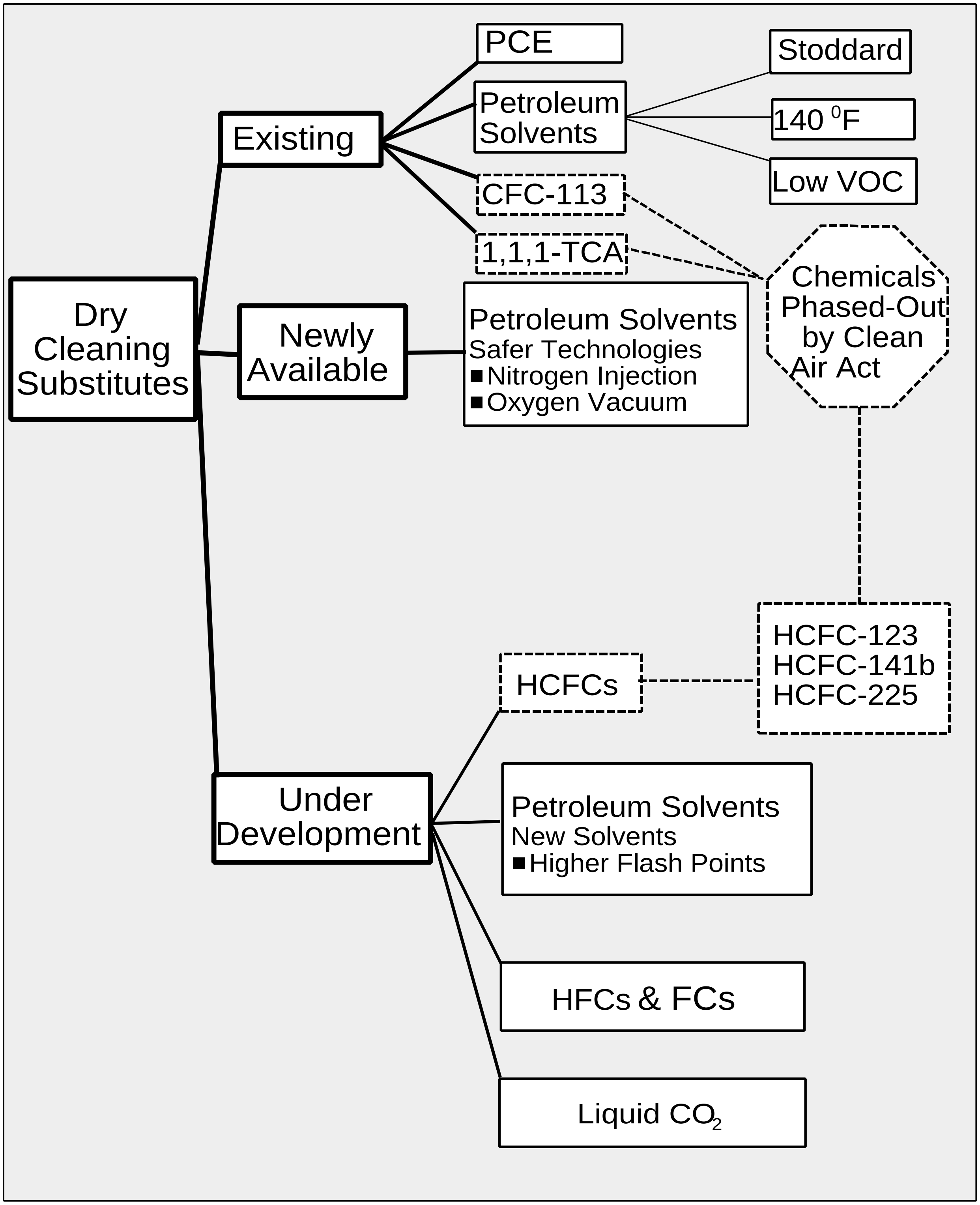
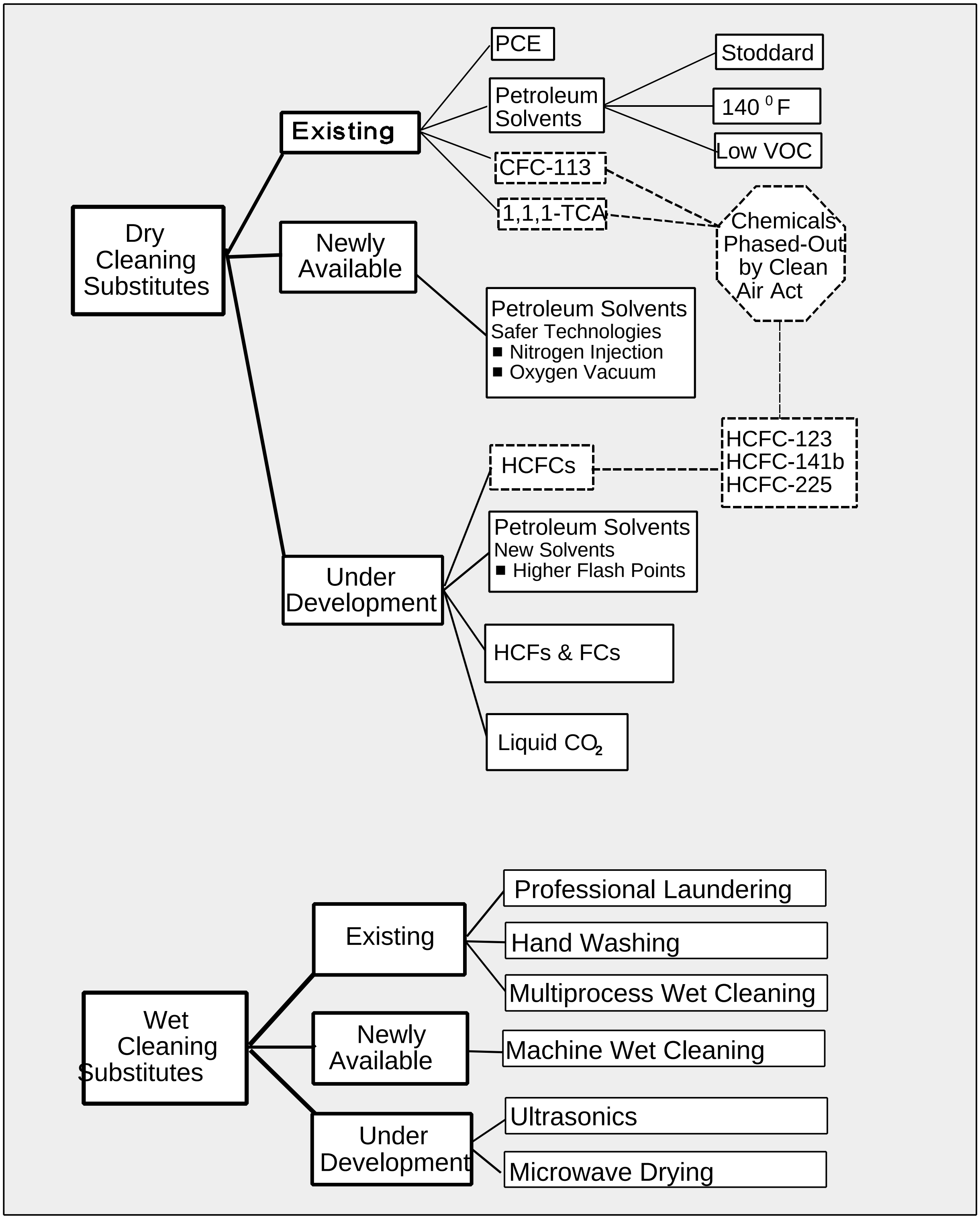


Figure 2-5 illustrates the final substitutes tree for professional garment cleaning that was developed during the Dry Cleaning Project.

FIGURE 2-5: GARMENT CLEANING ALTERNATIVES



Why Focus on Function?

The function of a product, process, or technology is the action for which it is especially fitted or used. Function implies a definite end or purpose that is served or a particular kind of work that is performed. By focussing on function, the CTSA process highlights the end served rather than the means to the end. This opens the evaluation to an array of functional alternatives that are often overlooked in traditional pollution prevention opportunities assessments. A focus on function also provides a unit of equivalency (for example, the amount of a chemical substitute required to perform a function) necessary to compare the risk, performance, and cost of alternatives. The complete list of products, processes, or technologies that can be used to perform a function is a use cluster.

Identifying Substitute Chemicals

The Industry and Use Cluster Profile typically lists the categories of chemicals (e.g., adhesive, cleaning solvent, surfactant, etc.) and the major chemicals in each use cluster. Early in the CTSA, project team members begin collecting data on the chemical and physical properties of these chemicals. A process description of the use cluster is prepared to help define the chemical properties of the chemical products which enable them to perform the desired function (e.g., the chemical properties of an organic solvent make it suitable for dissolving oily residues on clothes) and to identify any functional groups in the use cluster. A functional group is:

- A discrete, functional step of a multi-step process or system.

- The chemical components that can substitute for one another to perform a particular function of a chemical mixture.

For example, in the garment cleaning use cluster, the traditional dry cleaning process uses solvents to remove oils, stains, and odors. Although small amounts of water, detergent, and other additives may be used, chemical products in the dry cleaning process essentially employ one functional group: chemical cleaning solvents. On the other hand, the screen reclamation use cluster evaluated in the DfE Screen Printing Project typically consists of several steps to remove excess ink from a screen, remove the stencil that was used to block the ink, and remove any residual contaminants or haze to permit the screen to be reused.[8] Together these steps define two to three basic functions which must be performed to restore a used screen to a reusable condition:

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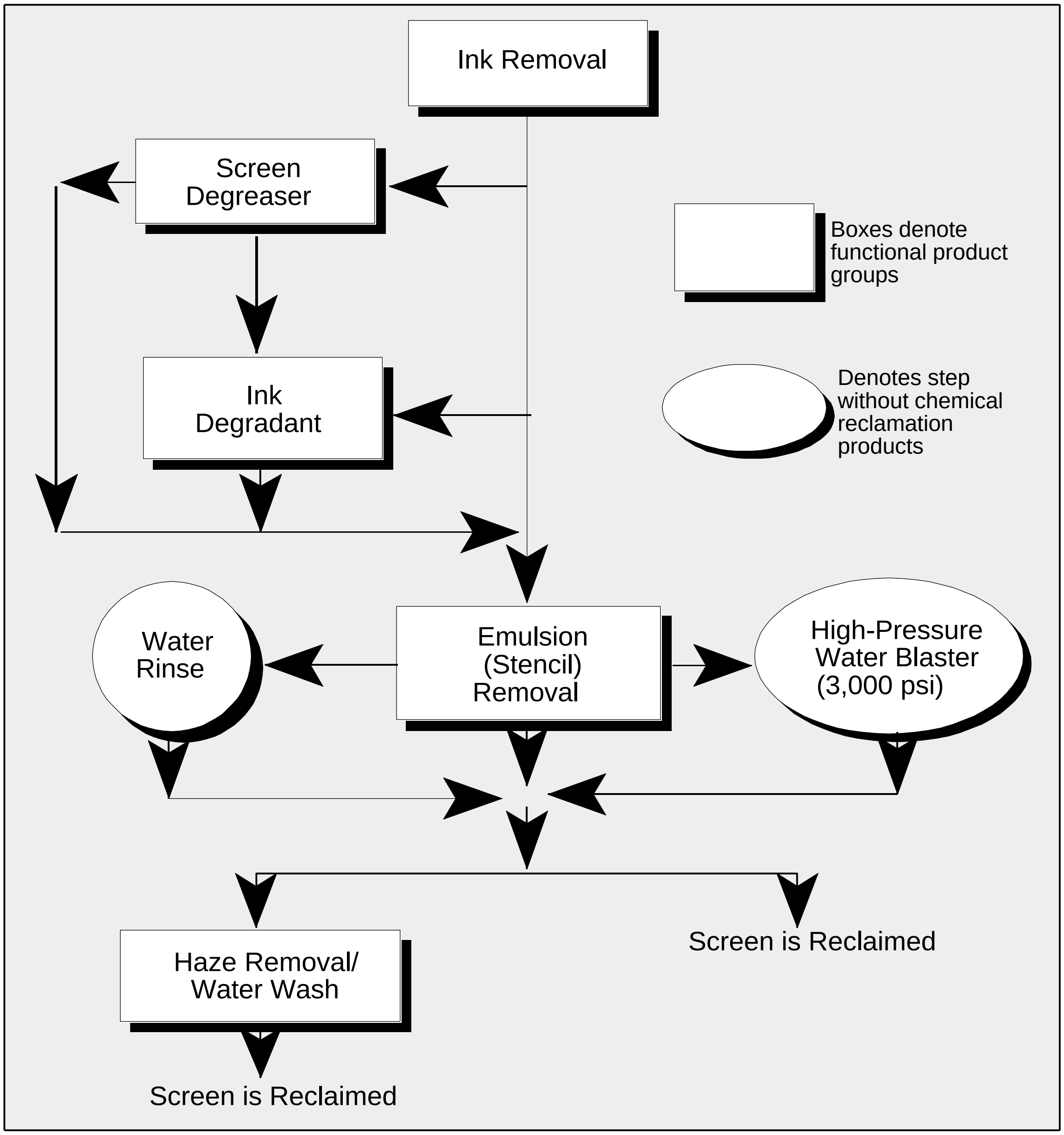
[8] The screen printing process involves stretching a porous mesh material over a frame to form a screen. Part of the screen mesh is blocked by a stencil to define an image. A rubber-type blade is swept across the surface of the screen, pressing ink through the uncovered mesh to print the image defined by the stencil. The screen and its stencil can be used repeatedly to print the same image multiple times, after which the screen is reclaimed enabling a new stencil to be applied.

removal of ink, removal of emulsion (stencil), and removal of haze.[9] Two additional functions, screen degreasing and ink degrading, may be performed depending on the screen reclamation method used. Figure 2-6 is a graphical model of the integration of screen reclamation methods, depicting these five functional groups.

FIGURE 2-6: INTEGRATION OF SCREEN RECLAMATION METHODS



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[9] Haze removal is required depending upon the type of ink used, effectiveness of ink removal and/or emulsion removal products, and the length of time that ink and stencil have been on the screen.

All of the chemical properties and data regarding the chemical properties which enable the chemicals to perform the desired function are analyzed together to identify alternative chemicals that have similar properties or that perform similar functions in other industries. In the Screen Reclamation CTSA, EPA looked at chemicals for which Pre-Manufacturing Notices (PMNs) required under the Toxic Substances Control Act (TSCA) had been filed in order to identify new or novel chemical substitutes. For potential substitutes that were identified, companies submitting PMNs were contacted to obtain permission to include these new chemicals in the assessment.

This valuable resource may not be available for CTSAs not carried out by EPA. EPA publishes Chemical-in-Progress Bulletins in the *Federal Register*, however, which are public sources of information that give generic chemical identities.[10] Routine searches of engineering and environmental literature, particularly for similar use clusters, also can be helpful.

Identifying Substitute Processes

During the Screen Printing Project, the project partners identified four main methods that are used to manually reclaim a screen. Because the actual process of screen reclamation can be performed using any of these methods, a variety of products used in each of these methods was evaluated. By comparing the chemicals used in the methods, as well as the methods themselves, a large array of choices becomes available. Figure 2-7 is a substitutes tree for screen reclamation, depicting the four main screen reclamation methods, the functional groups within each method, plus the additional alternatives of disposing of the screen mesh rather than reclaiming the screen, or using an automatic screen washer. A substitutes tree focussing on processes or methods can stimulate thought into how process steps can be combined, rearranged, or replaced to reduce risk and increase efficiency.

Method 2 in Figure 2-7 is the most common process used for screen reclamation, but each of the methods are currently used by the industry. An objective of the Screen Reclamation CTSA was to evaluate these alternative methods to provide standardized data on how well they work, what they cost, and their relative risk. Screen printers and other businesses are reluctant to change from a product or process that is time-tested to a new product or process unless there are demonstrated benefits. This illustrates the importance of including the range of traditional methods in a CTSA, since current industry practices may differ substantially in their environmental effects.

Identifying Substitute Technologies

Other industry sectors may also employ a number of different technologies to accomplish the same function. In the case of screen reclamation, most screen printers use some type of chemical cleaning procedure, but the project team wanted to stimulate thought on entirely new processes

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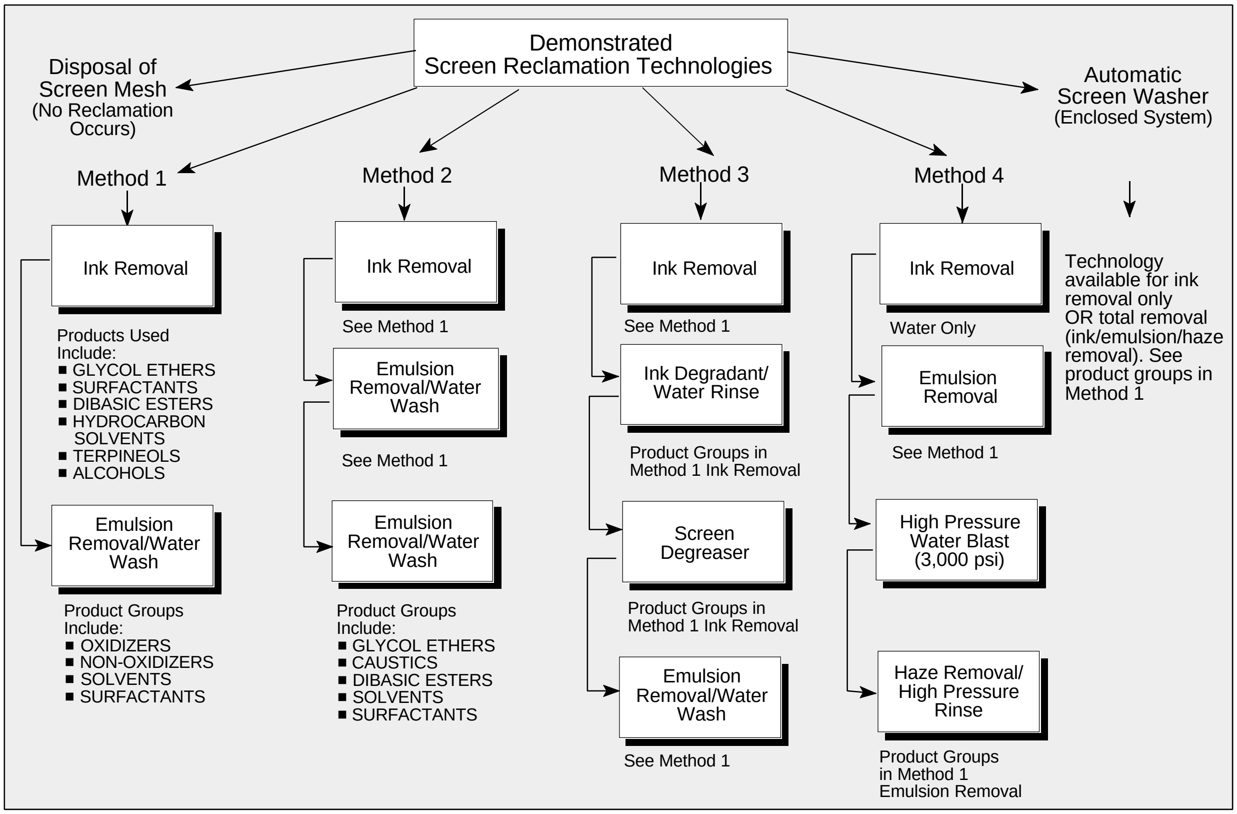
[10] Chemical-in-Progress Bulletins can also be found on the World Wide Web at the following URL: http://www.epa.gov/docs/chemLibCIP.

FIGURE 2-7: SCREEN PRINTING SUBSTITUTES TREE OF DEMONSTRATED TECHNOLOGIES



or technologies that could perform the screen reclamation function. Thus, the project team examined the functional requirements of the screen reclamation process and reviewed literature sources for similar functional requirements in other industries. Figure 2-8 illustrates some of the technologies identified, primarily paint stripping technologies. Currently, some of these technologies are used in high-technology applications and may not be economically feasible for the average screen printing establishment. Others may be both technically and economically viable. For example, a preliminary performance demonstration of a pressurized sodium bicarbonate (baking soda) spray system indicated the technology may be feasible with appropriate equipment modifications.

As previously mentioned, the PWB Project is focussing on "making-holes-conductive," the process of depositing a conductive surface in the barrels of drilled through-holes in preparation for electroplating. PWB manufacturers have traditionally used an electroless plating process to make the drilled through-holes conductive, but new technologies that deposit carbon, graphite, or palladium are also employed. To date, the project has identified eight basic processes that use alternative technologies to perform the making-holes-conductive function (Figure 2-9).
Each of these processes for making-holes-conductive is either currently used by the industry or being tested at PWB manufacturing plants.

SELECTING A SUBSET OF SUBSTITUTES FOR EVALUATION

Once several substitutes have been identified, the project team must decide which of these to evaluate. Traditional substitutes, those currently in widespread use, are usually selected for evaluation because they provide a baseline against which the risk, performance, and cost of all substitutes can be compared. In addition, dissimilar chemical formulations or methods within the range of traditional substitutes may pose vastly different risks. Nonetheless, if a substantial number of traditional substitutes are currently in use, the project team may have to place practical limits on the number evaluated. This is especially true for substitute chemical products.

The project team should also consider one or more new alternatives, depending on the project resources. Factors to consider when selecting new or novel alternatives include the following:

- The ability of an alternative to meet regulatory requirements in the application under review.
- The potential for reducing human health and environmental risk or net environmental impacts.
- The cost required to evaluate the alternative relative to others.
- The viability of the alternative in terms of its known relative cost or performance.

FIGURE 2-8: SCREEN PRINTING SUBSTITUTES TREE OF UNDEMONSTRATED TECHNOLOGIES

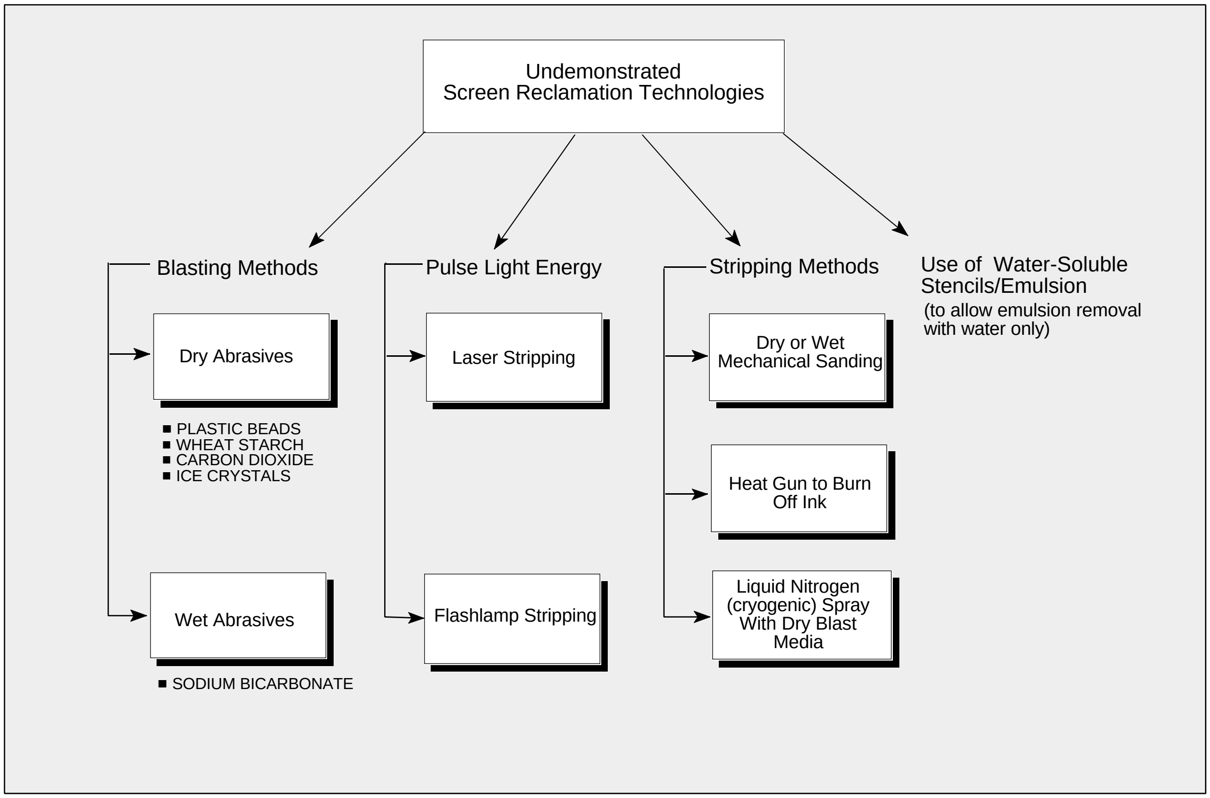
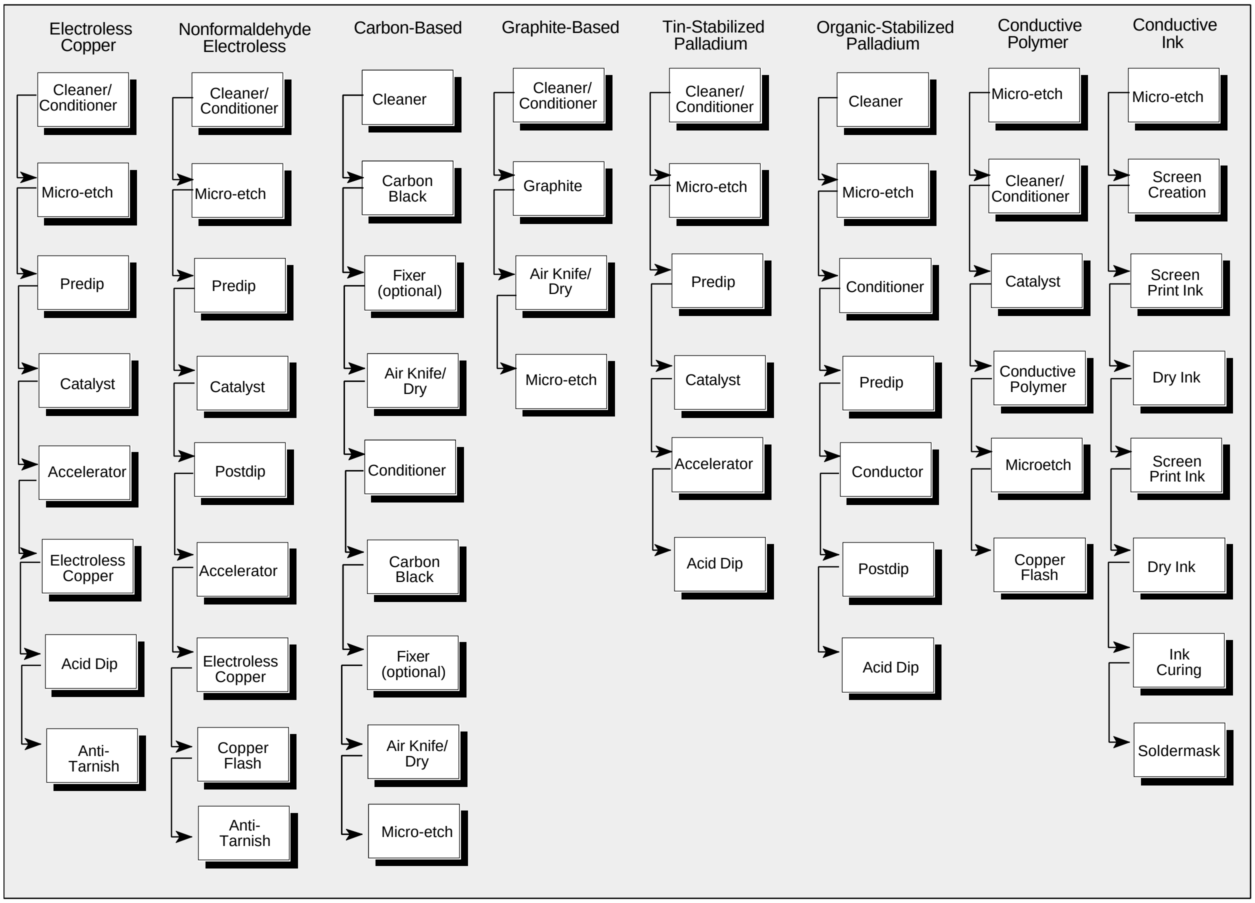


FIGURE 2-9: MAKING-HOLES-CONDUCTIVE SUBSTITUTES TREE



- The degree to which the suppliers or developers of the alternative are willing to participate in the project. Participation may include providing information or samples to the project.

- The applicability of the alternative to the industry as a whole.

- The degree to which the alternative is ready to enter the market (e.g., the research and development stage of the alternative).

- Whether or not implementing an alternative would require changes in process steps outside of the use cluster that would also have to be evaluated in the CTSA.

Participation by the developer(s) or supplier(s) of an alternative can be crucial to the project's success. For example, developers or suppliers of chemical products will need to provide information on their specific product formulations to conduct the risk characterization and samples of their products and material safety data sheets (MSDSs) for the performance assessments. Developers or suppliers of technologies will need to provide operating instructions in order to train staff of demonstration facilities in the correct use of the technology. Furthermore, if the technology has not been introduced to the market, the developer may need to provide one or more complete sets of equipment for the performance assessment.

Generic Chemical Formulations

The chemical formulations of commercial products containing several distinct chemicals are frequently considered proprietary. When undertaking a risk characterization or performance evaluation of such chemical products, the confidential nature of these formulations can complicate a CTSA analysis. Manufacturers of these products typically prefer not to reveal their chemical formulations because a competitor can potentially use the disclosed formulation to sell the product, often at a lower price, since the competitor did not invest the research and development resources in originally formulating and testing the product. In the DfE Screen Printing Project, suppliers of chemical products also did not want to list their brand name with the actual formulation because they feared a loss of market share if the product did not perform well in the performance demonstration or risk characterization. EPA was concerned about appearing to endorse brand name products that fared well in the CTSA evaluation. Due to these concerns, the project partners did not disclose the brand names or actual formulations of any chemical products in the Screen Reclamation CTSA.

However, to make the CTSA usable and flexible, the project partners devised a standard format for representing each chemical product with a generic product formulation. Each product was assigned a code name and each supplier was asked to give the confidential product formulation to EPA. While EPA used the confidential formulations to conduct a detailed risk characterization of each chemical product that appeared in the CTSA, the published CTSA represented a chemical product only by a code name and the generic formulation developed by EPA and the individual supplier. The generic formulations allow the users of the CTSA to compare different product systems while protecting the proprietary nature of the product formulation.[11] Without the generic product formulations, the suppliers in the DfE Screen Printing Project would not have participated in the submission of chemical products. While the generic formulations are important in obtaining supplier participation, they also make the CTSA a useful tool for evaluating other brand name products that may contain similar chemical constituents as those already evaluated. Given the formulation of a chemical product from a detailed MSDS, the human health risk, performance, and cost information can be compared with a product already evaluated in the CTSA. However, as a MSDS only lists chemical constituents which are hazardous to human health, environmental risks may not be able to be determined from the information presented solely on the MSDS.

A DfE team will usually ask suppliers to help develop the generic representative formulations since the suppliers are most knowledgeable of product components. A generic formulation may list only the primary chemicals and indicate the percent concentration of each chemical in a range, rather than the specific amount.[12] The team may agree to allow some proprietary chemicals to remain unidentified if they are present in small quantities (for example, less than one percent by weight) and not deemed hazardous in such a small quantity. However, some information about the chemical, such as the identity of a structurally similar compound, is necessary to determine if small quantities of the proprietary chemical could pose a hazard concern. Some of the chemicals may remain identified only by a generic family name, for example, replacing tripropylene glycol ether with the term propylene glycol series ether, although the risk characterization of the chemical product is still conducted using the specific chemical.

ESTABLISHING THE PROJECT BASELINE

A CTSA is a comparative evaluation requiring a baseline to compare the risk, performance, cost, and other environmental effects of alternatives (substitutes). DfE project teams select one or more alternatives that are currently in widespread use or familiar to most of the industry to serve as an industry standard(s) or project baseline(s). With a familiar baseline as the basis for comparison, the comparative data on risk, performance, cost, and conservation developed through the project will be understandable to the majority of industry. The number of alternatives selected depends on a number of factors, including the following:

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[11] Because the brand names of the chemical products in the Screen Reclamation CTSA were not associated with their individual performance, cost, and risk data, it was difficult for a printer to locate the product that they wished to purchase. To alleviate this problem, the project partners published the name, address, and phone number of all the participating suppliers in the CTSA; a printer would need to call a supplier, state the generic formulation or code name from the CTSA, and ask the supplier if they sold the product. While this system involves some work by the printer, the project partners felt that it was the only way to meet the needs of all participants.

[12] If the percent volumes are reported as a range, the exposure assessment and risk characterization would have to be calculated based on some representative number within that range, usually the midpoint.

- *Is there a clear, industry-wide baseline?* For many industries, it may be difficult to establish a single product, process, or technology as the baseline. Returning to the example of the Screen Reclamation CTSA, a baseline was established for the four main methods used in Screen Reclamation. A variety of products and technologies used in each of these methods was evaluated.

- *Is the type of product, process, or technology used dependent on the size of a business?* The baseline may differ for small and large businesses. For example, automated technologies that are cost-effective for large companies may not be economically feasible for small businesses. The decision to include different project baselines for both small and large industry sectors will depend in part on the resources available to the project team and the primary environmental issues the project team plans to address (see Setting the Boundaries of the Evaluation, below).

- *Are different products, processes, or technologies required to meet end-user performance requirements?* Performance requirements and the alternatives typically employed to meet them may vary depending on the end-use of the product or service an industry sector provides. For example, the Screen Printing Project focussed only on printed plastic or vinyl substrates, as other substrates, such as textiles, required different types of inks, stencils, and reclamation chemicals to meet performance requirements. The DfE project team may need to establish a baseline for each set of performance criteria or narrow the focus of the project to one set of performance criteria.

- *Is the industry standard static or constantly changing?* Industry standard practice can change rapidly, especially in industries that are continuously evolving to meet increasing technological or other demands. If the industry standard changes rapidly, the project team needs to build flexibility into the project baseline to ensure that current and pertinent data are collected.

- *Are suppliers of the project, process, or technology participating in the project and willing to provide data?* To provide an adequate basis for comparison, data on the baseline must be at least as complete as the data on the alternatives. Again, suppliers are a crucial link to obtaining adequate information.

SETTING THE BOUNDARIES OF THE EVALUATION

The goal of designing for the environment is to design products and processes that minimize environmental impacts throughout their life cycles. Due to the complexity of the product life cycle, however, businesses often focus their environmental improvement efforts on the areas where the greatest environmental improvement opportunities lie and where they can most influence change. The CTSA methodology provides a flexible format that enables DfE teams to use this concept to set the boundaries of the evaluation before embarking on a CTSA. Setting the boundaries of the evaluation involves the following considerations:

- *What are the life cycle stages where the most significant environmental effects are believed to occur?* Environmental effects occur in each stage of the life cycle of a product or process, from extraction and processing of raw materials through manufacturing, use, and disposal. For practical purposes, past DfE projects have focussed on the use and disposal stages of the life cycle, where the greatest environmental impacts were believed to occur and the most data were available. Other project teams may choose to focus on other life cycle stages.

- *What are the primary environmental issues associated with the use cluster?* The DfE partners in the dry cleaning and printing projects were most concerned about the chemical risk from using toxic chemicals in dry cleaning and printing establishments. Partners working on other industry sectors may identify other issues, such as energy or nonrenewable resource consumption, as the primary environmental issues associated with a use cluster.

- *To what degree can project partners influence change?* DfE projects are designed to promote continuous environmental improvement. Due to time and resource constraints, project partners typically elect to focus their efforts on the areas where they can most influence change. Again, in DfE projects this has been in the use and disposal of chemicals at operating facilities. Other industry sectors may find that their proactive suppliers actively participate in the project by seeking ways to reduce the environmental impacts of the products and services they provide.

Each of these considerations is related. For example, the product life cycle must be reviewed to identify the primary issues associated with a use cluster. Without participation by suppliers or representatives from up-stream processes, the project team may find their ability limited to gather data as well as influence change in the up-stream process. The life cycle concept and each of these considerations are discussed in more detail below.

The Life Cycle Concept

Businesses, whether manufacturers of consumer products, commercial products, or commercial service industries, have traditionally defined the life cycle of the product, goods, or service they provide as beginning with product conception and moving through design, manufacturing, use, and disposal. Performance, quality, and cost requirements for the manufacturing, use, and disposal phases of the product life cycle are established during product conception. The product designer is charged with ensuring that these requirements are met.

In the 1990s, the term "product life cycle" has taken on new meaning. Environmental decision-makers in all stakeholder sectors have recognized that, to ensure the overall environmental improvement of a product or process, all stages of the life cycle where significant environmental impacts can occur should be considered. This can include the extraction and processing of the raw materials used to make the product, product manufacturing, transportation, use, recycling, and disposal. The concept of designing products and processes for the environment combines these two definitions of the product life cycle. The environmental effects of all significant stages of the product life cycle can be evaluated to incorporate environmental considerations into the design and redesign of products and processes.

"Extended product responsibility" is an emerging principle of pollution prevention that advocates this life cycle approach to identifying opportunities to prevent pollution and addresses the question, "How much can project partners influence change?" Under this principle, there is assumed responsibility for the environmental impacts of a product throughout the product's life cycle, also called the "product chain," including up-stream impacts inherent in the selection of materials for the product, impacts from the manufacturer's production process, and down-stream impacts from the use and disposal of the product. Thus, a shared "chain of responsibility" is borne by designers, manufacturers, distributors, users, and disposers of products. The greater the ability of the actor (i.e., designer, manufacturer, etc.) to influence the life cycle impacts of the product system, the greater the degree of responsibility for addressing those impacts should be. Because effective measures to reduce the life cycle environmental impacts of a product system usually involve changes in more than one link in the product chain, extended product responsibility creates a need and an opportunity for partnerships throughout the product chain (President's Council on Sustainable Development, 1996).

The CTSA process provides a framework for bringing together the actors throughout the product chain to address life cycle environmental impacts. From their origins in chemical risk management, CTSAs conducted under the DfE Program have, thus far, focussed on the life cycle stage where:

- The greatest chemical risk is believed to occur.
- The overall environmental impacts can most be affected by choices made by manufacturers and users of chemical products.

In the printing, dry cleaning, and printed wiring board industries, this has been in the manufacturing or commercial process itself and in the release or disposal of chemicals from manufacturing or commercial facilities. As conceptualized, however, the CTSA process is intended to use a more holistic life cycle approach, to include all stages of the product life cycle. The methods outlined in this publication focus on the use and disposal of chemicals by a particular industry, but they can also be applied to other stages of the life cycle, such as the manufacturing processes of industry suppliers.

Identifying Life Cycle Boundaries

To set the boundaries of the evaluation from a life cycle perspective, the project team might ask, "In which stage of the life cycle are the greatest environmental impacts believed to occur?" In some cases, this will be apparent, in others, it will not. For example, when considering the life cycle of the automobile, practitioners of life cycle assessment[13] agree that significant environmental impacts occur during the use of the automobile, due to the substantial amount of energy consumed and the emissions of air pollutants. In the case of pesticides, the manufacturing of chemical ingredients and use by consumers may be equally important, since pesticide products are intentionally released to the environment during use.

On a practical note, the time and resources available to conduct a CTSA may determine the degree to which up-stream or down-stream processes can be included in the evaluation. Due to time and resource constraints and the lack of readily available data, the chemical manufacturing process and other up-stream processes were not quantitatively evaluated in past CTSAs.

The following considerations may be helpful when identifying the life cycle stages on which to focus:

- *Are the natural resources used in the use cluster in abundant supply?* Resources that are being rapidly depleted are a serious concern. An industry dependent on scarce resources may wish to focus on the extraction and processing of raw materials to evaluate the environmental impacts, especially the social benefits and costs, of alternatives.

- *Do the natural resources occur only in low concentrations in their natural state?* The extracting and processing of raw materials that occur naturally in low concentrations may be of great environmental impact. For example, some metals that are found only in low concentrations in their ores may require more mining and processing of raw materials, more water and chemical use for extracting the metals, generate more mill tailings, and consume excessive energy.

- *Is use of the product likely to cause risk to consumers exposed to toxic chemicals?* Some products may have the greatest environmental impact during use by consumers. For example, the risk to workers manufacturing solvent-based paints could be small compared to the risk to persons using the paints who do not use personal protective equipment.

- *What are the environmental impacts of disposal of the product?* Some products are intentionally released to the environment by the consumer after use. For example, the aquatic toxicity of household cleaning products that are rinsed down the drain by the consumer could be of significant concern.

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[13] Life cycle assessment (LCA) is another tool for evaluating the life cycle environmental impacts of a product or process. EPA defines LCA as follows: "A concept and methodology to evaluate the environmental effects of a product or activity holistically, by analyzing the whole life cycle for a particular product, process, or activity. The life cycle assessment consists of three complementary components — inventory, impact, and improvement — and an integration procedure known as scoping (EPA, 1993a)."

By focussing on the life cycle of the product, processes, or technologies in the use cluster, the project team will most likely identify many of the primary environmental issues associated with the use cluster, but in a holistic fashion.

Identifying Primary Environmental Issues

By involving representatives from up and down the product chain as well as public-interest groups, labor organizations, and other stakeholder communities, DfE partnerships provide an excellent forum for identifying the primary environmental issues associated with a use cluster. Diverse stakeholder groups bring different resources and unique perspectives to the table to ensure that important environmental issues are not overlooked. Examples of the issues the project team may elect to focus on include the following:

- Reducing risk to workers, surrounding populations (human and ecological), or consumers through use of substitutes, improved workplace practices that prevent pollution, or even pollution control technologies.

- Reducing energy impacts or conserving natural resources.

- Reducing workplace safety hazards.

The Dry Cleaning and Screen Printing Projects are good examples of the flexibility of the CTSA methodology in organizing information and in focussing on different types of environmental improvement opportunities. In the Dry Cleaning Project emphasis was placed on evaluating different types of pollution control methods as well as alternative cleaning technologies, whereas the screen printing project focussed on improving workplace practices and substituting chemical systems to reduce risk to workers.

Regardless of whether the focus is on alternative systems, technologies, or pollution control methods, the goal is to reduce risk, resource consumption, process safety hazards and/or other environmental effects, and provide tangible environmental improvements. The following are examples of questions a project team might ask to determine where the greatest improvement opportunities lie:

- *Where is a typical business located?* Facilities located in urban areas may have different impacts than those in rural areas. For example, dry cleaning facilities are typically located in or near residential areas. Therefore, the dry cleaning team elected to evaluate the risk to persons living near these shops.

- *Are many facilities located in areas with local or regional regulatory requirements?* Local or regional regulatory requirements may cause many businesses to seek alternative products or processes. For example, businesses that emit volatile organic compounds in non-ozone attainment areas may seek substitute chemical products that do not contribute to photochemical smog.

While these types of questions may identify the primary environmental issues associated with a use cluster, they will not necessarily identify the most significant problems for individual businesses. For example, a business located in a rural area where photochemical smog is not an overriding issue may be more concerned about the water releases to their septic system. Again, the flexible format of a CTSA is the key to providing sufficient information to enable individuals to make the best choices for their given situation.

Evaluating the Ability to Influence Change

DfE projects are action-oriented, designed to produce real, tangible environmental improvements. With limited resources available to the project, the project team needs to assess its ability to influence actors along the product chain to improve the environmental attributes of a product or process. In this regard, the project team may consider the following:

- *Which actors along the product chain are represented on the project team?* A DfE team strives to involve as many actors along the product chain as possible. Once again, suppliers are crucial to the project's success, not only for providing information on their products, but also for committing to strive to improve the environmental attributes of their products. In another example, public-interest groups can be instrumental in providing information to consumers on the improvements that businesses make when they implement a substitute.

- *What percentage of the overall market for the chemicals is used in the use cluster?* If the quantity of a chemical used by an industry is small relative to the overall market for the chemicals, the project participants may elect to not evaluate the environmental impacts and risks from the chemical manufacturing process. Their choice of whether or not to use that chemical would have only a slight effect on the overall risks from the chemical manufacturing process. The market information compiled in the Industry and Use Cluster Profile can be helpful when evaluating market share.

- *Is the CTSA project a priority of the project partners?* It is important to assemble project partners committed to an open, consensus-based evaluation process, but they must also be committed to the project at hand. If the selected use cluster is a low priority of the process partners, it may be difficult to accomplish the goals of a CTSA in a realistic time frame.

Each DfE project team will have a different set of questions or issues to address to set the boundaries of their own CTSA. While these questions and the questions in preceding sections may help the team to focus their project, an important point is that an open, consensus-oriented, cooperative evaluation process produces the best project design.

Chapter 3

DEVELOPING A CTSA

The aim of a CTSA is to develop as complete and systematic a picture as possible of the trade-offs among risk, competitiveness (i.e., performance, cost, etc.), and conservation associated with the substitutes in a use cluster. To accomplish this, a CTSA employs a modular approach to data collection and analysis utilizing "information modules." An information module is a standard analysis or set of data designed to build on or feed into other information modules to form an overall assessment of the substitutes. A CTSA records and presents facts collected in the information modules, but does not make value judgements or advocate particular choices.

This chapter summarizes the information module approach, describes the flow of information between modules, and provides an overview of the information modules currently in the CTSA methodology.

RECAP: Key Terms and Concepts

A ***Cleaner Technologies Substitutes Assessment (CTSA)*** is a repository for all of the technical information developed by a DfE project, including risk, competitiveness (i.e., performance, cost, regulatory status, market availability), and conservation data.

A ***use cluster*** is a product- or process-specific application in which a competing set of chemical products, processes, or technologies can substitute for one another to perform a particular function.

A ***functional group*** is: (1) a discrete, functional step of a multi-step process or system; or (2) the chemical components that can substitute for one another to perform a particular function of a chemical mixture.

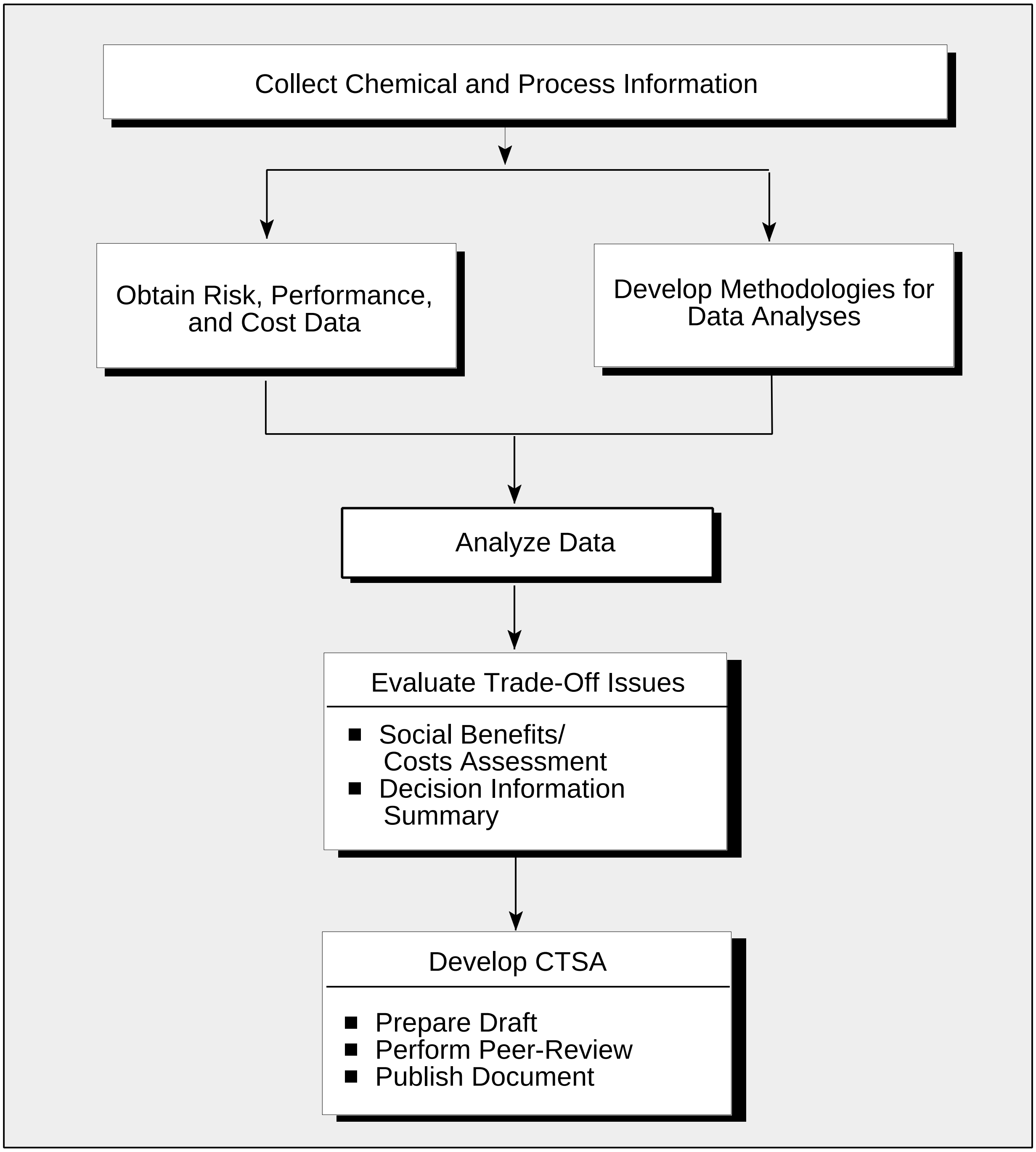
A ***substitute*** or an ***alternative*** is any traditional or novel product, technology, or process that performs a particular function.

A ***substitutes tree*** is a graphical depiction of: (1) the alternative chemical products, technologies, or processes that make up the use cluster; and (2) their relationship to each other within the functional category defined by the use cluster.

An ***information module*** is a standard analysis or set of data on the substitutes. Information modules are designed to build on or feed into one another to form an assessment of the substitutes.

Once a DfE project team determines the project focus, establishes the project baseline, and sets the boundaries of the evaluation, they are ready to begin collecting data and identifying specific methodologies for data analysis. Figure 3-1 is a simplified flow diagram of the process for developing a CTSA.

FIGURE 3-1: STEPS TO PRODUCE A CTSA



A CTSA typically starts with the collection of basic chemical properties and process information, followed by the collection of risk, competitiveness, and conservation data. At the same time, the project team develops methodologies for data analysis to ensure that all necessary data are collected. The next step is to analyze the collected data to determine the relative human health and environmental risk, competitiveness, and resource conservation of alternatives. Past DfE projects have shown that the choice of an alternative will frequently involve making trade-offs. For example, when compared to the baseline, an alternative may cost slightly more, but have substantially reduced risk.

To evaluate the trade-off issues, project partners prepare data summaries related to risk (releases of pollutants to the environment, potential exposure levels, risk of chemical exposure to human health and the environment), competitiveness (performance, cost, market availability, regulatory status), and conservation (energy impacts and effects of resource conservation). All of this information is combined to evaluate the social benefits and costs of implementing an alternative. Finally, the risk, competitiveness, and conservation data summaries are organized together with the results of the social benefits/costs assessment in a decision information summary that records and presents facts, but does not make value judgements or advocate particular choices.

Following the overview of the information module approach below, the flow of information in a CTSA and the steps in Figure 3-1 are discussed in more detail.

OVERVIEW OF THE INFORMATION MODULE APPROACH

The information module approach of the CTSA methodology is modeled after the risk management process that EPA conducts under the authority of the Toxic Substances Control Act (TSCA), with some important distinctions. The following sections describe this risk management process and its relationship to the CTSA process. The benefits of this modular approach are also discussed.

The Risk Management Process

Under TSCA, EPA has regulatory authority to perform the following activities regarding existing chemicals: (1) gather toxicity, production, use, disposal, and fate information; (2) assess human and environmental exposure; (3) determine if a chemical poses unreasonable risks; and (4) take appropriate actions to control these risks, based on a social benefits and costs analysis.[1] TSCA is the only U.S. statute under which multi-media risk assessments are performed as part of the regulatory rulemaking process.

To identify potential risk early in the screening process, EPA uses a two-phase risk management process. Phase 1 is a screening level risk assessment and fact-finding mechanism, intended to ensure that EPA only focusses on chemicals with the potential to present unreasonable risk to

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[1] "Unreasonable risk" generally has been interpreted to mean greater overall benefits (reduced risk, etc.) than costs incurred in mitigating the risks.

human health and the environment. If this initial investigation finds that unreasonable risk may exist, chemicals are evaluated further in Phase 2.

Phase 2 is a more detailed and comprehensive risk assessment process that includes a thorough evaluation of the hazards and exposures to specific chemicals, identification of strategies to reduce or eliminate risk, and an evaluation of pollution prevention opportunities. To the extent possible, EPA bases the Phase 2 assessments on existing information, although new data may have to be generated. Each member of an EPA assessment team is responsible for completing one or more standardized analyses (information modules) on the chemicals, including Chemical Properties, Market Information, Chemistry of Use & Process Description, Source Release Assessment, Human Health and Environmental Hazards Summaries, Exposure Assessment, and Risk Characterization modules. These information modules build on or feed into each other to form an assessment of the chemical. EPA's standardized assessment process is designed to promote efficiency and consistency among results. *RM2 Handbook: Preparing RM2 Assessments for Single Chemicals* describes the EPA risk management process in more detail (Carstens, 1996).

Relationship of CTSA Process to EPA's Risk Management Process

The CTSA process is modeled after EPA's risk management process, with these important distinctions:

- *The CTSA process is designed to assist a voluntary decision-making process and, as such, is not as rigorous or detailed an evaluation as the regulatory rulemaking process.* In order to respond to a project team's needs in a timely manner and reduce resource needs, the CTSA process is designed to collect only the information necessary to adequately assist an individual making a voluntary business decision. As such, the data collection and analysis performed in a CTSA are quite detailed, but it is not necessary or intended to be as rigorous as the regulatory rulemaking process. For example, past CTSAs have qualitatively evaluated the social benefits and costs of implementing an alternative, but have not monetized overall social benefits and costs, which may be required for regulatory rulemaking.

- *A CTSA adds additional information modules to collect data on issues related to competitiveness, conservation, and pollution prevention.* A CTSA contains the risk-related information modules in Phase 2 of EPA's risk management process, plus additional modules to address competitiveness issues (e.g., performance, cost, etc.) and conservation issues (energy impacts and resource conservation). A CTSA also compiles extensive information on pollution prevention opportunities, including improved workplace practices that prevent pollution, that may be more comprehensive than those compiled in the risk management process.

By building on EPA's risk management process, the CTSA process has a range of standardized data collection and analytical methods already available that can be tailored to the needs of a specific project.

Benefits of the Modular Approach

The primary benefits of the information module approach arise from its flexible format, allowing DfE project teams to tailor a CTSA to fit their needs. Additional analyses or modules can be added or deleted, depending on the specific concerns and priorities of project participants. Information can be easily organized to meet the requirements of a specific project and of the people who will use the assessment.

For example, a DfE project team that already has information on the performance and cost of alternatives may focus on collecting risk information. The risk data can be compiled in a CTSA along with the previously available data on performance and cost. In another example, an energy-intensive industry such as the aluminum industry may be most concerned with the energy impacts of alternative processes. The project team in this example may elect to focus their efforts on identifying alternatives to reduce energy consumption and place less emphasis on the chemical risk component of a CTSA.

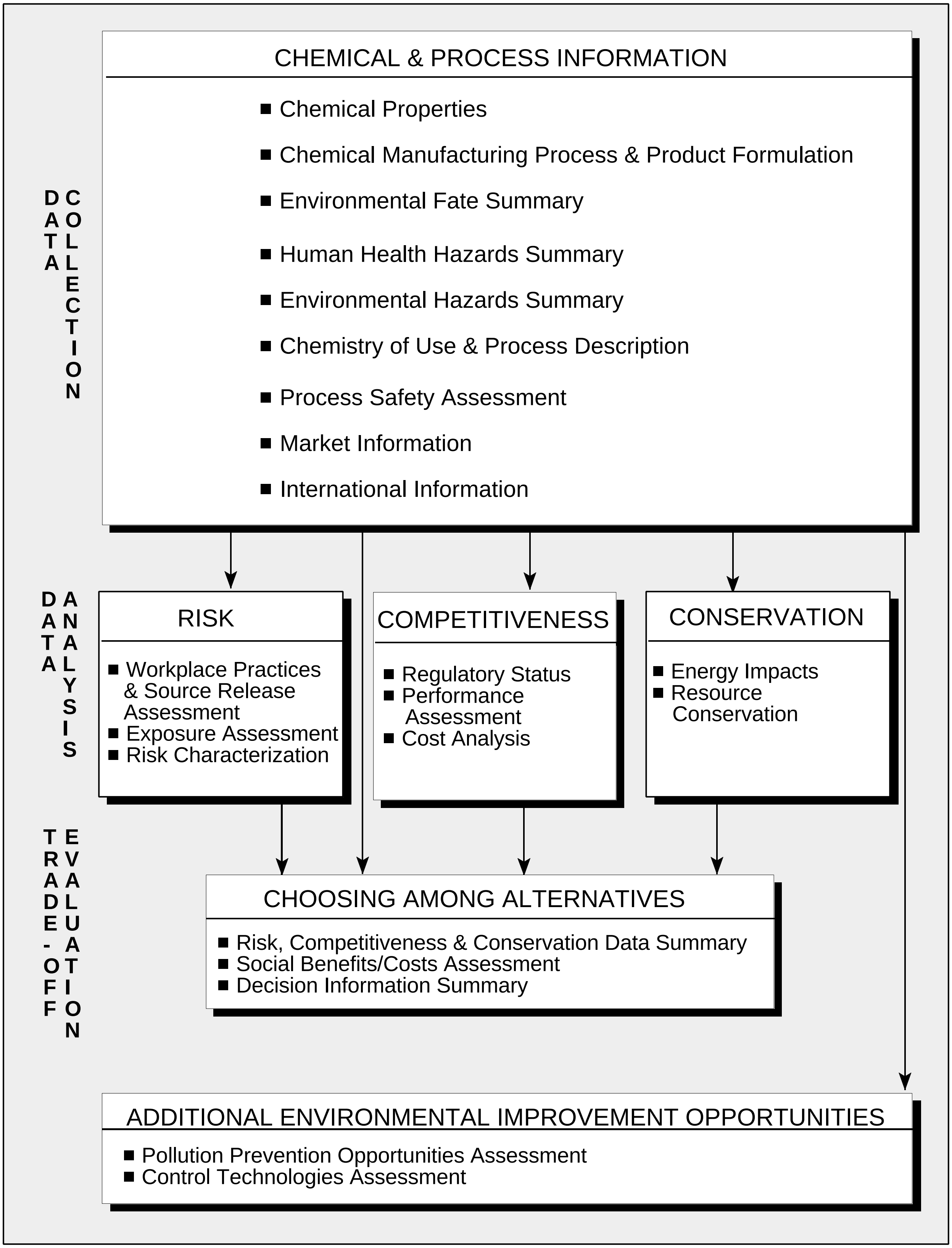
FLOW OF INFORMATION IN A CTSA

A CTSA can be viewed as a three-stage process involving data collection, data analysis, and an evaluation of the trade-offs among risk, competitiveness, and conservation. Figure 3-2 illustrates the basic flow of information in a CTSA. Each of the bullets in the figure represents one of the information modules that may be included in a CTSA. The modules included in a specific CTSA can vary, depending on the information needs of the project team.

Basic chemical and process information are collected in the first stage for use in the analyses performed later in a CTSA. In the data analysis stage, the chemical and process-specific information are combined with additional data and systematically analyzed in eight modules. These modules are divided into three groups focussing on risk, competitiveness, and conservation. In the third stage, the results of the analytical modules are brought together to evaluate the trade-offs to an individual and to society among risk, competitiveness, and conservation considerations. Again, the goal of a CTSA is not to recommend specific alternatives, but to present the trade-offs among risk, competitiveness, and conservation in a way that allows decision-makers to select the alternative that best fits their own goals, values, and requirements. The choices of substitutes are made by individuals outside of the CTSA process.

Throughout the CTSA process, data are collected on additional environmental improvement opportunities, particularly pollution prevention opportunities that could be implemented regardless of which substitute is used. The Control Technologies Assessment module may or may not feed directly into the overall evaluation of alternatives, depending on whether or not the alternatives are affected by existing regulations and the information needs of the project team.

FIGURE 3-2: CTSA INFORMATION FLOWS



Although the CTSA process is depicted in Figure 3-2 as a linear, step-wise process, DfE project teams frequently work on the data collection and data analysis components at the same time. For example, a project team may begin by collecting preliminary data on the regulatory status of substitutes from the Regulatory Profile document to ensure that chemicals being banned or phased-out are eliminated from consideration early in the CTSA process. In addition, data requirements and information needs frequently cycle between modules to ensure that the appropriate data needs are identified and data requirements are met. If a performance demonstration project is planned as part of the Performance Assessment module, it is an excellent opportunity to collect data on cost, energy use, and resource consumption. This means that the appropriate data requirements should be identified first in the Cost Analysis, Energy Impacts, and Resource Conservation modules, respectively.

The interactive nature of the modular approach requires careful coordination between disciplines to ensure consistency of goals and terminology so that the modules fit together in a final analysis. For example, one must be careful from module to module that similar terminology and units are employed. Something as simple as a chemical name must be verified with a Chemical Abstract System Registry Number (CAS RN)[2] since chemical synonyms can be confused or used differently by different disciplines.

Table 3-1 gives an overview of each of the information modules currently in the CTSA process. The following sections summarize the data collected or analytical results of each module and list some of the uses of data. The module descriptions in Part II of this publication describe in detail the data that are transferred to and from each module.

Chemical and Process Information

Table 3-2 lists the information modules that develop data on basic chemical properties and process information, some of the primary outputs from these modules, and how the data are used in a CTSA. DfE technical workgroup members typically begin by collecting data on basic chemical properties and developing a process description of the use cluster. However, data collection for these modules do not have to be complete before the project team begins collecting data needed for other modules in a CTSA.

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[2] A CAS RN is a unique identification code assigned to a chemical.

TABLE 3-1: OVERVIEW OF CTSA INFORMATION MODULES

Component	Module	Overview
Chemical & Process Information	Chemical Properties	The chemical and physical properties of a substance are characteristics which identify it from other substances. In this module, the physical and chemical characteristics of the chemicals in the use cluster are detailed.
	Chemical Manufacturing Process & Product Formulation	The Chemical Manufacturing Process & Product Formulation module describes: (1) the process for manufacturing the chemicals in the use cluster; and (2) the chemical product formulation process, if applicable. Past CTSAs have qualitatively described these processes. However, if up-stream processes are being quantitatively evaluated in a CTSA a more quantitative description would be needed.
	Environmental Fate Summary	The environmental fate of chemicals describes the processes by which chemicals move and are transformed in the environment. Some of the processes that should be addressed include: persistence in air, water, and soil; reactivity and degradation; migration in groundwater; removal from effluents by standard waste water treatment methods; and bioaccumulation in aquatic or terrestrial organisms.
	Human Health Hazards Summary	Human health hazards assessment is the process of identifying the potential effects that a chemical may have on humans who are exposed to it, and of determining the levels at which these effects may occur. Exposure to a chemical may occur by inhalation, oral, or dermal routes through the production, use, or disposal of the chemical or products containing the chemical. Human health toxicity data are combined with data from the Exposure Assessment module to assess human health risk in the Risk Characterization module.
	Environmental Hazards Summary	Environmental hazards assessment is the process of identifying the adverse effects that a chemical may have on organisms in the environment. Currently, the CTSA process for environmental hazards assessment focuses on aquatic toxicity. This module collects data on measured or predicted toxicity of chemicals to aquatic organisms to characterize potential hazards of chemical discharges to receiving waters. Toxicity data are combined with data from the Exposure Assessment module to assess ecological risk in the Risk Characterization module.
	Chemistry of Use & Process Description	The Chemistry of Use & Process Description module identifies: (1) the chemical/physical properties which contribute to the effectiveness of the chemicals in the use cluster; and (2) the process in which the chemicals are used. A process flow diagram is created that schematically describes the process operations, equipment, and material flows.
	Process Safety Assessment	The Process Safety Assessment module screens potential chemical substitutes to determine if they could potentially pose a safety hazard in the workplace. Process operating characteristics and workplace practices are combined with physical hazard data, precautions for safe handling and use, and other data to determine if a substitute might pose a safety hazard.
	Market Information	The Market Information module contains economic data used to evaluate the importance of the target industry sector to the overall market and conversely, the economic importance of the alternatives to the industry sector. Market information includes chemical/technology cost information, production, and manufacturing volumes, and an analysis of market trends that could affect future supply and demand.
	International Information	The International Information module collects data pertaining to the use or production of alternatives in other parts of the world, the impact of international trade on the selection of alternatives, and the impacts of switching to an alternative on international trade. Primarily, international trade issues are driven by the source and availability of alternatives and possible indirect costs (e.g., taxes, tariffs, etc.) imposed on alternatives.

TABLE 3-1: OVERVIEW OF CTSA INFORMATION MODULES

Component	Module	Overview
Risk	Workplace Practices & Source Release Assessment	The Workplace Practices & Source Release Assessment module identifies: (1) the workplace practices that contribute to environmental releases and worker exposure; and (2) the sources, amounts, and characteristics of environmental releases.
	Exposure Assessment	Exposure assessment is the quantitative or qualitative evaluation of the contact an organism (human or environmental) may have with a chemical or physical agent, which describes the magnitude, frequency, duration, and route of contact.
	Risk Characterization	Risk characterization (also referred to in the CTSA process as risk integration) is the integration of hazard and exposure information to quantitatively or qualitatively assess risk. Risk characterization typically includes a description of the assumptions, scientific judgments, and uncertainties that are part of this process.
Competitiveness	Regulatory Status	The Regulatory Status module determines the statutes and regulations that govern a particular chemical or industrial process.
	Performance Assessment	The Performance Assessment module measures how well a substitute performs to meet the functional requirements of the use cluster. In order to allow a comparative evaluation of the performance of baseline products or processes with the performance of substitutes, performance data are collected for both. This module provides assistance in developing methodologies for obtaining comparative performance data.
	Cost Analysis	The Cost Analysis module identifies the costs associated with the baseline process, as well as suitable substitutes, and calculates comparative costs between the baseline process and the substitutes. As a minimum, the cost analysis should identify the direct costs of the baseline process and the substitutes. If time and resources permit, data are also collected on indirect and future liability costs as well as any less-tangible benefits that occur through the implementation of a substitute.
Conservation	Energy Impacts	Energy consumption, either during the manufacture of a chemical or the use of a substitute product, process, or technology can vary with a selected chemical or process change. This module provides a procedure for evaluating the energy impacts of substitutes in a use cluster.
	Resource Conservation	Resource conservation is the process of selecting and using products, processes, or technologies that minimize the overall consumption of resources while effectively achieving a desired function. This module addresses materials use rates and provides methods for identifying the relative amounts of resources or materials consumed as a consequence of changing from a chemical, process, or technology to a substitute.

TABLE 3-1: OVERVIEW OF CTSA INFORMATION MODULES

Component	Module	Overview
Additional Environmental Improvement Opportunities	Pollution Prevention Opportunities Assessment	Pollution prevention is the process of reducing or preventing pollution at the source through changes in production, operation, and raw materials use. This module provides methods for identifying pollution prevention opportunities that can provide additional benefits beyond the benefits realized if one of the alternatives evaluated in the CTSA is implemented.
	Control Technologies Assessment	Control technologies are methods which can be used to minimize the toxicity and volume of pollutants. This module provides methods for identifying control technologies that may be suitable for on-site treatment and disposal of product or process waste streams.
Choosing Among Alternatives	Risk, Competitiveness & Conservation Data Summary	The Risk, Competitiveness & Conservation Data Summary module organizes data from the risk, competitiveness, and conservation components of a CTSA together with data from the Process Safety Assessment, Market Information, and International Information modules to: (1) identify the trade-off issues associated with any one substitute; and (2) compare the trade-off issues across substitutes. Data summaries are transferred to the Social Benefits/Costs Assessment and to the Decision Information Summary modules for further analysis.
	Social Benefits/ Costs Assessment	Social Benefits/Costs Assessment is the process of qualitatively and systematically evaluating the impacts made on all society by individual decisions. Social benefits/costs assessment includes the benefits and costs to the individual of alternative choices (referred to as private benefits and costs) and the benefits and costs to others who are affected by the choices (referred to as external benefits and costs). Consideration of these effects in decision-making by industry could result in improvements for industry and society as a whole.
	Decision Information Summary	The Decision Information Summary is the final module of a CTSA. It combines the results of the Risk, Competitiveness & Conservation Data Summary with the Social Benefits/Costs Assessment to identify the overall advantages and disadvantages of the baseline and the substitutes from both an individual business perspective and a societal perspective. The actual decision of whether or not to implement an alternative is made by individual decision-makers outside of the CTSA process, who typically consider a number of other factors, such as their individual business circumstances, together with the information presented in a CTSA.

TABLE 3-2: CHEMICAL AND PROCESS INFORMATION		
Module	**Summary of Results**	**Uses of Data**
Chemical Properties	Basic chemical properties, including chemical identity (CAS RN), structure, vapor pressure, water solubility, density, melting and boiling points, flammability, chemical synonyms.	Identify potential chemical substitutes; provide chemical identity and/or properties data to almost all other modules in a CTSA.
Chemical Manufacturing Process & Product Formulation	Description of chemical manufacturing and chemical product formulation processes.	Input to other modules to evaluate environmental impacts of chemical manufacturing and chemical product formulation, if up-stream processes are being evaluated in a CTSA.
Environmental Fate Summary	Chemical fate property values; summaries of processes by which chemicals degrade and are transported in the environment.	Combine with source release data from the Workplace Practices & Source Release Assessment module to assess exposure.
Human Health Hazards Summary	Effects that chemical exposure may have on humans and the levels at which these effects may occur.	Guide the selection and use of chemicals less toxic to humans; combine with exposure data to characterize risk to human health.
Environmental Hazards Summary	Toxicity of chemicals to the aquatic environment; aquatic toxicity concern concentrations.	Guide the selection and use of chemicals that are less toxic to aquatic organisms; combine with exposure data to characterize ecological risk.
Chemistry of Use & Process Description	Process flow diagram of substitutes; characteristics of the chemicals contributing to their effectiveness.	Identify potential substitutes; provide basis for Workplace Practices & Source Release Assessment module.
Process Safety	Potential safety hazards posed by alternatives; precautions or actions needed to mitigate potential safety hazards.	Guide the selection and use of safer alternatives; trade-off issue evaluated in the Social Benefits/Costs Assessment and the Decision Information Summary modules.
Market Information	Total U.S. production of chemicals and total use by the industry; chemical and equipment prices; market trends.	Help set the boundaries of the evaluation; identify market trends that could effect the availability of substitutes; inform the Cost Analysis and Exposure Assessment modules; identify potential substitutes; potential trade-off issue in the Social Benefits/Costs Assessment and the Decision Information Summary modules.
International Information	Alternatives and market trends in international markets; international trade issues.	Identify potential substitutes; assess international implications of choosing an alternative; potential trade-off issue evaluated in the Social Benefits/Costs Assessment and the Decision Information Summary modules.

Data collected in many of the chemical and process information modules will be partially driven by the boundaries of the evaluation, as determined by the project team (see Chapter 2). For example, the data collected in the Market Information module typically includes chemical and equipment market trends and the amounts used by the industry under study. However, an energy-intensive industry especially concerned about energy impacts may be more interested in energy sources (i.e., hydroelectric, coal, etc.) and trends in energy prices. In this example, the data needs for the Energy Impacts module might drive the scope and direction of the Market Information module.

Risk

Table 3-3 lists the risk-related information modules from Figure 3-2, some of the primary outputs from these modules, and some of the uses of the risk-related data. These modules typically build upon data compiled in the chemical and process information modules.

TABLE 3-3: RISK[a,b]

Module	Summary of Results	Uses of Data
Workplace Practices & Source Release Assessment	Survey of workplace practices; profile of a model facility, including worker activities potentially resulting in chemical exposure, and the nature and quantity of both on-site and off-site chemical releases.	Provide environmental release data and information worker activities to the Exposure Assessment module; identify pollution prevention or control technology opportunities.
Exposure Assessment	Occupational, consumer and ambient exposures, including routes of exposure, estimates of dose, and ambient concentrations.	Guide the selection and use of alternatives with reduced potential for chemical exposure; identify sources of chemical exposure and identify methods for reducing exposure; input to the Risk Characterization module; potential trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.[c]
Risk Characterization	Potential risk to human health from ambient environment, consumer and occupational exposures; potential risks to aquatic organisms.	Guide the selection and use of alternatives with reduced risk to human health and the environment; identify sources that pose greatest risk to human health and the environment; guide in selecting ways to manage risks; trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.

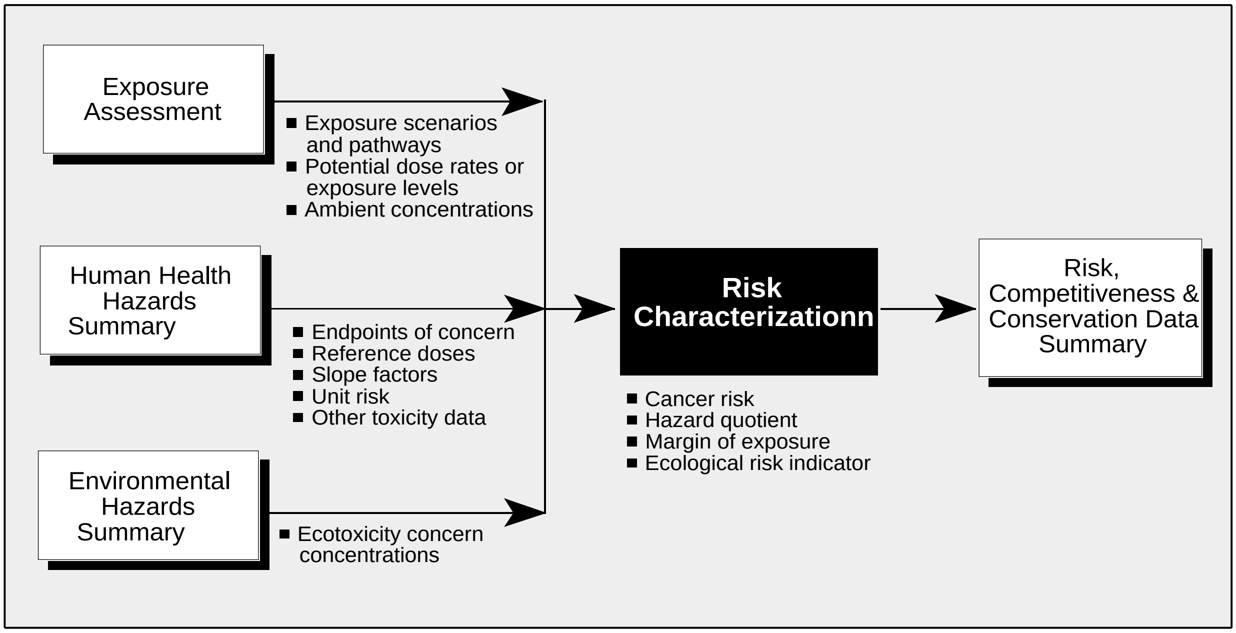
a) Data for the chemical hazard component of risk (risk is the integration of hazard and exposure) are collected in the Chemical & Process Information component of a CTSA.

b) The risk summary of the Risk, Competitiveness & Conservation Data Summary module presents process safety concerns together with other risk-related data. However, process safety data are collected in the data collection stage of a CTSA since some process safety data, such as data regarding chemical safety hazards, are needed in the data analysis stage. Early collection of process safety data can also ensure that substitutes posing unacceptable safety hazards are not carried through the entire CTSA evaluation process.

c) Exposure levels may be included in these modules if risk could not be characterized due to a lack of hazard data.

For example, Figure 3-3 shows the flow of information into and out of the Risk Characterization module. The Exposure Assessment module identifies potential routes of exposure, estimates potential dose rates or levels of exposure, and estimates concentrations in the ambient environment from use or disposal of the chemicals in the use cluster. The Human Health Hazards Summary and Environmental Hazards Summary[3] modules provide information on the doses or concentrations of chemicals at which adverse health or environmental effects may occur. The exposure data and hazard data are then combined to characterize the potential risk of chemical releases to human health and the environment. Similar flow diagrams for each module are in the module descriptions in Part II of this publication. The flow diagrams illustrate the transfers of data between modules and list two or three examples of data elements that are transferred. Not all interconnections are shown in the flow diagrams; the focus is on linkages directly related to a particular module.

FIGURE 3-3: RISK CHARACTERIZATION MODULE: EXAMPLE INFORMATION FLOWS



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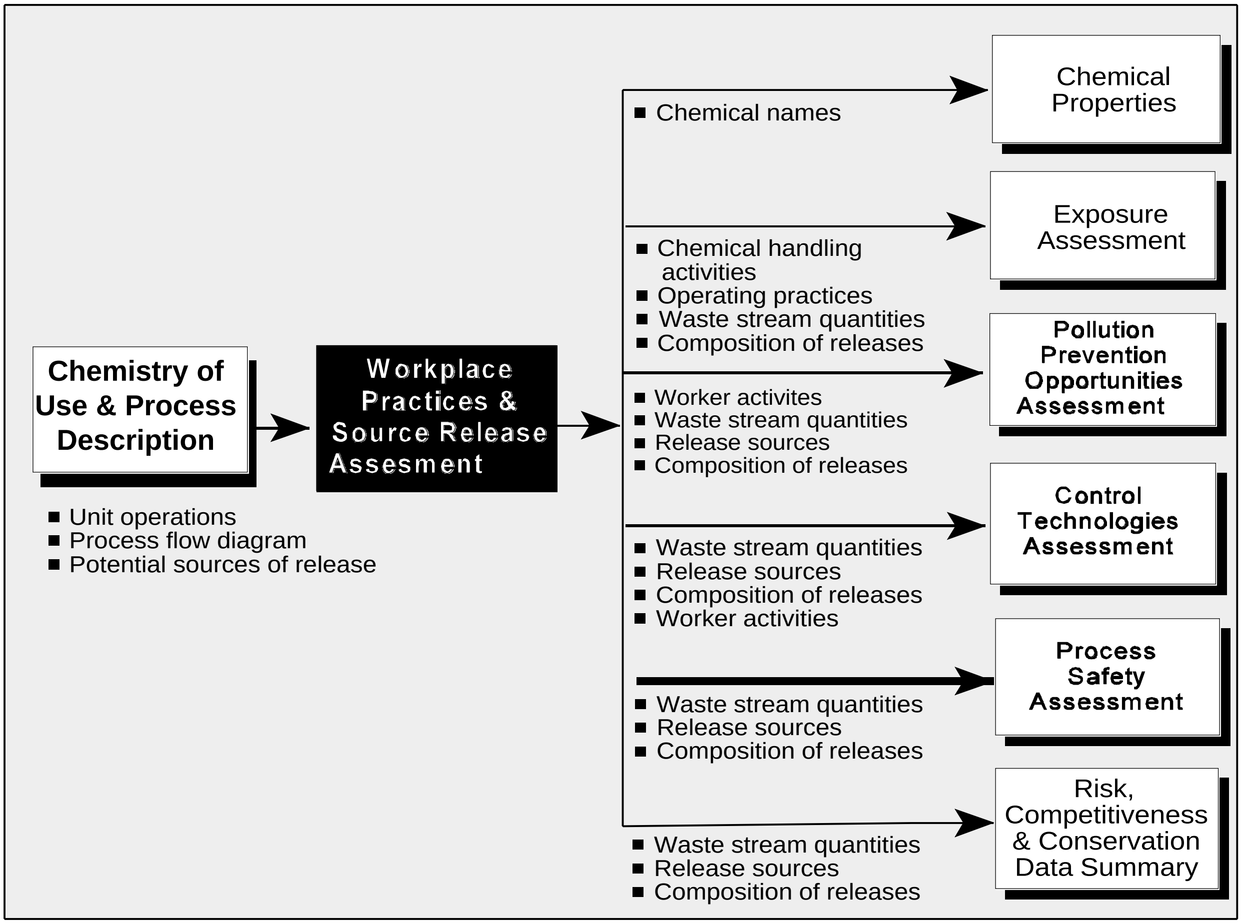
[3] Environmental hazard summaries prepared in CTSA pilot projects and the module description in this publication focus on aquatic toxicity. Other techniques and information could be used to assess other environmental hazards, such as avian toxicity.

In another example, data on how workers store, handle and use chemicals, the sources of chemical releases, and the nature and quantity of releases from a typical facility are generated in the Workplace Practices & Source Release Assessment module (Figure 3-4). Past CTSA projects have designed a Workplace Practices questionnaire to collect industry-wide data in order to develop a model of a typical facility. The Workplace Practices questionnaires developed for the Screen Printing Project and the PWB Project are presented in Appendix A.

FIGURE 3-4: WORKPLACE PRACTICES & SOURCE RELEASE ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



The Chemistry of Use & Process Description module provides preliminary information on the process to guide the design of the Workplace Practices questionnaire and inform the source release assessment. Operating practices and environmental release data from the Workplace Practices & Source Release Assessment module are used in a variety of modules, but are particularly important to developing exposure scenarios and estimating exposure. These data are also used to identify pollution prevention opportunities or sources that can be controlled to mitigate chemical releases. By studying workplace practices in the screen reclamation process, the DfE team identified several simple workplace practices that screen printers can use to reduce chemical usage, exposure and risk, such as keeping solvent containers closed when not in use or draining excess solvent from cleaning rags into closed containers.

Competitiveness

Table 3-4 lists the competitiveness modules from Figure 3-2, some of the primary data or results obtained from these modules, and some of the uses of these data. These modules are designed to develop industry-wide data on some of the issues traditionally important to industry when choosing among alternatives, such as performance and cost. The information is developed using a consistent basis, such as cost per unit of production, to facilitate comparison of the alternatives.

TABLE 3-4: COMPETITIVENESS[a]

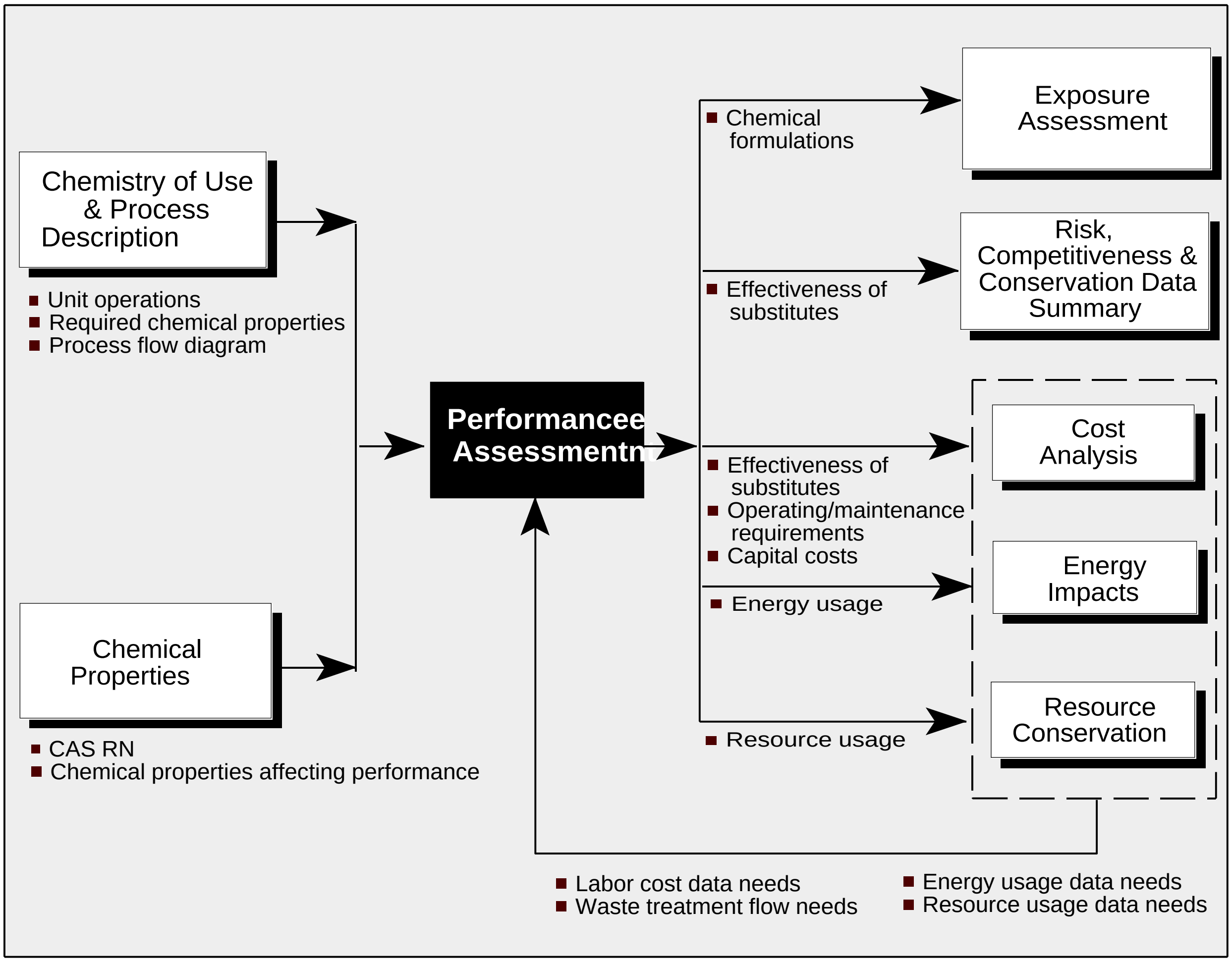
Module	Summary of Results	Uses of Data
Regulatory Status	Regulatory status of alternative chemicals, processes, and technologies.	Guide the selection and use of alternatives with reduced regulatory costs; help select subset of alternatives for evaluation; trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.
Performance Assessment	Effectiveness of alternatives in achieving the desired function; energy and natural resources consumption data; cost data.	Guide the selection and use of more effective, efficient alternatives; provide data to the Energy Impacts, Resource Conservation and Cost Analysis modules; trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.
Cost Analysis	Capital, operating, and maintenance costs of alternatives; indirect costs; may include other costs, such as liability costs, or less tangible benefits or costs (e.g., benefit of improved sales due to proactive corporate environmental policies).	Guide the selection and use of more cost-effective alternatives; trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.

a) The competitiveness summary of the Risk, Competitiveness & Conservation Data Summary module presents market information and international information concerning the availability of substitutes together with other competitiveness-related data. However, these data are compiled in the data collection stage of a CTSA since some information, such as chemical use volumes, may be needed to help set the boundaries of the evaluation and for data analysis (e.g., in the exposure assessment).

The Performance Assessment module is an example of an interactive module that is designed to fulfill data needs of other modules as well as evaluate the comparative performance of the substitutes. The goal of the Performance Assessment module is to collect standardized data on objective evaluation criteria as well as subjective issues such as operator impressions of an alternative. The Performance Assessment module typically involves a performance demonstration of alternatives in a laboratory or manufacturing setting in the presence of an unbiased observer; but may only involve an assessment of existing performance information. Because a performance demonstration is conducted under controlled or standardized conditions, it also provides an excellent opportunity for collecting data for other modules, such as the Energy Impacts, Resource Conservation, and Cost Analysis modules.

Figure 3-5 illustrates the flow of information into and out of the Performance Assessment module. If a performance demonstration project is planned, data needs for the Cost Analysis, Energy Impacts and Resource Conservation modules are identified in these modules and included in a performance demonstration project workplan. The performance demonstration team is then responsible for collecting the data and communicating data back to the appropriate module. A performance demonstration project can also be used to collect exposure data on new alternatives not in use by the industry.

FIGURE 3-5: PERFORMANCE ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



Conservation

Table 3-5 lists the information modules related to conservation issues. The primary data or results of these modules and some of the uses of these data are also identified. The results of these modules can be used by themselves to guide the selection and use of alternatives that conserve energy and other resources. In a CTSA, the results of these modules are usually combined with other modules to identify the trade-offs among alternatives.

TABLE 3-5: CONSERVATION

Module	Summary of Results	Uses of Data
Energy Impacts	Sources and rates of energy consumption of alternatives.	Guide the selection and use of less energy-intensive alternatives; provide energy consumption rates to the Cost Analysis module; trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.
Resource Conservation	Types of resources consumed; sources and rates of resource consumption of alternatives.	Guide the selection and use of less resource-intensive alternatives; provide resource consumption rates to the cost analysis module; trade-off issue evaluated in the Social Benefits/Costs Assessment and Decision Information Summary modules.

Additional Environmental Improvement Opportunities

Table 3-6 lists the Pollution Prevention Opportunities Assessment and Control Technologies Assessment modules, the primary results of these modules, and some of the uses of these data. These modules can be stand-alone modules or build on other sections of a CTSA. For example, in past DfE industry projects, the Pollution Prevention Opportunities Assessment module has focussed primarily on pollution prevention opportunities above and beyond the implementation of a substitute, such as improved workplace practices. The Control Technologies Assessment module can be used to identify control technologies required for regulated alternatives or to identify potentially feasible treatment technologies.

TABLE 3-6: ADDITIONAL ENVIRONMENTAL IMPROVEMENT OPPORTUNITIES

Module	Summary of Results	Uses of Data
Pollution Prevention Opportunities Assessment	Methods to prevent pollution through improved workplace practices or equipment modifications.	Raise employee awareness of the benefits of pollution prevention; implement pollution prevention activities or complete program to reduce risk and costs.
Control Technologies Assessment	Methods to reduce chemical releases, and thus, exposure and risk through control technologies.	Identify applicable control technologies; provide control technology requirements to the cost analysis.

Choosing Among Alternatives

Table 3-7 lists the final information modules of a CTSA where data from the other modules are brought together to form an assessment of the baseline and alternatives. The Risk, Competitiveness & Conservation Data Summary module prepares data summaries of data collected in both the data collection and data analysis stages of a CTSA. These data summaries are provided to the Social Benefits/Costs Assessment module for an evaluation of the net benefits or costs to society of implementing a substitute as compared to the baseline. The results of the Social Benefits/Costs Assessment are presented together with the risk, competitiveness and conservation data summaries in the Decision Information Summary module. In addition to presenting information collected throughout a CTSA, the Decision Information Summary module discusses the uncertainty in the information and recognizes that there are additional factors beyond those assessed in a CTSA which individual businesses may consider when choosing among alternatives. None of these modules recommend alternatives, since the final selection of an alternative will depend on the situation and values of those making the selection.

TABLE 3-7: CHOOSING AMONG ALTERNATIVES

Module	Summary of Results	Uses of Data
Risk, Competitiveness & Conservation Data Summary	Risk, competitiveness, and conservation data summaries, including uncertainties in the data, and data interpretation, as appropriate (e.g., assignment of high, medium, or low concern levels to human health and environmental risk data).	Input to the Social Benefits/Costs Assessment and Decision Information Summary modules.
Social Benefits/Costs Assessment	Qualitative assessment of benefits or costs of substitutes in terms of effects on health, recreation, productivity, and other social welfare issues; identifies who will benefit and who will bear the costs.	Guide the selection and use of alternatives that provide societal benefits and have reduced social costs; trade-off issue evaluated in the Decision information Summary module.
Decision Information Summary	Identifies trade-off issues associated with any one substitute; compares the trade-off issues across substitutes; does not recommend substitutes.	Lay out information to allow individual businesses to make the best choice for their particular situation, while considering social benefits and costs of individual choices.

Data are organized in the trade-off evaluation modules to accomplish the following:

- Identify the trade-off issues associated with any one substitute (e.g., reduced worker exposure but increased operating costs; reduced risk but increased energy consumption and reliance on scarce natural resources).

- Compare the trade-off issues across substitutes.

The goal is to present the data in a manner that allows individual businesses to make the best choices for their particular situation, while considering the social benefits and costs of their decision. For example, the alternative preferred by different shops within an industry sector may vary depending on the performance required for customer satisfaction, the required turn-around time, or water and energy costs. A business located in an urban area might be more concerned about volatile organic compounds (VOCs) that contribute to photochemical smog than aqueous waste streams released to the local publicly-owned treatment works, particularly when the business considers the impacts to society of the cumulative effect of many businesses emitting VOCs.

If an alternative is clearly superior in all respects, except it does not meet one of several performance requirements, it may be time to reevaluate the performance requirements. For example, unbleached paper made from 100 percent recycled fiber may not meet the traditional brightness performance criteria of virgin paper, but many consumers concerned about the environmental effects of the chlorine bleaching process are willing to accept less brightness for less pollution. This illustrates how performance needs can vary from business to business, sometimes allowing for more or fewer choices among the alternatives identified. In another example, an industry may find that a new substitute with reduced risk performs within acceptable limits, but does not perform as well as the current industry standard. If performance was the only criteria, clearly the industry standard would prevail. Factoring the reduced risk into the evaluation, however, makes the new substitute preferable as long as performance requirements are met.

IDENTIFYING DATA ANALYSIS METHODS AND ANALYZING DATA

The DfE project team will need to identify the specific methods they will use to analyze the project data and evaluate the risk, performance, cost, and other environmental impacts associated with each alternative. The module descriptions in Part II of this publication give guidelines for data analysis and provide references for analytical models. The Screen Printing: Screen Reclamation CTSA (EPA, 1994c) and the Lithographic Blanket Wash CTSA (EPA, 1996a) provide examples of the methods used for those projects. The following appendices are reproduced from either the Screen Printing Screen Reclamation or Lithographic Blanket Wash CTSAs:

- Appendix B, Environmental Releases and Occupational Exposure Assessment.
- Appendix C, Population Exposure Assessment for Screen Reclamation Processes.
- Appendix D, Background on Risk Assessment for Screen Reclamation Processes.
- Appendix E, Background and Methodology for Performance Demonstration.

- Appendix F, Chemical Volume Estimates.
- Appendix G, Cost Analysis Methodology.
- Appendix H, Environmental Fate Summary Initial Review Exposure Report.
- Appendix I, Risk, Competitiveness & Conservation Data Summary and Social Benefits/Costs Assessment.
- Appendix J, Cost of Illness Valuation Methods.

DEVELOPING A CTSA DOCUMENT

A CTSA document is the repository of all of the technical information collected in a DfE industry project. As a minimum, it should include the following:

- A profile of the use cluster describing the overall product or process in which the use cluster occurs; market information; the traditional products, processes, and technologies in the use cluster; and potential substitutes, including those evaluated in the CTSA, those not evaluated, and the reasons for excluding substitutes from evaluation.
- Information on chemicals in the use cluster, including the basic chemical properties data, market data, hazards summary data, and regulatory status.
- Summaries of the methodologies used to evaluate each of the trade-off issues (e.g., risk, performance, cost, social benefits and costs, energy impacts, resource conservation, process safety, international implications, and regulatory status).
- Results of the evaluations, including a summary of the trade-off issues.
- Descriptions of other environmental improvement opportunities identified during the course of the CTSA.

The project team circulates a draft CTSA for review and comment among the project partners and other interested parties. The team responds to comments and publishes a final document for dissemination to anyone interested in a compilation of all the project's technical work. Usually the project team will develop summary reports to disseminate to a wider, less technical, audience.

Design for the Environment: Building Partnerships for Environmental Improvement (EPA, 1995a) describes how to develop summary reports to communicate the results of a DfE industry project.

Chapter 4

OVERVIEW OF THE MODULE DESCRIPTIONS

The CTSA process is applicable to any industry sector that can benefit from the reduced risk and increased efficiency that results from using a cleaner product, process, or technology. Information needs and understanding of environmental issues differ from business to business and from industry to industry, however. For example, the issues and methods of assessing risk and exposure for computer workstations would differ substantially from those of the dry cleaning industry. Industries dominated by a few large companies, such as the aerospace industry, will have different data requirements than an industry with thousands of member companies, such as the printing industry.

For these reasons, the module descriptions in this publication are developed to:

- Provide basic information suitable for a wide audience with a broad range of information needs.
- Give a DfE project team a basic understanding of the analytical concepts and methodology for completing a module.
- Provide references for sources of more detailed information.

The module descriptions were *not* formulated to give a complete accounting of all of the assumptions, analytical methods, or steps required for some of the more complicated analyses, such as exposure assessment. For these analyses, the reader is referred to published guidance, with references provided in the module descriptions. In addition, many of the modules describe analyses or data evaluations that cannot be performed without substantial expertise and experience (e.g., the Human Health Hazards Summary, Environmental Hazards Summary, Exposure Assessment, and Risk Characterization modules). For these and other analyses, users of this publication who do not have the necessary expertise are urged to seek assistance in completing the module.

FORMAT OF THE MODULE DESCRIPTIONS

Each of the module descriptions is organized according to a standard format that emphasizes the basic concepts behind each module. The descriptions do not necessarily provide a detailed accounting of all of the steps for completing the module. If, however, the basic methodology is the same regardless of the industry (e.g., data sources and methods for collecting or estimating chemical properties data), the module gives a brief, step-by-step methodology.

The following describes the sections that are presented in each module:

- The ***Overview*** section provides a brief overview of the types of data collected or analysis performed in each module.

- The ***Goals*** section contains a list of the module's goals. This may include a description of how this module fits into the DfE process, whether information from this module is necessary input for any other module(s), and types of information a DfE project team would gain by completing this module.

- The ***People Skills*** section includes a description of the skills, knowledge, or expertise required to complete the module. It should be noted that different types of knowledge are required to complete different modules. For example, the Human Health Hazards Summary requires expertise in toxicology and epidemiology, while the Chemical Properties module requires a basic understanding of chemistry.

- The ***Definition of Terms*** section lists definitions of some of the technical terms used in the module, and is intended to familiarize the reader with the terms and data points described in the Approach/Methodology section. In some cases, other relevant terms are included although they are not used in the module *per se*. Many of the definitions include typical units of measure; equivalent English units follow metric units where appropriate.

- The ***Approach/Methodology*** section provides a brief summary of the basic module steps, including any data transfers to or from other modules. Some modules consist almost entirely of a data collection effort (e.g., the Chemical Properties module) while in others, data collection is the first step of a more complex analysis (e.g., the Exposure Assessment module).

- The ***Methodology Details*** section provides details and/or examples of the more complex steps in the Approach/Methodology section. In some of the modules this includes examples of a table or other format used to present module results.

- The ***Flow of Information*** section contains examples of the information transfers into and out of the module (e.g., the Market Information module receives information from the Chemical Properties module and transfers information to the Cost Analysis module). It also illustrates these inputs and outputs between modules in a flow diagram, and lists two or three examples of data elements that are transferred.

- The ***Analytical Models*** section provides a table of references for analytical models or software that can be used to complete this module, and the type of analysis performed by the model. For this and the next two sections, references are listed in shortened format (author, date, title), with complete references given in the reference list following Chapter 10.

- The ***Published Guidance*** section provides a table of published guidance on methods for conducting this type of assessment, guidelines for interpreting results, and guidance on using standard default assumptions. This includes document references in shortened format and descriptions of the type of information provided.

- The ***Data Sources*** section provides a table of data sources and the types of data to be found in the source. This includes on-line data bases, standard desk references, and other sources of published data.

The modules are described in Chapters 5 through 10, and are grouped together in the chapters according to the basic kind of information collected or analyses performed. Chapter 5 describes the modules concerning basic chemical and process information. Chapter 6 presents the risk-related modules. Chapter 7 presents modules traditionally related to competitiveness, including performance, cost and regulatory status. The modules in Chapter 8 address conservation issues, including energy impacts and resource conservation. Chapter 9 discusses additional improvement opportunities that may be realized through a pollution prevention or control technology assessment. Chapter 10 describes how all of this information is brought together to evaluate the trade-off issues from a societal or individual business perspective.

Chapter 5

CHEMICAL & PROCESS INFORMATION

This chapter presents module descriptions for the chemical and process information component of a CTSA which consists of nine data gathering modules:

- Chemical Properties.
- Chemical Manufacturing Process & Product Formulation.
- Environmental Fate Summary.
- Human Health Hazards Summary.
- Environmental Hazards Summary.
- Chemistry of Use & Process Description.
- Process Safety Assessment.
- Market Information.
- International Information.

The Chemical Properties, Environmental Fate Summary, Human Health Hazards Summary, and Environmental Hazards Summary modules collect data on the properties of the chemicals in the use cluster. The Chemical Manufacturing Process & Product Formulation, Chemistry of Use & Process Description, Process Safety Assessment, Market Information, and International Information modules collect data relating to the chemicals themselves, and/or the substitute products, processes, or technologies in which they are used. The information compiled in each of these modules is used later in the data analysis components of a CTSA.

For example, the Chemical Properties module provides chemical identity information to almost every module in the CTSA. Among other things, this minimizes the potential for confusion caused by chemical synonyms and ensures that DfE team members from different disciplines have a common point of reference on chemical names. The Hazards Summary modules combine with data from the Exposure Assessment module to characterize human health and ecological (aquatic) risks. The Chemistry of Use & Process Description module clearly defines the processes in the use cluster so that DfE team members working on different process-related modules have a common understanding of the processes.

Only the Process Safety Assessment, Market Information, and International Information modules of this component provide information directly to the final trade-off evaluations of a CTSA. The Process Safety Assessment module provides data on potential chemical hazards (e.g., fire, explosion, etc.) and precautions for safe use of equipment or chemicals to the Risk, Competitiveness & Conservation Data Summary module for evaluation in the Social Benefits/Costs Assessment and Decision Information Summary modules. The Market Information and International Information modules provide data on domestic and foreign supply and demand and relevant trade issues.

CHEMICAL PROPERTIES

OVERVIEW: Chemical properties, physical properties, and the chemical structure of a substance are characteristics which identify it from other substances. In this module, the physical and chemical characteristics of the chemicals in the use cluster are detailed.

GOALS:

- Identify the physical and chemical characteristics along with the chemical structures of the chemicals in the use cluster.
- Determine a discrete appropriate name and Chemical Abstracts Service Registry Number (CAS RN), defined below for each chemical to be used throughout the assessment.
- Facilitate the identification of potential chemical substitutes with similar properties to the chemicals in the use cluster.
- Provide chemical names and/or properties to the following modules: Chemical Manufacturing Process & Product Formulation, Environmental Fate Summary, Human Health Hazards Summary, Environmental Hazards Summary, Chemistry of Use & Process Description, Process Safety Assessment, Market Information, Workplace Practices & Source Release Assessment, Exposure Assessment, Regulatory Status, Performance Assessment, and Control Technologies Assessment.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of the basic concepts of chemistry, particularly physical and chemical properties.

Within a business or DFE project team, the people who might supply these skills include a chemist, chemical engineer, or an environmental scientist.

DEFINITION OF TERMS:

<u>Boiling Point (bp)</u>: The temperature at which a liquid under standard atmospheric pressure (or other specified pressure) changes from the liquid to the gaseous state. It is an indication of the volatility of a substance. The distillation range in a separation process, the temperature at which the more volatile liquid of a mixture forms a vapor, is used for mixtures in the absence of a bp. Typical units are ^oC or ^oF.

Chemical Abstracts Service Registry Number (CAS RN): A unique identification code, up to ten digits long, assigned to each chemical registered by the Chemical Abstract Service. The CAS RN is useful when searching for information on a chemical with more than one name. Over six million chemicals have been assigned CAS RNs.

Chemical Structure: A description of how atoms in a chemical are connected and arranged, including types of bonds between atoms.

Corrosivity: As defined by EPA (40 CFR 261.22), a solid waste exhibits the characteristic of corrosivity if: (1) it is aqueous and has a pH less than or equal to 2 or greater than or equal to 12.5, as determined by a pH meter using an EPA test method (Method 9049 in EPA Publication SW-846); (2) it is a liquid and corrodes steel at a rate greater than 6.35 mm (0.250") per year when tested at 55 ^{o}C as determined by the test method specified in the National Association of Corrosion Engineers Standard TM-01-69 as standardized in EPA Publication SW-846. As defined by OSHA (29 CFR 1910.1200), a chemical is corrosive if it causes visible destruction of, or irreversible alternation in living tissue by chemical action at the site of contact.

Density: The mass of a liquid, solid, or gas per unit volume of that substance, i.e., the mass in grams contained in 1 cubic centimeter (1 ml) of a substance at 20 ^{o}C and 1 atmosphere pressure. Typical units are g/ml or lbs/in^{3}.

Explosive: As defined by OSHA (29 CFR 1910.1200), a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

Flammable: As defined by OSHA (29 CFR 1910.1200), a chemical that falls into one of the following categories:

- Flammable aerosol: An aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening.
- Flammable gas:
  - A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less; or
  - A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than 12 percent by volume, regardless of the lower limit.
- Flammable liquid: Any liquid having a flashpoint below 100 ^{o}F (37.8 ^{o}C), except any mixture having components with flashpoints of 100 ^{o}F (37.8 ^{o}C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.
- Flammable solid: A solid, other than a blasting agent or explosive as defined in 29 CFR 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

Flash Point: As defined by OSHA (29 CFR 1910.1200), the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

- Tagliabue Closed Tester: (see American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24-1979 [ASTM D 56-79]) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 ^oF (37.8 ^oC), that do not contain suspended solids and do not have a tendency to form a surface film under test.
- Pensky-Martens Closed Tester: (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7-1979 [ASTM D 93-79]) for liquids with a viscosity equal to or greater than 45 SUS at 100 ^oF (37.8 ^oC), or that contain suspended solids, or that have a tendency to form a surface film under test.
- Setaflash Closed Tester: (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester [ASTM D 3278-78].) Typical units are ^oC or ^oF.

Melting Point (mp): The temperature at which a substance changes from the solid to the liquid state. It indicates the temperature at which solid substances liquefy. Typical units are ^oC or ^oF.

Molecular Weight (MW): A summation of the individual atomic weights based on the numbers and kinds of atoms present in a molecule of a chemical substance. For polymers, this may include molecular weight distributions or average number MW (MW_n), ranges, and averages. Typical units are g/mole, daltons, or lbs/mole.

Physical State: Describes a chemical substance as a gas, liquid, or solid under ambient or other given conditions.

Reactivity: As defined by EPA (40 CFR 261.23), a solid waste is considered reactive if it exhibits any of the following properties: (1) is normally unstable and readily undergoes violent change without detonating; (2) reacts violently or forms potentially explosive mixtures with water; (3) when mixed with water, generates toxic gases, vapors, or fumes in a quantity that can present a danger to human health or the environment; (4) is a cyanide or sulfide bearing waste which, when exposed to a pH between 2 and 12.5, can generate toxic gases, vapors, or fumes in a quantity that can present a danger to human health in the environment; (5) is capable of detonation or explosive reaction if subjected to a strong initiating source or if heated under confinement; (6) is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure; or (7) is a forbidden Class A or Class B explosive as defined by the Department of Transportation (49 CFR 173). As defined by OSHA (29 CFR 1910.1200), water-reactive means a chemical will react with water to release a gas that is either flammable or presents a health hazard.

Vapor Pressure (Pv): The pressure exerted by a chemical in the vapor phase in equilibrium with its solid or liquid form. It provides an indication of the relative tendency of a substance to volatilize from the pure state. Typical units are mm Hg, torr, or in. Hg.

Water Solubility (S): The maximum amount of a chemical that can be dissolved in a given amount of pure water at standard conditions of temperature and pressure. Typical units are mg/L, g/L, or lbs/gal.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for obtaining chemical properties data. Methodology details for Step 6 are presented in the next section of this module.

Step 1: Prepare a list of chemical names from the substitutes tree, the Industry and Use Cluster Profile, and other pertinent documents as chemicals are identified (e.g., by the Performance Assessment or Workplace Practices & Source Release Assessment modules).

Step 2: Obtain the CAS RN and the chemical structure for each chemical on the list and identify synonyms. This will expedite the search for data on chemical properties. (Refer to Tables 5-2, 5-3, and 5-4.)

Step 3: Determine the appropriate name to be used to identify the chemical from the synonyms.

Step 4: Collect measured and/or estimated data for all of the terms listed in the Definition of Terms, when applicable. Many sources of data can be searched by CAS RN. Data are generally available from suppliers of the chemicals. (See material safety data sheets [MSDSs], described in the Process Safety Assessment module.)

Step 5: Use standard or accepted mathematical models or computer programs to estimate the data. (See Table 5-2: Mathematical Models Used to Estimate Chemical Properties.)

Step 6: Provide pertinent chemical properties to the appropriate modules (see Methodology Details below).

METHODOLOGY DETAILS: This section presents the methodology details for completing Step 6 in the above section.

Details: Step 6, Providing Pertinent Chemical Properties to the Appropriate Modules

Table 5-1 lists examples of data that the Chemical Properties module transfers to other modules in a CTSA.

TABLE 5-1: DATA TRANSFERRED FROM THE CHEMICAL PROPERTIES MODULE

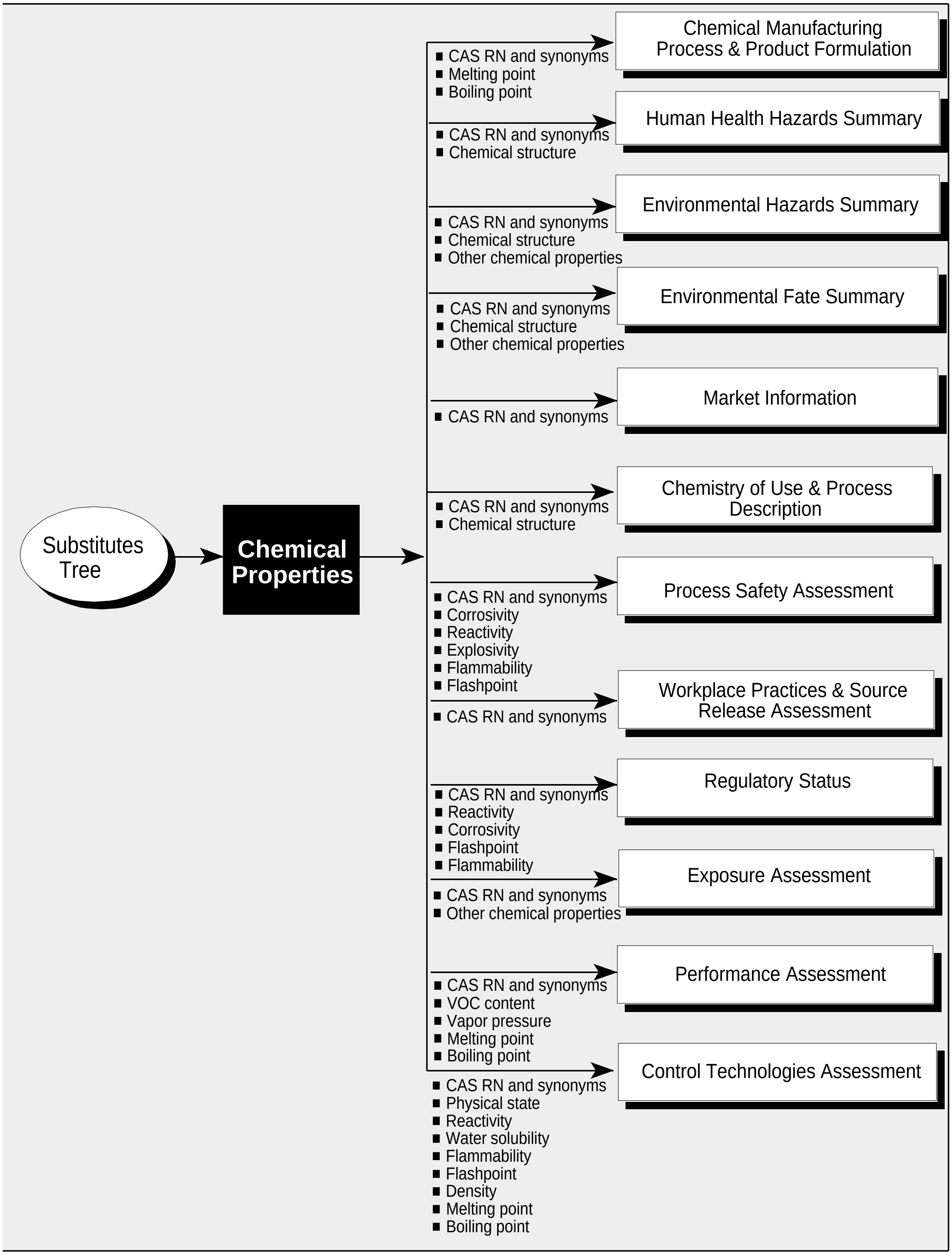
Module	Data Transferred
Chemical Manufacturing Process & Product Formulation	CAS RN, synonyms, mp, bp
Human Health Hazards Summary	CAS RN, synonyms, chemical structure
Environmental Hazards Summary	CAS RN, synonyms, chemical structure, S.

TABLE 5-1: DATA TRANSFERRED FROM THE CHEMICAL PROPERTIES MODULE

Module	Data Transferred
Environmental Fate Summary	CAS RN, synonyms, chemical structure, Pv, S, mp, bp, physical state, MW
Market Information	CAS RN, synonyms
Chemistry of Use & Process Description	CAS RN, synonyms, chemical structure
Process Safety Assessment	CAS RN, synonyms, corrosivity, reactivity, explosivity, flammability, flashpoint
Workplace Practices & Source Release Assessment	CAS RN, synonyms
Regulatory Status	CAS RN, synonyms, reactivity, flammability, flashpoint, corrosivity
Exposure Assessment	CAS RN, synonyms, chemical structure, Pv, S, physical state
Performance Assessment	CAS RN, synonyms, Pv, bp, flashpoint
Control Technologies Assessment	CAS RN, synonyms, physical state, reactivity, S, flammability, flash point, mp, bp, density

FLOW OF INFORMATION: The Chemical Properties module is the basic starting point for many of the other modules in the CTSA. The Chemical Properties module receives chemical names from the substitutes tree and other sources and transfers data to the Chemical Manufacturing Process & Product Formulation, Human Health Hazards Summary, Environmental Hazards Summary, Environmental Fate Summary, Market Information, Chemistry of Use & Process Description, Process Safety Assessment, Workplace Practices & Source Release Assessment, Regulatory Status, Exposure Assessment, Performance Assessment, and Control Technologies Assessment modules. Example information flows are shown in Figure 5-1.

FIGURE 5-1: CHEMICAL PROPERTIES MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 5-2 presents references for analytical models that can be used to estimate chemical properties.

TABLE 5-2: MATHEMATICAL MODELS USED TO ESTIMATE CHEMICAL PROPERTIES

Reference	Type of Model
Hunter, R.S. and F.D. Culver. 1992. *MicroQSAR Version 2.0: A Structure-Activity Based Chemical Modeling and Information System.*	Personal computer-based system of models. Uses quantitative structure-activity relationships to estimate chemical properties and aquatic toxicity values.
Syracuse Research Corporation (SRC). Continually Updated. Estimation Programs Interface (EPI$^{©}$).	A shell program used to access a series of models used to estimate S, mp, bp, Pv, and environmental fate properties.
Syracuse Research Corporation (SRC). Updated Periodically. MPBVP$^{©}$.	This program estimates the mp, bp, and Pv of organic compounds.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 5-3 presents a reference for published guidance on chemical and physical properties and the use of estimation models for these properties.

TABLE 5-3: REFERENCES FOR CHEMICAL AND PHYSICAL PROPERTIES

Reference	Type of Guidance
Lyman, W.J., et. al. 1990. *Handbook of Chemical Property Estimation Methods.*	Methods for estimating density, Pv, S, and other chemical properties relevant to the Chemical Properties module.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 5-4 lists sources of chemical and physical property data.

TABLE 5-4: SOURCES OF CHEMICAL AND PHYSICAL PROPERTIES DATA

Reference	Type of Data
Aldrich Chemical Company, Inc. 1990. *Catalog Handbook of Fine Chemicals*.	Commercial catalog containing over 27,000 organic and inorganic chemicals (mostly for research and development). Entries list the chemical name, CAS RN, structure, MW, and possibly the mp or bp, density, refractive index, a Beilstein reference, and other data (e.g., "hygroscopic, irritant, or moisture sensitive").
Beilstein. Beilstein on-line data base. Updated Periodically.	Data base containing data on known organic compounds. Its unique feature is its ability to define reactants in products. It is an extensive collection of physical properties and chemical reactions.
Buckingham, J. 1982. *Dictionary of Organic Compounds*.	Five volume set (plus supplements) with molecular formula and name index. Lists, with references, synthesis, spectra, physical properties, and derivatives for a large number of organic compounds.
Chemical Abstracts Systems. 1994.	Data base containing CAS RNs and chemical and physical properties.
Farm Chemicals Handbook '87. 1987.	A commercial "magazine" of registered agricultural herbicides, fungicides, and pesticides. Contains measured values of Pv, S, and many others. Usually listed by the agricultural trade name.
Handbook of Chemistry and Physics (CRC). 1992-1993.	Handbook containing CAS RNs and chemical and physical properties.
Hawley, Gessner G., et. al., Ed. 1981. *Condensed Chemical Dictionary*.	A compendium of technical data and descriptive information covering many thousands of chemicals, including their industrial uses. Also includes trademark names.
HSDB®. Hazardous Substances Data Bank (HSDB). Updated Periodically.	On-line data base containing CAS RNs, synonyms, and chemical and physical properties.
Merck Index. 1989.	Handbook containing chemical and physical properties and CAS RNs.
Perry's Chemical Engineering Handbook. 1984.	Handbook containing chemical and physical data.

TABLE 5-4: SOURCES OF CHEMICAL AND PHYSICAL PROPERTIES DATA

Reference	Type of Data
RTECS®. Registry of Toxic Effects of Chemical Substances. 1995.	An on-line data base that contains chemical identity information such as chemical name, CAS RN, synonyms, molecular formula, MW, and others. Also included are toxicity and mutagenicity information.
Sax, N. Irving and Richard J. Lewis, Sr. 1987. *Hazardous Chemicals Desk Reference*.	Handbook containing CAS RNs and chemical and physical properties as well as synonyms, hazard ratings, and current standards for exposure limits.
Syracuse Research Corporation (SRC). 1994. Environmental Fate Data Bases (EFDB©).	Data base containing CAS RNs and chemical and physical property information.
Syracuse Research Corporation (SRC). Updated Periodically. Water Solubility Data Base.	A compilation of measured S data, as well as data on other physical property values for over 4,000 (and growing) chemicals stored on a searchable computer data base (ChemBase v.1.4). It currently contains referenced data from the Arizona data base, the Syracuse data base, the Merck Index, on-line Beilstein, other pertinent literature, and journal articles.
U.S. Department of Health and Human Services. 1985. CHEMLINE: Chemical Dictionary Online.	An on-line interactive chemical dictionary file containing one million chemical substance records. The data elements consist of CAS RNs, molecular formula, synonyms, ring information (part of the structure of some chemicals), and a locator to other on-line data bases that would contain further information on that compound.
U.S. Environmental Protection Agency. 1995d. *Integrated Risk Information System (IRIS®).*	An on-line data base that contains information and data on numerous chemical substances. Information includes substance identification (name and CAS RN) and physical properties such as color/form, odor, bp, mp, MW, density, vapor density, Pv, solubilities, flash point, and others.
Verschueren, K. 1983. *Handbook of Environmental Data on Organic Chemicals.*	An extensive text compiling information on organic chemicals. The data given include formula, physical appearance, MW, mp, bp, Pv, and solubility.

TABLE 5-4: SOURCES OF CHEMICAL AND PHYSICAL PROPERTIES DATA

Reference	Type of Data
Worthing, Charles R. and S. Barrie Walker. 1987. *Pesticide Manual*.	An index of agricultural pesticides which contains chemical names and physical properties, such as mp or bp, Pv, S, and other useful measured values.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

CHEMICAL MANUFACTURING PROCESS & PRODUCT FORMULATION

OVERVIEW: Chemical manufacturing is the process through which a chemical is synthesized from raw materials or other chemical feedstocks. Product formulation is the process by which chemical products, composed of one or more ingredients, are prepared according to the product formula. This module: (1) describes the process for manufacturing the chemicals in the use cluster; and (2) describes the chemical product formulation process, if applicable. In both cases, the descriptions focus on the industrial or laboratory means of synthesis, the necessary starting materials and feedstocks, by-products and co-products, isolated or non-isolated intermediates, and relevant reaction conditions (e.g., temperature, pressure, catalyst, solvents, and other chemicals).

GOALS:

- Describe the processes for manufacturing chemicals in the use cluster.
- Describe the process for formulating chemical products used in the use cluster, if applicable.
- Compile chemical manufacturing and product formulation data to be used by subsequent modules if the impacts of these up-stream processes are being evaluated in a CTSA.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of chemical feedstocks, synthetic chemical reaction catalysts, and reaction conditions.
- Understanding of chemical manufacturing processes, including both batch and continuous processes, as well as chemical equilibria, kinetics, and heat and mass transfer.

Within a business or DfE project team, the people who might supply these skills include a chemist and a chemical or process engineer. Vendors of the chemicals or chemical formulations may also be a good resource.

DEFINITION OF TERMS:

Catalyst: A substance that accelerates a chemical reaction but which itself is not consumed in the reaction.

Chemical By-product: An unintended chemical compound that is formed by a chemical reaction.

Chemical Intermediate: A chemical substance that is formed during the reaction and then undergoes further reaction to produce a product.

Chemical Product: In a CTSA, refers to products in the use cluster composed of one or more chemicals for which product formulation data must be obtained.

Chemical Reaction: The process that converts a substance into a different substance.

Feedstock: A raw material, pure chemical, or chemical compound that is used to synthesize a chemical.

Unit Operation: A process step that achieves a desired function.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for describing the chemical manufacturing processes and product formulation methods of chemicals or chemical products. Methodology details for Steps 3, 4, and 9 follow this section.

Chemical Manufacturing

Step 1: Obtain chemical information, including CAS RNs, synonyms, melting points, and boiling points from the Chemical Properties module.

Step 2: Determine the primary industrial mode of synthesis for each chemical in the use cluster (refer to data sources in Table 5-5).

Step 3: Develop a chemical manufacturing process flow diagram for the primary mode of synthesis. The diagram should identify the major unit operations and equipment, as well as all input and output streams (see Methodology Details for an example chemical manufacturing process description).

Step 4: Identify any chemical intermediates, catalysts, feedstocks, and chemical products or by-products involved in the synthesis that have the potential for release.

Product Formulation

Step 5: Obtain chemical product formulation data for any chemical products being evaluated in the CTSA from the Performance Assessment module. When proprietary chemical products are being used, only generic formulations may be available.

Step 6: Determine the primary industrial method of formulation for each chemical product being evaluated. Mixing operations, with or without the addition of heat or pressure, are typical manufacturing processes for product formulations.

Step 7: Develop a process flow diagram for the primary industrial method of formulation. The diagram should include the unit operations, material flows, and equipment used in the formulation process. If a chemical reaction occurs in the formulation process, determine if any special reaction conditions are required (e.g., the presence of heat, cooling, a catalyst, etc.). If a product is formulated by mixing only (e.g., does not involve chemical reactions), determine if any special conditions (e.g., heat, pressure, etc.) are required to get ingredients into solution. This information can be used to evaluate the energy impacts of the alternatives.

Step 8: Identify any chemical intermediates, catalysts, feedstocks, and chemical products or by-products involved in the product formulation process that have the potential for release.

Transferring Information

Step 9: Provide the following information to the modules listed below:

- Energy usage resulting from the chemical manufacturing and product formulation processes (e.g., heat, pressure, etc.) to the Energy Impacts module.
- Material streams usage resulting from the chemical manufacturing or product formulation processes (e.g., chemical feedstocks, catalysts, etc.) to the Resource Conservation module.

METHODOLOGY DETAILS: This section presents the methodology details for completing Step 3, 4, and 9 from the Chemical Manufacturing section above.

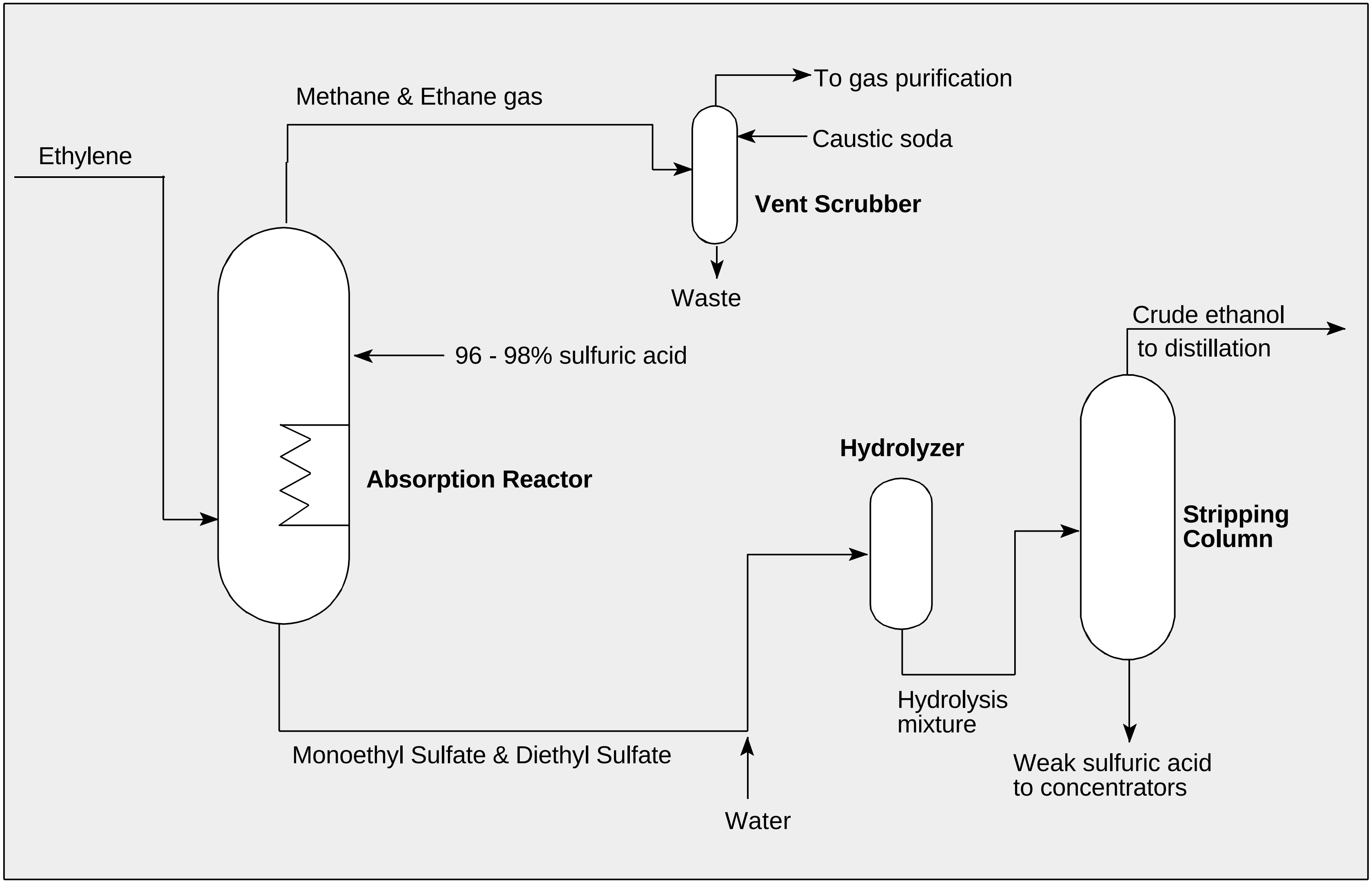
Details: Steps 3 and 4, Example Description of Chemical Manufacturing Process

The following description of the synthetic preparation of ethanol by indirect hydration is an example of the chemical manufacturing process description developed in Steps 3 and 4. The process information was gathered from the data sources listed in the Table 5-5.

Indirect Hydration of Ethanol

The preparation of ethanol from ethylene using sulfuric acid is a three step hydration process as discussed below. A flow diagram for this process is shown in Figure 5-2.

FIGURE 5-2: PROCESS FLOW DIAGRAM FOR THE MANUFACTURE OF ETHANOL BY INDIRECT HYDRATION



Step 1: Formation of monoethyl sulfate and diethyl sulfate by the absorption of ethylene in concentrated sulfuric acid.

$$CH_2 = CH_2 + H_2SO_4 \rightarrow CH_3CH_2OSO_3H$$

(Ethylene) (Sulfuric Acid) (Monoethyl Sulfate)

$$2\ CH_2 = CH_2 + H_2SO_4 \rightarrow (CH_3CH_2O)_2SO_2$$

(Ethylene) (Sulfuric Acid) (Diethyl Sulfate)

Step 2: Formation of ethanol by hydrolysis of ethyl sulfates.

$$CH_3CH_2OSO_3H + H_2O \rightarrow CH_3CH_2OH + H_2SO_4$$

(Monoethyl Sulfate) (Water) (Ethanol) (Sulfuric Acid)

$$(CH_3CH_2O)_2SO_2 + 2\ H_2O \rightarrow 2\ CH_3CH_2OH + H_2SO_4$$

(Diethyl Sulfate) (Water) (Ethanol) (Sulfuric Acid)

$$(CH_3CH_2O)_2SO_2 + CH_3CH_2OH \rightarrow CH_3CH_2OSO_3H + (CH_3CH_2)_2O$$

(Diethyl Sulfate) (Ethanol) (Monoethyl Sulfate) (Diethyl Ether)

Step 3: Reconcentration of the dilute sulfuric acid.

The primary input streams for this process are the hydrocarbon feedstock containing 35-95 percent ethylene, methane, and ethane; 96-98 percent sulfuric acid, and water.

The adsorption is carried out in a column reactor at 80 ^{o}C and 1.3-1.5 MPa of pressure where the ethylene feedstock is adsorbed in an exothermic reaction with the sulfuric acid. The column is cooled to reduce the reaction temperature and to limit corrosion problems. The hydrolysis of the ethyl sulfates in the second step of the process is done using just enough water to produce a 50-60 percent sulfuric acid solution. The resulting mixture is separated by a stripping column to yield sulfuric acid and a gaseous mixture of alcohol, ether, and water. The gaseous mixture is mixed with water and then distilled until pure. Finally, the sulfuric acid is then reconcentrated using a reboiler and a two stage vacuum evaporation system until the concentration is above 90 percent.

The primary output streams and by-products of this reaction are the following:

- Ethanol (product).
- Dilute 50-60 percent sulfuric acid.
- Scrubber waste containing the unreacted methane and ethane as well as any other gases present.
- Diethyl ether (by-product).

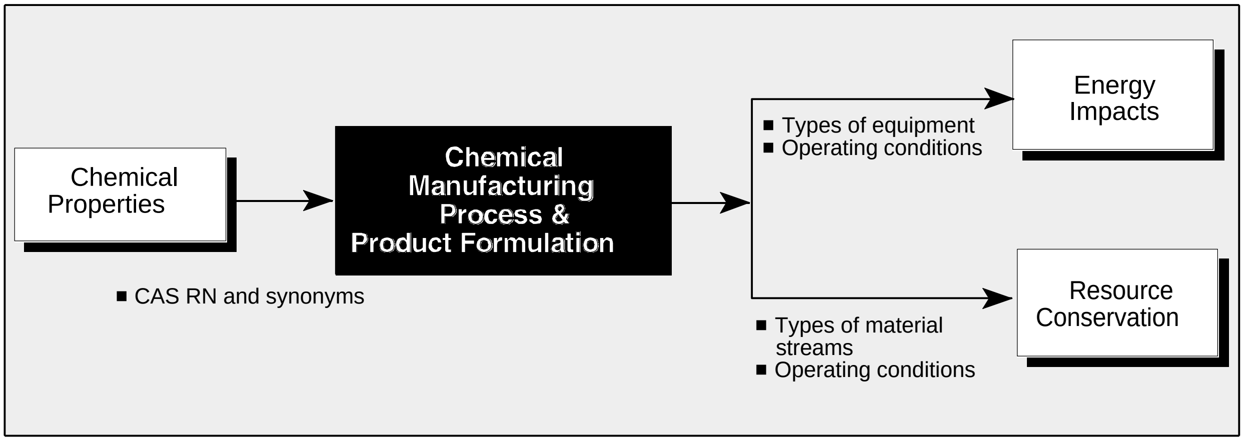
The intermediate compounds of monoethyl sulfate and diethyl sulfate are also present, although they are not waste streams, because they are consumed by the process.

Details: Step 9, Transferring Information

Past CTSAs have not quantitatively evaluated the chemical manufacturing and product formulation processes. Instead, attention has focussed on the relative effects of up-stream processes on energy and other resources consumption. If the effects of up-stream processes on human health and environmental risks are being quantified in a CTSA, the identities of chemical intermediates, catalysts, feedstocks, and chemical products or by-products are transferred to the Chemical Properties module and other modules that ultimately feed into the risk characterization. Process flow diagrams are transferred to the Workplace Practices & Source Release Assessment module.

FLOW OF INFORMATION: In a CTSA, this module receives information from the Chemical Properties module and transfers information, if desired, to the Energy Impacts and Resource Conservation modules. Example information flows are shown in Figure 5-3. This module could also transfer information to other modules if these processes are being fully and quantitatively evaluated. For example, chemical intermediates released during chemical manufacturing process could be evaluated in the hazards summary modules.

FIGURE 5-3: CHEMICAL MANUFACTURING PROCESS & PRODUCT FORMULATION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: None cited.

DATA SOURCES: Table 5-5 lists data sources for both chemical manufacturing processes and product formulation methods.

TABLE 5-5: SOURCES OF CHEMICAL MANUFACTURING PROCESS AND PRODUCT FORMULATION INFORMATION

Reference	Type of Data
HSDB®. Hazardous Substance Data Bank (HSDB). Updated Periodically.	Contains brief summaries of chemical manufacturing processes.
Kirk-Othmer Encyclopedia of Chemical Technology. Updated Periodically.	Comprehensive source of chemical synthesis processes.
Ullmann, Fritz. 1985. *Ullmann's Encyclopedia of Industrial Chemistry*.	Comprehensive source of chemical synthesis processes.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

ENVIRONMENTAL FATE SUMMARY

OVERVIEW: The environmental fate of chemicals describes the processes by which chemicals move and are transformed in the environment. Environmental fate processes that should be addressed include: persistence in air, water, and soil; reactivity and degradation; migration in groundwater; removal from effluents by standard waste water treatment methods; and bioaccumulation in aquatic or terrestrial organisms.

Note: *There is no single accepted methodology for evaluating the environmental behavior of chemicals; this is particularly true in the selection of mathematical models to predict environmental fate parameters. Thus it is important to document the approach and specific procedures used in the module. The approach presented below is one suggested by the types of information included in recent EPA Risk Management Reports.*

GOALS:

- Retrieve data or estimate key environmental fate parameters for each chemical in the use cluster.
- Prepare environmental fate and treatability summaries for each chemical.
- Provide data to the Human Health Hazards Summary, Environmental Hazards Summary, Exposure Assessment, and Control Technologies Assessment modules.

PEOPLE SKILLS: The following lists the types of skills or knowledge needed to complete this module.

- Knowledge of the physical, chemical, and biological reactions of chemicals in the environment.
- Knowledge of standard waste water treatment systems and unit processes.
- Experience with the use of mathematical models for predicting the fate and transformation of chemicals in the environment.

Note: *The analysis described in this module should only be undertaken by someone familiar with environmental fate calculations. Furthermore, peer-review of the completed environmental fate summary is recommended.*

DEFINITION OF TERMS: Several terms from the Chemical Properties module are also used in the Environmental Fate Summary module and are defined here as well.

Chemical Properties

Vapor Pressure (Pv): The pressure exerted by a chemical in the vapor phase in equilibrium with its solid or liquid form. It provides an indication of the relative tendency of a substance to volatilize from the pure state. Typical units are mm Hg, torr, or in. Hg.

Water Solubility (S): The maximum amount of a chemical that can be dissolved in a given amount of pure water at standard conditions of temperature and pressure. Typical units are mg/L, g/L, or lbs/gal.

Environmental Fate

Atmospheric Residence Time (τ): The ratio of the total mass of a chemical in an atmospheric compartment to either the total emission rate or the total removal rate, under steady-state conditions. Units are typically in hours or days.

Biochemical Oxygen Demand (BOD): The amount of oxygen consumed by microorganisms, over a specified time period, to metabolize a substance. Under certain environmental conditions, a high BOD may result in a reduction in oxygen levels in receiving waters to below critical levels for sustaining aquatic life.

Bioconcentration Factor (BCF): The equilibrium ratio of the concentration of a chemical in an exposed organism to the concentration of the chemical in the surrounding water.

Biodegradation: The transformation of chemical compounds by living organisms. Not confined to microorganisms (e.g., bacteria, fungi) but chiefly a microbial process in nature; typically expressed in terms of a rate constant and/or half-life.

Chemical Oxygen Demand (COD): The amount of oxygen consumed in the oxidation of a chemical substrate by a strong chemical oxidant (such as dichromate).

Half-life ($t_{½}$): The time required to reduce the concentration of a chemical to 50 percent of its initial concentration. Units are typically in hours or days.

Henry's Law Constant (H_c): The air/water partition coefficient, describing the relative concentrations of a chemical in air (the vapor phase) and the chemical dissolved in water, in a closed system at equilibrium. H_c can be measured directly or estimated as the ratio of Pv to S, and gives an indication of a chemical's tendency to volatilize from water to air or dissolve into water from air. H_c is typically expressed in units of atm-m^3/mole or in dimensionless terms.

Hydrolysis: A chemical transformation process in which a chemical reacts with water. In the process, a new carbon-oxygen bond is formed with oxygen derived from the water molecule, and a bond is cleaved within the chemical between carbon and some functional group.

Hydroxyl Radical Rate Constant ($K_{OH\cdot}$): The rate constant (in cm^3/mol/sec) for the reaction of photochemically produced hydroxyl radicals with organic compounds in the atmosphere.

Ionization or Acid Dissociation Constant (K_a, pK_a): An equilibrium ratio of the dissociation products and the parent compound in aqueous solutions. The degree of dissociation can alter the solubility and adsorption characteristics of the compound. The pK_a is the negative log of K_a.

Mobility: The tendency for a chemical to move in the environment (i.e., through soil with the percolation of water).

Octanol-Water Partition Coefficient (K_{ow}): The equilibrium ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol/water system, typically expressed in log units (log K_{ow}). K_{ow} provides an indication of a chemical's S, fat solubility (lipophilicity), its tendency to bioconcentrate in aquatic organisms, and to sorb to soil or sediment.

Organic Carbon Partition Coefficient (K_{oc}): The proportion of a chemical sorbed to the solid phase, at equilibrium in a two-phase, water/soil or water/sediment system expressed on an organic carbon basis. Chemicals with higher K_{oc} values are more strongly sorbed and, therefore, tend to be less mobile in the environment.

Oxidation: In general, a reaction in which electrons are transferred from a chemical to an oxidizing agent, or where a chemical gains oxygen from an oxidizing agent. (Also see Redox and Reduction.)

Percent Removal: The amount of the chemical that can be removed from sewage by standard waste water treatment processes, expressed in terms of the percent of the initial amount removed from the influent (liquid) waste stream. The chief processes that may contribute to removal from a liquid waste stream are degradation (biotic or abiotic), sorption, and volatization (also known as air stripping).

Persistence: The ability of a chemical substance to remain in a particular environment in an unchanged form.

Photolysis: The transformation of a chemical by light energy.

Plant Uptake: The uptake of a chemical into plants is expressed in terms of a bioconcentration factor for vegetation (B_v), which is the ratio of the concentration in the plant tissue to the concentration in soil.

Redox: Reduction-oxidation reactions. Oxidation and reduction occur simultaneously; in general, the oxidizing agent gains electrons in the process (and is reduced) while the reducing agent donates electrons (and is oxidized).

Reduction: In general, a reaction in which electrons are transferred to a chemical from a reducing agent, or where oxygen is removed from a chemical. (Also see Oxidation and Redox.)

Soil or Sediment Sorption Coefficient (K_d): The equilibrium ratio between a chemical sorbed to the solid phase and in solution in a two-phase, soil/water or sediment/water system.

Smog-Forming Potential: The chemical reaction of hydrocarbons to produce atmospheric photochemical oxidants such as ozone and other by-products contributing to the formation of smog.

Transport: The movement of a chemical through the environment, within a single phase or from one phase to another.

Treatability: The amenability of a chemical substance or waste stream to removal during waste water treatment, without adversely affecting the normal operation of the treatment plant.

Ultraviolet (UV): That part of the electromagnetic spectrum at a frequency higher than visible light (corresponding to wavelengths of 3000-4000 Å).

Volatilization: The transport process by which a chemical substance enters the atmosphere by evaporation from soil or water.

ADDITIONAL TERMS: The following additional terms are not used in this module discussion *per se*, but are likely to be found in the literature pertaining to chemical fate parameters.

Acclimation: The process in which continuous exposure of a microbial population to a chemical results in a more rapid transformation (biodegradation) of the chemical than initially observed.

Activated Sludge: The flocculated mixture of microorganisms and inert organic and inorganic material normally produced by aeration of sewage. Constitutes the biological treatment process most frequently employed for purification of domestic sewage.

BOD/COD Ratio: The ratio of the BOD to the COD for a chemical mixture.

Direct Aqueous Photolysis Rate Constant (k_d): The rate constant (in day^{-1} or $year^{-1}$) for the direct photolytic transformation of an organic compound in water.

Ozone Rate Constant(k_{O3}): The rate constant (cm^3/mol/sec) for the reaction of ozone with an organic compound.

Photooxidation: A process in which solar radiation generates an oxidizing agent, such as the hydroxyl radical, which reacts with (and transforms) a chemical.

Wet Deposition: The process by which a chemical that is dissolved in water in the atmosphere reaches land or a water body via precipitation (synonym: atmospheric washout).

APPROACH/METHODOLOGY: The following outlines the technical approach or methodology for preparing an environmental fate summary. Further methodology details for Steps 3 and 4 follow this section.

Step 1:	Obtain CAS RNs and synonyms, information on chemical structure, and physical and chemical properties of the chemicals in the use cluster from the Chemical Properties module.
Step 2:	Obtain measured or estimated environmental fate and treatability data for each chemical from primary and secondary sources (see Table 5-7: Sources of Environmental Fate Data).
Step 3:	If environmental fate and treatability data are not available, estimate parameters using regression equations and mathematical models (see Details: Step 3, below).
Step 4:	Prepare environmental fate and treatability summaries for each chemical, focussing on water, air, soil and waste water treatment environments as appropriate. Fate summaries should focus on the fate processes that are most important for that particular chemical. (See Details: Step 4, below.)
Step 5:	Provide environmental fate summaries and environmental fate parameter values, and identify any products of chemical degradation (if applicable) to the Human Health Hazards Summary, Environmental Hazards Summary, and Exposure Assessment modules; and provide treatability parameters (e.g., percent removal), environmental fate, and treatability summaries to the Control Technologies Assessment module.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 3 and 4, and examples of environmental fate and treatability summaries. If necessary, additional information on these and other steps can be found in the previously published guidance.

Details: Step 3, Estimating Environmental Fate Parameters

Numerous mathematical models, such as regression equations, have been developed for estimating environmental parameters for chemicals. Only a few examples will be presented here; many others exist, and the ones most appropriate for a given chemical will depend on the circumstances. Published guidance should be consulted for selecting specific methods and equations.

The K_{oc} of a chemical can be estimated from K_{ow}, from S or from BCF, for example:

$$\log K_{oc} = 0.544 \log K_{ow} + 1.377$$

$$\log K_{oc} = -0.55 \log S + 3.64$$

$$\log K_{oc} = 0.681 \log BCF + 1.963$$

The τ for a chemical can be estimated from the rate at which the chemical reacts with hydroxyl radicals, for example:

$$\tau_{OH\cdot} = 1/\{K_{OH} [OH\cdot]\}$$

where:

K_{OH} is in liters/mole/sec and $[OH\cdot]$ is in units of moles/liter

The bioconcentration of a chemical in aquatic species can be estimated from the chemical's octanol-water partition coefficient (K_{ow}), for example:

$$\log BCF = 0.76 \log K_{ow} - 0.23$$

Details: Step 4, Preparing Environmental Fate and Treatability Summaries

Examples of environmental fate and treatability summaries (from the Screen Printing CTSA) for acetone and dichloromethane are shown below:

Environmental Fate Summary for Acetone

If released on soil, acetone will volatilize into the air or leach into the ground where it will probably biodegrade. Photolysis will be important on terrestrial surfaces and in surface waters exposed to sunlight. If released to water, acetone may also be lost due to volatilization (estimated $t_{1/2}$ is 20 hours from a model river) and biodegradation. Bioconcentration in aquatic organisms and adsorption to sediment should not be important transport processes in water. In the atmosphere, acetone will be lost by photolysis and reaction with photochemically produced hydroxyl radicals. Half-life estimates from these combined processes average 22 days and are shorter in summer and longer in winter. In air, acetone may also be washed out by rain. A rapid and a moderate biodegradation rate for acetone used in the Sewage Treatment Plant (STP) fugacity model results in 97 and 84 percent predicted total removal from waste water treatment plants, respectively.

Environmental Fate Summary for Dichloromethane

If released to soil, dichloromethane is expected to display high mobility. It may rapidly volatilize from both moist and dry soil to the atmosphere. Aerobic biodegradation may be important for dichloromethane in acclimated soils. If released to water, volatization to the atmosphere is expected to be a rapid process. Neither bioconcentration in fish and aquatic organisms, nor adsorption to sediment and suspended organic matter are expected to be significant. Dichloromethane has been found to slowly biodegrade under aerobic conditions. It is also expected to slowly biodegrade under anaerobic conditions in sediment and groundwater. If released to the atmosphere, dichloromethane is expected to persist for long periods of time. The estimated $t_{1/2}$ for the gas-phase reaction of dichloromethane with hydroxyl radicals is approximately 88 days. Direct photolytic degradation is not expected to occur. Dichloromethane may undergo atmospheric removal by wet deposition processes, although any removed by this process is expected to rapidly re-volatilize to the atmosphere. Using a slow biodegradation rate for dichloromethane in the STP fugacity model, 64 percent total removal can be predicted from waste water treatment plants.

Also, Appendix H presents an example of an Initial Review Exposure Report for dichloromethane. This form shows the environmental fate data that are typically reported along with some additional chemical property and toxicity information.

Relevant Environmental Fate Properties by Environmental Medium

For each type of environment, the types of fate and property data that are likely to be most relevant are listed below.

For water, the following are likely to be the most important properties and processes which should be considered in developing an environmental fate summary:

- S.
- Volatilization (H_c, $t_{1/2}$).
- Adsorption to sediments and suspended particulate matter (K_{oc}, K_d).
- Photolysis ($t_{1/2}$).
- Hydrolysis (rate constant and $t_{1/2}$).
- BCF.
- Biodegradation.

For soil, the following are likely to be the most important properties and processes which should be considered in developing an environmental fate summary:

- S.
- Volatilization (H_c).
- Adsorption to organic matter (K_{oc} and K_d).
- Adsorption to inorganic matter.
- Potential for groundwater contamination.
- Potential for uptake by plants.
- Biodegradation.
- Hydrolysis.
- Photolysis on soil surfaces.

For air, the following are likely to be the most important properties and processes which should be considered in developing an environmental fate summary:

- Volatility (Pv, H_c).
- τ.
- Photolysis ($t_{1/2}$).
- Reactivity with hydroxyl radicals, ozone (k_{O_3}), and other oxidants.
- UV absorption.
- Smog-forming potential.
- Ozone depleting potential.
- Wet deposition.

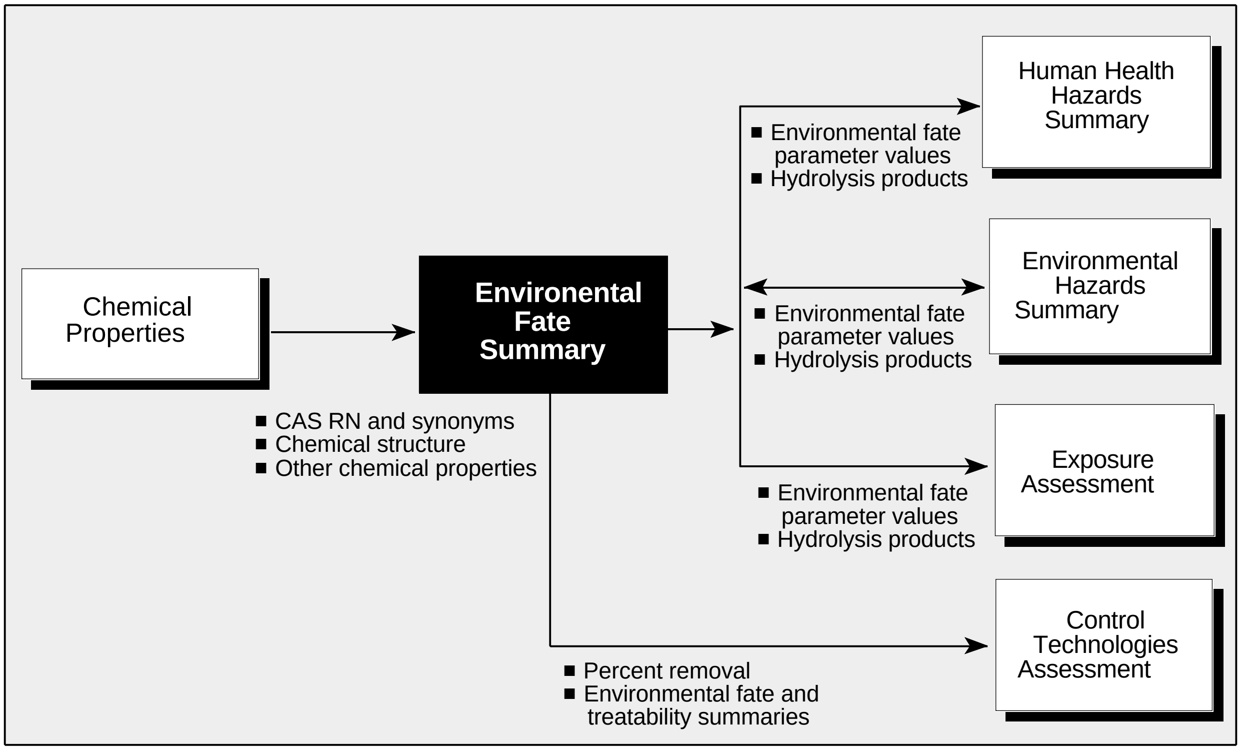
For treatability, the following are likely to be the most important properties and processes which should be considered in developing an environmental fate summary:

- Biodegradability.
- Sorption potential (K_{oc}).
- Volatilization (H_c).
- Hydrolysis.

Environmental Fate Summary

FLOW OF INFORMATION: In a CTSA, the Environmental Fate Summary module receives information from the Chemical Properties module and transfers information to the Human Health Hazards Summary, Environmental Hazards Summary, Exposure Assessment, and Control Technologies Assessment modules. Example information flows are shown in Figure 5-4.

FIGURE 5-4: ENVIRONMENTAL FATE SUMMARY MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Environmental fate and transport modeling is performed as part of the Exposure Assessment module. Models for estimating environmental fate parameters are included in Table 5-6, below.

PUBLISHED GUIDANCE: EPA has not published comprehensive guidance on the development of environmental fate summaries. Individual program offices may utilize different approaches. Table 5-6 lists references in which methods for estimating chemical properties and environmental fate parameters are discussed.

TABLE 5-6: REFERENCES FOR ESTIMATING ENVIRONMENTAL FATE PARAMETERS

Reference	Type of Guidance
BioByte, Inc. CLOGP for Windows, Version 1.0. 1996. MACLOGP (for Macintosh computers), Version 2.0. 1996. CLOGP VAX/VMS, Version 2.10. 1996.	Mathematical models used to estimate K_{ow}. Three versions currently available (as of June, 1996).
Boethling, R.S. 1993. "Structure Activity Relationships for Evaluation of Biodegradability in the EPA's Office of Pollution Prevention and Toxics."	Describes the development, validation, and application of SARs in EPA OPPT.
Briggs, G.C. 1981. "Theoretical and Experimental Relationships between Soil Adsorption, Octanol-Water Partition Coefficients, Water Solubilities, Bioconcentration Factors, and the Parachor."	BCFs are estimated for neutral compounds from K_{ow}.
Hamrick, K.J., et. al. 1992. "Computerized Extrapolation of Hydrolysis Rate Data."	Provides estimates of hydrolysis rate constants at specific temperatures.
Hassett, J.J. 1981. "Correlation of Compound Properties with Sorption Characteristics of Nonpolar Compounds by Soils and Sediments: Concepts and Limitations."	Sorption constants for nonpolar organic compounds are correlated with S, K_{ow}, or with organic carbon content of soil or sediment.
Kollig, H.P. 1993. *Environmental Fate Constants for Organic Chemicals under Consideration for EPA's Hazardous Waste Identification Projects*.	Literature-derived data as well as model computations are used to estimate hydrolysis, adsorption, and oxidation-reduction parameters.

TABLE 5-6: REFERENCES FOR ESTIMATING ENVIRONMENTAL FATE PARAMETERS	
Reference	**Type of Guidance**
Lyman, W.J., et. al. 1990. *Handbook of Chemical Property Estimation Methods*.	Describes methods for estimating residence time, K_{ow}, K_{oc}, BCF, acid dissociation constants, hydrolysis, aqueous photolysis, biodegradation, and volatilization rates, and other chemical properties.
Mackay, D., et. al. 1992. *Illustrated Handbook of Physical-Chemical Properties and Environmental Fate for Organic Chemicals*.	Provides physical-chemical data and fugacity calculations for organic compounds.
Meylan, W., et. al. 1992. "Molecular Topology/Fragment Contribution Method for Predicting Soil Sorption Coefficients."	Program for estimating K_{oc} based on molecular connectivity indices and structure-based correction factors.
Syracuse Research Corporation (SRC). Continually Updated. Estimation Programs Interface (EPI©).	Series of models to estimate log K_{ow}, volatilization $t_{½}$ for water, soil-sediment sorption coefficient, H_c, biodegradation, atmospheric oxidation rates, rate of hydrolysis, rate of removal in waste water treatment plants, and other chemical properties.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 5-7 lists major sources of environmental fate data.

TABLE 5-7: SOURCES OF ENVIRONMENTAL FATE DATA	
Reference	**Type of Data**
Bedar, R.G. 1976. *Biodegradability of Organic Compounds*.	Biodegradability values for various organic compounds.
Callahan, M.A., et. al. 1979. *Water-related Environmental Fate of 129 Priority Pollutants*.	Information on environmental fate of priority pollutants in aqueous systems.
Darnall, K.R. 1986. "Reactivity Scale for Atmospheric Hydrocarbons Based on Reaction with Hydroxyl Radicals."	A classification of atmospheric chemical reactivity and potential for smog formation based on hydroxyl radical rate constants.
Farley, F. 1977. *Photochemical Reactivity Classification of Hydrocarbons and Other Organic Compounds*.	Classification for photochemical reactivity of organic compounds.
Hansch, C. and A. Leo. 1987. *The Log P Data Base*.	List of K_{ow} values.

TABLE 5-7: SOURCES OF ENVIRONMENTAL FATE DATA

Reference	Type of Data
Helfgott, T.B., et. al. 1977. *An Index of Refractory Organics*.	Biodegradability values for various organic compounds.
Hendry D.G. and R.A. Kenley. 1979. *Atmospheric Reaction Products of Organic Compounds.*	Rate constants (K_{OH}) for the reaction of organic compounds with hydroxyl radical.
Howard, P.H., et. al. 1991. *Handbook of Environmental Degradation Rates.*	Provides environmental degradation $t_{½}$ data for chemicals in soil, air, surface water and groundwater, and aerobic and anaerobic aqueous biodegradation.
HSDB®. Hazardous Substances Data Bank (HSDB). Updated Periodically.	On-line data base including measured and estimated chemical property and environmental fate parameters.
Kollig, H.P. 1993. *Environmental Fate Constants for Organic Chemicals Under Consideration for EPA's Hazardous Waste Identification Projects.*	Literature-derived data as well as model computations to estimate hydrolysis, adsorption, and oxidation-reduction parameters.
Lyman, W.J., et. al. 1974. *Survey Study to Select a Limited Number of Hazardous Materials to Define Amelioration Requirements*.	List of BOD_5/COD ratios for various organic compounds.
Mabey, W. and T. Mill. 1978. "Critical Review of Hydrolysis of Organic Compounds in Water Under Environmental Conditions."	Data on hydrolysis rate constants of organic compounds.
Mackay, D., et. al. 1992. *Illustrated Handbook of Physical-Chemical Properties and Environmental Fate for Organic Chemicals*.	Provides physical-chemical data and fugacity calculations for organic compounds.
Pitter, P. 1976. "Determination of Biological Degradability of Organic Substances."	List of removal efficiencies and average rate of biodegradation for various organic compounds.
Reinbold, K.A., et. al. 1979. *Adsorption of Energy-Related Organic Pollutants: A Literature Review*.	Adsorption data extracted from the literature.
State of California Air Resources Board. 1986. *Adoption of a System for the Classification of Organic Compounds According to Photochemical Reactivity*.	Relative atmospheric reactivity scale.
Syracuse Research Corporation (SRC). 1994. Environmental Fate Data Bases (EFDB©).	Comprehensive on-line and personal computer-based data base containing quantitative data on environmental fate parameters.

TABLE 5-7: SOURCES OF ENVIRONMENTAL FATE DATA	
Reference	**Type of Data**
Trapp, S. 1993. "Modelling the Uptake of Organic Compounds into Plants."	Describes estimating plant-soil BCFs using a fugacity model based on the ratio of K_{ow}:K_{oc}, the lipid fraction of plants, the organic carbon and water content of the soil, and transfer and metabolism kinetics.
U.S. Environmental Protection Agency. 1974. *Proceedings of the Solvent Reactivity Conference*.	Classification of chemical reactivity for compounds associated with mobile source emissions.
U.S. Environmental Protection Agency. 1991a. *The Environmental Fate Constants Information System Database (FATE).*	Provides data on H_c, K_{ow}, K_{oc}, K_d, k_{OH}, pK_a, and oxidation-reduction reactions of organic compounds.
U.S. Environmental Protection Agency. 1994d. *Treatability Database. Version 5.0.*	Personal computer-based collection of data including H_c, K_{ow}, treatability of organic compounds, and other chemical properties.
Verschueren, K. 1983. *Handbook of Environmental Data on Organic Chemicals.*	Information derived from primary literature on environmental parameters, including treatability.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

HUMAN HEALTH HAZARDS SUMMARY

OVERVIEW: Human health hazards assessment is the process of identifying the potential effects that a chemical may have on humans who are exposed to it, and of determining the levels at which these effects may occur. Exposure to a chemical may occur by inhalation, oral, or dermal routes through the production, use, or disposal of the chemical or products containing the chemical.

GOALS:

- Compile existing information on potential health effects resulting from exposure to a chemical.
- Guide the selection and use of chemicals that pose less risk to humans.
- Assess the potential toxicity of chemicals in a use cluster to humans from available human data, supplementing with animal data when adequate human data are not available.
- Identify the target organ(s) of toxicity by examining the potential effects resulting from acute (short-term) and chronic (long-term) exposure to the chemical by routes pertinent to human exposure.
- Determine if there are levels of concern for the chemical (e.g., the no-observed adverse effect level [NOAEL] and the lowest-observed adverse effect level [LOAEL]), as well as references doses (RfD), carcinogen slope factors (q_1*), and cancer weight-of-evidence classifications.
- Provide the above listed information, including the levels of concern, to the Risk Characterization module.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Expertise in evaluating the adverse effects of chemicals on humans, animals, and other biological systems. This requires an understanding of clinical toxicology; procedures and results of standard toxicological test methods; pharmacokinetics, a discipline that includes chemical absorption, distribution, metabolism, and excretion; species differences among experimental animals; the cellular, biochemical, and molecular mechanisms of action of the chemicals; and relationships between chemical structure and toxicity.
- Expertise in analyzing data on adverse effects in human populations (in this case, from exposure to chemicals) and extracting information to identify possible causes. This

discipline requires knowledge of standard protocols for epidemiological studies; demographics; risk factors (e.g., smoking, alcohol consumption, race, sex, obesity, etc.); formal logic; and statistics.

- Expertise in the collection, organization, and interpretation of numerical data; especially the analysis of population characteristics by inference from sampling. This requires knowledge of population parameter estimation (involves a quantitative measure of some property of a sample), hypothesis testing (involves determining if differences in sample statistics [e.g., means] are of sufficient magnitude to distinguish differences between population parameters), and modeling.

Note: The analysis presented in this module should not be undertaken without the assistance of someone with expertise in human health hazards assessment. Furthermore, peer-review of the completed hazard summary is recommended.

DEFINITION OF TERMS: Sources for the following definitions include Alderson, UNDATED ("Epidemiological Method"); Amdur, et. al., 1991 (*Casarett and Doull's Toxicology*); ATSDR, UNDATED (*Toxicological Profile Glossary)*; EPA, 1986a ("Guidelines for Estimating Exposures"); EPA, 1986b (*EPA Toxicology Handbook*); EPA, 1988a ("Part II. Proposed Guidelines for Assessing Female Reproductive Risk"); EPA, 1988b ("Part III. Proposed Guidelines for Assessing Male Reproductive Risk"); EPA, 1991b ("Guidelines for Developmental Toxicity Risk Assessment"); EPA, 1994e (HEAST); EPA, 1995d (IRIS® glossary); Hodgson, et. al., 1988 (*Dictionary of Toxicology)*; Huntsberger and Leaverton, 1970 (*Statistical Inference in Biomedical Sciences*); Lilienfeld and Lilienfeld, 1988 (*Foundations of Epidemiology)*; Norell, 1992 (*A Short Course in Epidemiology)*; and Dorland, 1994 (*Dorland's Illustrated Medical Dictionary*).

Acute Toxicity: Immediate toxicity. Its former use was associated with toxic effects that were severe (e.g., mortality) in contrast to the term "subacute toxicity" that was associated with toxic effects that were less severe. The term "acute toxicity" is often confused with that of acute exposure.

Association: In a formal, scientific context, a statistical relationship between a disease or adverse effect and biological or social characteristics.

Carcinogenicity: The ability of an agent to induce a cancer response.

Chronic Toxicity: Delayed toxicity. However, the term "chronic toxicity" also refers to effects that persist over a long period of time whether or not they occur immediately or are delayed. The term "chronic toxicity" is often confused with that of chronic exposure.

Confounder (Confounding Variable, Factor): A factor that is covariant with the studied exposure in the study base and masks the ability to distinguish the risk of developing the studied disease occasioned by any association between exposure and disease.

Developmental Toxicity: Adverse effects produced prior to conception, during pregnancy, and during childhood. Exposure to agents affecting development can result in any one or more of the following manifestations of developmental toxicity: death, structural abnormality, growth alteration, and/or functional deficit. These manifestations encompass a wide array of adverse developmental end points, such as spontaneous abortion, stillbirths, malformations, early postnatal mortality, reduced birth weight, mental retardation, sensory loss and other adverse functional or physical changes that are manifested postnatally.

Dose-Response: The relationship between the amount of an agent (either administered, absorbed, or believed to be effective) and changes in certain aspects of the biological system (usually adverse effects), apparently in response to that agent.

Exposure Level: In general, a measure of the magnitude of exposure, or the amount of an agent available at the exchange boundaries (i.e., lungs, gastrointestinal tract, or skin), during some specified time. In the Exposure Assessment and Risk Characterization modules, "exposure level" is used specifically as a measure of exposure expressed as a concentration rather than as a potential dose rate.

Extrapolation: An estimation of a numerical value of an empirical (measured) function at a point outside the range of data which were used to calibrate the function. For example, the quantitative risk estimates for carcinogens (according to EPA guidelines at the time of this writing) are generally low-dose extrapolations based on observations made at higher doses. Another example is extrapolation of health effects from occupational to general exposure levels.

Human Equivalent Concentration (HEC): The human exposure concentration of an agent that is believed to induce the same magnitude of toxic effect as that which a known animal or occupational exposure concentration has induced. For HEC, the exposure concentration has been adjusted for dosimetric differences between experimental animal species and humans. If occupational human exposures are used for extrapolation, the human equivalent concentration represents the equivalent human exposure concentration adjusted to a continuous basis.

International Agency for Research on Cancer (IARC) Classification: A method for evaluating the strength of evidence supporting a potential human carcinogenicity judgment based on human data, animal data, and other supporting data. A summary of the IARC carcinogenicity classification system includes:

- Group 1: Carcinogenic to humans.
- Group 2A: Probably carcinogenic to humans.
- Group 2B: Possibly carcinogenic to humans.
- Group 3: Not classifiable as to human carcinogenicity.
- Group 4: Probably not carcinogenic to humans.

Irritation: An inflammatory response, usually of skin, eye, or respiratory tract, induced by direct action of an agent.

LC_{50} (Lethal Concentration): The concentration of a chemical in air that causes death in 50 percent of the test organisms at the end of the specified exposure period. LC_{50} values typically represent acute exposure periods, usually 48 or 96 hours. Typical units are mg/m^3 or ppm.

LD_{50} (Lethal Dose): The dose of a chemical taken by mouth, absorbed by the skin, or injected that is estimated to cause death in 50 percent of the test animals.

Lowest-Observed Adverse Effect Level (LOAEL): The lowest dose level in a toxicity test at which there are statistically or biologically significant increases in frequency or severity of adverse effects in the exposed population over its appropriate control group.

Modifying Factor (MF): An uncertainty factor that is greater than zero and less than or equal to 10; the magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated with the standard uncertainty factors (e.g., the completeness of the overall data base and the number of species tested); the default MF is 1.

Mutagen: An agent that produces a permanent genetic change in a cell (other than changes that occur during normal genetic recombination).

Neurotoxicity: Any toxic effect on any aspect of the central or peripheral nervous system. Such changes can be expressed as functional changes (such as behavioral or neurological abnormalities) or as neurochemical, biochemical, physiological or morphological perturbations.

No-Observed Adverse Effect Level (NOAEL): The highest dose level in a toxicity test at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects in the exposed population over its appropriate control; some effects may be produced at this level, but they are not considered adverse, nor precursors to adverse effects.

Odds Ratio (OR): A technique for estimating the relative risk (see below) from case-control (retrospective) studies. This refers to the odds, among diseased individuals, of being exposed as compared to non-diseased individuals.

Pharmacokinetics: The dynamic behavior of chemicals within biological systems. Pharmacokinetic processes include uptake, distribution, metabolism, and excretion of chemicals.

Proportionate Mortality Ratio (PMR): The number of deaths from a specific cause and in a specific period of time per 100 deaths in the same time period.

q_1*: See Slope Factor.

Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of the daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. RfCs are generally reported as a concentration in air (mg/m^3).

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of the daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. RfDs are reported as mg/kg-day.

Reportable Quantity (RQ): The quantity of a hazardous substance that is considered reportable under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Reportable quantities are: (1) one pound; or (2) for selected substances, an amount established by regulation either under CERCLA or under Section 311 of the Clean Water Act. Quantities are measured over a 24-hour period.

Reproductive Toxicity: The occurrence of effects on the male or female reproductive system that may result from exposure to environmental agents. The manifestations of such toxicity may include alteration in sexual behavior, fertility, pregnancy outcomes, or modifications in other functions that are dependent on the integrity of the reproductive system.

Risk: In general, risk pertains to the probability and severity of adverse effects (e.g., injury, disease, or death) under specific circumstances. In the context of a CTSA, risk is an expression of the likelihood of adverse health or environmental effects from a specific level of exposure; only cancer risk is estimated as a probability.

Risk Assessment: The determination of the kind and degree of hazard posed by an agent, the extent to which a particular group of people has been or may be exposed to the agent, and the present or potential health risk that exists due to the agent.

Risk Characterization: The integration of hazard and exposure information to quantitatively or qualitatively assess risk. Risk characterization typically includes a description of the assumptions, scientific judgments, and uncertainties that are part of this process.

Slope Factor (q_1*): A measure of an individual's excess risk or increased likelihood of developing cancer if exposed to a chemical. It is determined from the upperbound of the slope of the dose-response curve in the low-dose region of the curve. More specifically, q_1* is an approximation of the upper bound of the slope when using the linearized multistage procedure at low doses. The units of the slope factor are usually expressed as 1/(mg/kg-day) or $(\text{mg/kg-day})^{-1}$.

Standardized Mortality Ratio (SMR): The ratio of observed events to events expected if the age- and sex-specific mortality rates of a standard population (usually the general population) are applied to the population under study.

Structure Activity Relationship (SAR): The relationship of the molecular structure and/or functional groups of a chemical with specific effects. SARs evaluate the molecular structure of a chemical and make qualitative or quantitative correlations of particular molecular structures and/or functional groups with specific effects.

Subchronic Exposure: Multiple or continuous exposures occurring usually over 3 months. This applies to animal, not human, exposure.

Subchronic Toxicity: Effects from subchronic exposure. This also applies to animal, not human exposure.

Uncertainty Factor (UF): One of several, generally 10-fold factors, used in operationally deriving the RfD or RfC from experimental data. UFs are intended to account for: (1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using LOAEL data rather than NOAEL data.

Unit Risk: The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water or 1 $\mu g/m^3$ in air (with units of risk per $\mu g/m^3$ air or risk per µg/L water).

Upper Bound: An estimate of the plausible upper limit to the true value of the quantity. This is usually not a statistical confidence limit unless identified as such explicitly, together with a confidence level.

Weight-of-Evidence Classification (EPA): In assessing the carcinogenic potential of a chemical, EPA classifies the chemical into one of the following groups, according to the weight-of-evidence from epidemiologic and animal studies:

- Group A: Human Carcinogen (sufficient evidence of carcinogenicity in humans).
- Group B: Probable Human Carcinogen (B1 - limited evidence of carcinogenicity in humans; B2 - sufficient evidence of carcinogenicity in animals with inadequate or lack of evidence in humans).
- Group C: Possible Human Carcinogen (limited evidence of carcinogenicity in animals and inadequate or lack of human data).
- Group D: Not Classifiable as to Human Carcinogenicity (inadequate or no evidence).
- Group E: Evidence of Noncarcinogenicity for Humans (no evidence of carcinogenicity in adequate studies).

(The "Proposed Guidelines for Carcinogen Risk Assessment" [EPA, 1996b] propose use of weight-of-evidence descriptors, such as "Likely" or "Known," "Cannot be determined," and "Not likely," in combination with a hazard narrative, to characterize a chemical's human carcinogenic potential - rather than the classification system described above.)

ADDITIONAL TERMS: The following additional terms are not used in this module discussion *per se*, but are likely to be found in the literature pertaining to human health hazard and toxicity studies.

Acute Exposure: Exposure occurring over a short period of time. (The specific time period varies depending on the test method and test organism or the receptor of interest.)

Case-Control Study: An epidemiological study in which comparisons are made between a group of persons who have a disease (cases) and a group who do not (controls) regarding possible exposures prior to study.

Case Report: An anecdotal description of the occurrence of a disease or adverse effect in an individual or group of individuals.

Case Study: A detailed analysis of an individual or group.

Chronic Exposure: Continuous or intermittent exposure occurring over an extended period of time, or a significant fraction of the animal's or the individual's lifetime.

Cohort Study: Epidemiological study comparing the morbidity and/or mortality of a group or groups of people (called exposed) who have had a common insult (e.g., exposure to a chemical suspected of causing disease) with a group believed to be unexposed or with the general population.

Correlation: The degree to which two or more phenomena occur together or vary in similar directions.

Cross-Sectional Study: An epidemiological study in which comparisons are made between a group of persons who are found to have an exposure and a group who does not (unexposed). The characteristics under comparison are present in both exposed and unexposed groups at the time of the study and exposure status is often determined after individuals are selected for study. Also called a "prevalence" study.

EPA Health Advisory: An estimate of acceptable drinking water levels for a chemical, based on health effects information. A health advisory is not a legally enforceable federal standard, but serves as technical guidance to assist federal, state, and local officials.

Human Equivalent Concentration (HEC): See definition for Human Equivalent Dose.

Human Equivalent Dose (HED): The human dose of an agent that is believed to induce the same magnitude of toxic effect as that which a known animal or occupational dose has induced. For HEC, the dose has been adjusted for dosimetric differences between experimental animal species and humans. If occupational human exposures are used for extrapolation, the HED represents the equivalent human exposure concentration adjusted to a continuous basis.

Irreversible Effect: Effect characterized by the inability of the body to partially or fully repair injury caused by a toxic agent.

Latency Period: The time between the initial induction of a health effect and the manifestation (or detection) of the health effect; crudely estimated as the time (or some fraction of the time) from first exposure to detection of the effect.

Potentiation: The ability of one chemical to increase the effect of another.

Prevalence Study: An epidemiological study that examines the relationship between exposure and diseases as they exist at a given period in time. (See also Cross-Sectional Study.)

Prospective Study: A study using a population sample based on exposure status, where exposure may be related to the development of the disease under investigation. The individuals are then followed for several years to see which ones develop and/or die from the disease. Also described by the terms "cohort," "incidence," and "longitudinal." When based on exposure status determined from some time in the past, this may be called "historical prospective."

Relative Risk: The likelihood that an exposed individual will have a disease expressed as a multiple of the likelihood among unexposed (with disease incidence expressed as incidence rate or cumulative incidence).

Retrospective Study: Epidemiological study in which comparisons are made between a group of persons who have a disease (cases) and a group who do not (controls). An attempt is made to determine whether the characteristics (e.g., exposure to a chemical) were present in the past. Also described as "case control," or "case history" studies.

Reversible Effect: An effect that is not permanent, particularly an adverse effect that diminishes when exposure to a toxic chemical ceases.

Spurious Association: A statistical association that represents a statistical artifact or bias. It may arise from biased methods of selecting cases and controls, recording observations or by obtaining information by interview, and cannot be identified with certainty.

Statistical Tests of Significance: Methods for determining on a probabilistic basis if differences in groups under treatment (or observation) could have resulted by chance, or if they represent "rare" events. Also called "statistical tests of hypotheses." The question of random occurrence may be put in the form of a hypothesis to be tested, called the "null hypothesis."

Subacute Exposure: A term, no longer commonly used, that denotes exposures that are longer than acute and shorter than subchronic.

Subacute Toxicity: Effects from subacute exposure.

Subclinical Toxicity: An observable effect which may or may not have any clinical significance (i.e., not biologically significant). With humans it may also mean that the individual's illness is undetected.

Toxicity Assessment: Characterization of the toxicological properties and effects of a chemical, including all aspects of its absorption, metabolism, excretion and mechanism of action, with special emphasis on the identification of a dose-response relationship.

Transient Effect: An effect that disappears over time (irrespective of whether or not exposure continues).

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for preparing a summary human health hazards profile for a CTSA. Further details for Steps 4 through 8 are presented in the next section of this module.

Step 1: Obtain the CAS RN, synonyms, and information on the chemical structure from the Chemical Properties module.

Step 2: Review the Environmental Fate Summary module to determine if the chemical persists long enough in any environmental medium to be a potential health hazard and if any chemical degradation products need to be considered.

Step 3: Review preliminary exposure pathways from the Exposure Assessment module, if available. The main routes to consider are oral, inhalation, and dermal.

Step 4: Obtain peer-reviewed literature, beginning with secondary sources (e.g., EPA's Integrated Risk Information System [IRIS], EPA review documents, Agency for Toxic Substance and Disease Registry [ATSDR] Profiles, and the Hazardous Substances Data Bank [HSDB]). Resort to primary sources (e.g., journal articles) only when secondary sources are lacking or when more recent information is available in the primary literature that adds new information to the data base for that chemical.

This should include a review of the pharmacokinetics of the chemical and an evaluation of the following toxicological endpoints for both humans and animals:

- Acute toxicity.
- Irritation/sensitization.
- Neurotoxicity.
- Subchronic/chronic toxicity (includes systems such as renal, hepatic, hematopoietic, etc.).
- Developmental/reproductive toxicity.
- Genotoxicity.
- Carcinogenicity.

Step 5: Review the acquired literature and critically evaluate the quality of studies (e.g., use of controls, appropriate numbers of animals, selection of appropriate human study groups, statistical analysis of the data).

Step 6: Construct a health hazards profile for each chemical using the most recent data available. Measured data should take precedence over modeled data. Toxicity summaries should include NOAELs, LOAELs, and RfDs or RfCs for chemicals not causing cancer; and q_1*, unit risk values, and weight-of-evidence classifications for carcinogens. Secondary sources that may contain these types of data are listed in Table 5-11: Sources of Human Health Hazard Data.

Note: Data requirements for toxicity summaries may change as EPA guidance is updated, e.g., changes in the proposed carcinogen risk assessment guidelines (EPA, 1996b).

Present the data clearly and accurately, using consistent units so that comparisons may be easily made. Use the original dose units as well as converted units where possible. Note any assumptions made in dose conversions. Explicitly identify any data that are not peer-reviewed.

Step 7: If some chemicals do not have the values listed in Step 6 and if the necessary data are available, RfDs, carcinogenicity slope factors, and unit risk values or other measures may be calculated. See Details: Step 7 (below), and Table 5-10: Published Guidance on Health Hazards Assessment.

Step 8: In a tabular format, list the toxicity values and classifications that are described in Step 6 (see Details: Step 8, below) and provide to the Risk Characterization module.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 4 through 8. If necessary, additional information on these and other steps can be found in the previously published guidance (see Table 5-10: Published Guidance on Health Hazards Assessment).

Details: Step 4, Obtaining Literature Information

In vitro studies are useful for mutagenicity assays and for determining structure-activity relationships and mechanisms of toxicity. Note that because of the importance of the various manifestations of neurotoxicity, EPA places these effects in a separate section, rather than under acute or chronic/subchronic toxicity, which could also be appropriate.

Toxicity values that are important for risk characterization include, but are not limited to, the following:

- LD_{50} values for mammalian species.
- Concentrations of the chemical that cause irritation to the eyes, nose, or respiratory passages.
- Concentrations or doses that result in acute neurotoxicity; NOAEL and/or LOAEL for subchronic/chronic neurotoxicity.

- NOAEL and/or LOAEL for subchronic/chronic non-carcinogenic systemic effects. If an RfD is available, inclusion of the experimental details of the key study used to derive that value is required.
- NOAEL or LOAEL for developmental/reproductive toxicity. Note that RfDs may be based on developmental or reproductive effects.
- Epidemiological or animal bioassay data for carcinogenicity. This would include q_1* and unit risk values, if available. The EPA, National Toxicology Program, and IARC classify chemicals as to their carcinogenicity. These classifications should be included when available. (Note that epidemiological data may be available for other adverse effects such as developmental or reproductive effects.)
- Regulatory standards and guidelines (e.g., RfDs and RfCs; Occupational Safety and Health Administration [OSHA], American Conference of Governmental Industrial Hygienists, Inc. [ACGIH], and National Institute for Occupational Safety and Health [NIOSH] exposure limits; drinking water standards; and drinking water health advisories).

Details: Step 5, Evaluating Data Quality

Statistics are used to evaluate the magnitude of response in a study and to determine if an effect is the result of exposure to a chemical. If statistics have not been performed on a particular study, and if there are data for more than one dose, one possible protocol would be to first test for a trend. If there is no trend, then determine if any dose group shows an increase or decrease relative to controls. If data are quantal proportions, some form of categorical analysis is appropriate.

Commonly used statistical tests include analysis of variance and Bartlett's tests for homogeneity (for endpoints such as organ and body weights, hematology, and biochemistry); Dunnett's multiple comparison tables (for significance of differences); and life table test, incidental tumor test, Fisher's exact test, and Cochran-Armitage trend test (for analysis of tumor incidence data). Statistical methods are described in references listed in Table 5-10. A statistician and a health hazard assessment expert should be consulted for information regarding when and how these tests are used and whether they are appropriate for the data in hand. It is generally not necessary to perform statistics on data from HSDB, NIOSH, ATSDR, IRIS or other references listed under Sources of Human Health Hazards Data in Table 5-11.

Details: Step 6, Constructing the Health Hazards Profile

The level of detail presented in the health hazards profile may vary. For example, key studies (such as those used in the derivation of toxicity values such as chronic RfDs, RQs, or carcinogenicity slope factors) require more detailed reporting than supporting studies. A detailed, but concise, description would include experimental details and incidence data for effects, relating exposure and effect. Supporting studies may be described with fewer details and, where appropriate, as ranges of values. Adequate citations should be provided for both key and supporting studies. When epidemiological data are available, epidemiological summaries should include population observed, comparison population, SMRs, PMRs, or ORs and confounding factors.

The health hazards profile for discrete organic chemicals can be constructed using concentrations or doses derived from experimental studies or can be estimated from structure activity relationships (SARs; see next paragraph). The toxicity of inorganic chemicals typically cannot be accurately estimated using SARs. The hazard profile for inorganic chemicals should therefore be constructed using effective concentrations based on measured toxicity test data. If no data are available, actual data from the nearest structural analog can be used. Chemical mixtures such as petroleum products (i.e., mineral spirits or solvent naphtha) may be evaluated from information on the mixture, information from a "sufficiently similar" mixture, or information on the individual components of the mixture. Constructing a Health Hazard Profile for chemical mixtures is a complex process and the EPA "Guidelines for the Health Risk Assessment of Chemical Mixtures" should be consulted (see published guidance listed in Table 5-10).

When measured data are not available, evaluate data from studies on structurally-related compounds. The use, application, development, and validation of SARs have been discussed in a number of publications (see *Federal Register* citations in Table 5-10). The use and interpretation of SARs require expertise and caution. Computer models that calculate toxicity values based on SARs are available (see Table 5-9: Computer Programs Used in Human Health Hazards Assessment). Briefly, the EPA approach to SARs involves the evaluation and interpretation of available and pertinent data on the chemical under study or its potential metabolites; evaluation of test data on analogous substances and potential metabolites; and the use of mathematical expressions for biological activity or quantitative structure activity relationships (QSARs).

Details: Step 7, Deriving Health Hazard Values

Reference Dose/Reference Concentration (RfD/RfC)

RfDs and RfCs are derived following a thorough examination of the toxicologic and epidemiologic literature for the subject chemical and selection of the studies that are judged to be appropriate for risk assessment. The LOAEL or NOAEL (chronic, subchronic, developmental, or reproductive toxicity) is divided by uncertainty factors and a modifying factor to derive the RfD. If a study has more than one NOAEL, the highest is selected. If there is no NOAEL the RfD may be derived from a LOAEL by applying an uncertainty factor of up to 10. The lowest of the LOAELs for systemic, developmental, or reproductive toxicity is chosen.

The RfD is calculated as follows:

$$\text{RfD} = \frac{\text{NOAEL (mg/kg-day)}}{\text{UFs x MF}}$$

where:

NOAEL = No-observed adverse effect level
UFs = Uncertainty factors
MF = Modifying factor (see Definition of Terms)

Ufs account for the following:

- The variation in sensitivity among the members of the human population (a factor of 10).
- The extrapolation of animal data to humans (a factor of 10).
- Extrapolation from less than lifetime exposure (a factor of 10).
- The use of LOAEL, rather than NOAEL, data (a factor of 10).
- Extrapolation from experimental data that do not fully consider all possible adverse effects (a factor of from 1 to 10).

The methodology for the inhalation RfC includes dosimetric adjustments to account for the species-specific relationships of exposure concentrations to deposited/delivered doses. This requires knowledge of the anatomy and physiology of the lungs and airways to accurately estimate the amount of the inhaled chemical that would reach the tissue where the effects occur. The RfC is calculated similarly to RfD, as follows:

$$\text{RfC} = \frac{\text{NOAEL}_{[\text{HEC}]}\ (\text{mg/m}^3)}{\text{UFs} \times \text{MF}}$$

where:

$\text{NOAEL}_{[\text{HEC}]}$ = the NOAEL or equivalent effect level dosimetrically adjusted to a human equivalent concentration (HEC)

Slope Factor

The slope factor is a measure of the incremental risk or increased likelihood of an individual developing cancer if exposed to a unit dose of the chemical for a lifetime. The risk is expressed as a probability (i.e., one chance in ten or one chance in one million), and the unit dose is normally expressed as 1 mg of the chemical per unit body weight (kg) per day:

Slope Factor = Risk per unit dose, or Risk per mg/kg-day

When based on animal data, the slope factor is derived by extrapolating from the incidences of tumors occurring in animals receiving high doses of the chemical to low exposure levels expected for human contact in the environment. The EPA uses q_1^* for its risk assessments (see definition of slope factor). The q_1^* for a chemical, in units of $(\text{mg/kg-day})^{-1}$, is based on the linearized multistage procedure for carcinogenesis and can be calculated by computer program (e.g., GLOBAL).

Slope factor or q_1^* values are used in the Risk Characterization module to estimate cancer risk (in the range where it is expected to be linearly related to exposure). It should be noted that the proposed carcinogen risk assessment guidelines (EPA, 1996b), if adopted, may require modifications to this approach.

Unit Risk

The slope factor, or q_1*, can also be used to determine the incremental cancer risk that would occur if the chemical was present in an environmental medium such as drinking water at a unit concentration (i.e., 1 μg of chemical per liter of drinking water). The calculation for drinking water usually assumes the person weighs 70 kg and drinks 2 liters of water per day:

$$\text{Drinking Water Unit Risk} = q_1^* \times 1/70\ \text{kg} \times 2\ \text{L/day} \times 10^{-3}$$

Air unit risk (risk per μg/m^3) is derived from the linearized multistage procedure and calculated using the GLOBAL program.

Details: Step 8, Tabulating Toxicity Values

Table 5-8 is an example format for tabulating toxicity values.

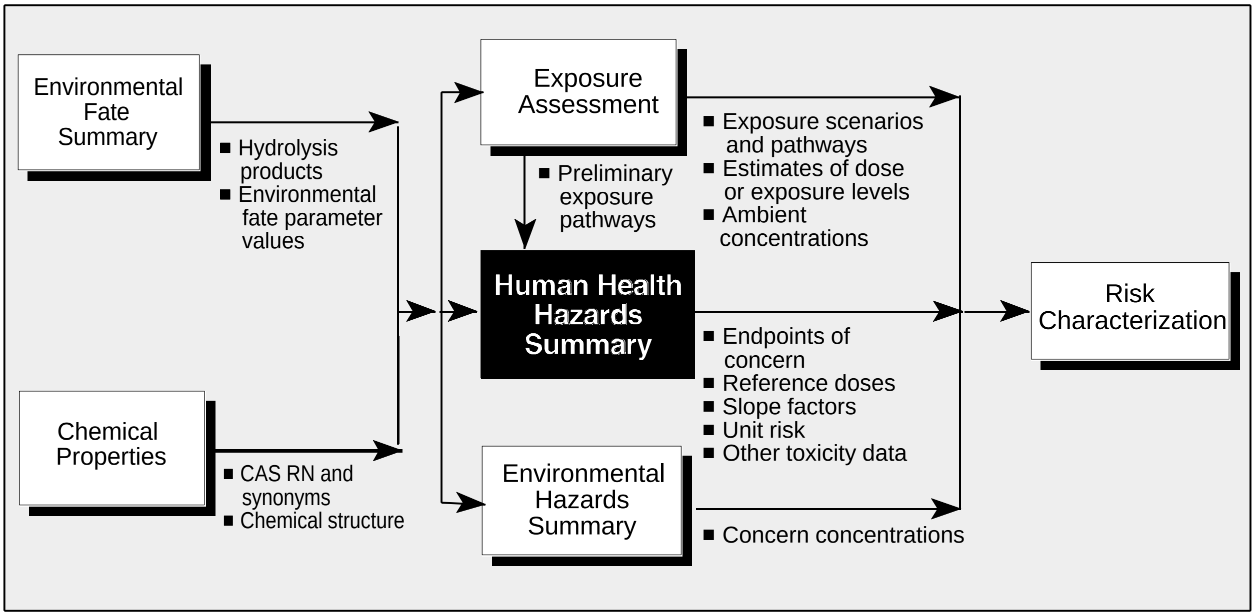
TABLE 5-8: SUMMARY TABLE FOR TOXICITY OF CHEMICALS AND POTENTIAL SUBSTITUTES

Chemical	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
LD_{50}/LC_{50}										
Irritation (yes or no) 1. eye 2. skin 3. respiratory	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.
Sensitization (yes or no)										
Neurotoxicity (yes or no)										
Developmental Toxicity (yes or no)										
NOAEL/LOAEL[a] (target organ or effect)										
RfD/RfC										
EPA WOE[b]										
Oral Slope Factor $(\text{mg/kg-day})^{-1}$										
Unit Risk 1. air (risk per μg/m^3) 2. water (risk per μg/L)	1. 2.	1. 2.	1. 2.	1. 2.	1. 2.	1. 2.	1. 2.	1. 2.	1. 2.	1. 2.
Exposure Limits 1. ACGIH 2. OSHA 3. NIOSH	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.	1. 2. 3.

a) If more than one NOAEL select the highest; if no NOAEL, but more than one LOAEL, select the lowest. Include NOAEL/LOAELs for neurotoxicity and developmental toxicity, if available.
b) WOE = weight-of-evidence classification for carcinogenicity.

FLOW OF INFORMATION: This module receives information from the Chemical Properties, Environmental Fate Summary, and Exposure Assessment modules, and transfers information to the Risk Characterization module. Example information flows are shown in Figure 5-5. This module can also be used alone to guide the selection and use of chemicals that are less toxic to humans.

FIGURE 5-5: HUMAN HEALTH HAZARDS SUMMARY MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 5-9 presents references of computer programs that can be used when estimating toxicity reference values.

TABLE 5-9: COMPUTER PROGRAMS USED IN HUMAN HEALTH HAZARDS ASSESSMENT	
Reference	**Type of Model**
GLOBAL92 ICF Kaiser International, Inc.	A program which uses quantal cancer dose-response animal bioassay data to predict the probability of a specific health effect by fitting a specific form of mathematical model to the data provided.

TABLE 5-9: COMPUTER PROGRAMS USED IN HUMAN HEALTH HAZARDS ASSESSMENT

Reference	Type of Model
QSAR: A Structure-Activity Based Chemical Modeling and Information System. 1986.	Modified structure-activity correlations are used to estimate chemical properties, behavior, and toxicity. Developed by U.S. EPA, Environmental Research Laboratory, Duluth, MN, Montana State University Center for Data Systems and Analysis, and Pomona College Medicinal Chemistry Project.
RISK81 Contact Daniel Krewski Health and Welfare Canada	For low-dose extrapolation of quantal response toxicity data.
TOXRISK Crump, K., et. al. 1995.	Software package for performing standard types of health risk assessments. Provides some quantal and time-to-tumor models.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 5-10 presents references for published guidance on health hazard assessment.

TABLE 5-10: PUBLISHED GUIDANCE ON HEALTH HAZARDS ASSESSMENT

Reference	Type of Guidance
Abramson, J.H. 1988. *Making Sense of Data: A Self-Instruction Manual*.	Interpretation of epidemiological data.
Armitage, P. and G. Berry. 1994. *Statistical Methods in Medical Research*.	Methods for statistical analysis.
Barnes, D.G. and M. Dourson. 1988. "Reference Dose (RfD): Description and Use in Health Risk Assessments."	Condensed description of RfD derivation.
Breslow, N.E. and N.E. Day. 1980. *Statistical Methods in Cancer Research. Vol. I: The Analysis of Case-control Studies*.	Methods for the statistical analysis of epidemiological studies.
Breslow, N.E. and N.E. Day. 1987. *Statistical Methods in Cancer Research. Vol. II: The Analysis of Cohort Studies*.	Methods for the statistical modeling of epidemiological studies.
Clayton, D. and M. Hills. 1993. *Statistical Models in Epidemiology*.	Methods for the statistical modeling of epidemiological studies.

TABLE 5-10: PUBLISHED GUIDANCE ON HEALTH HAZARDS ASSESSMENT

Reference	Type of Guidance
Gad, S.D. and C.S. Weil, Eds. 1986. *Statistics and Experimental Design for Toxicologists*.	Methods for statistical analysis.
Gart, J.J., et. al. 1986. *Statistical Methods in Cancer Research. Vol. III: The Analysis of Long-term Animal Experiments*.	Methods for the statistical analysis of chronic animal studies.
O'Bryan, T.R. and R.H. Ross. 1988. "Chemical Scoring System for Hazard and Exposure Identification."	Ranking system for 11 parameters, including acute and chronic toxicity.
Snedecor, G.W. and W.G. Cochran. 1980. *Statistical Methods*.	General statistical methods.
U.S. Environmental Protection Agency. 1984a. *Methodology and Guidelines for Ranking Chemicals Based on Chronic Toxicity Data*.	Describes derivation of reportable quantity (RQ); incorporates a 10-point severity ranking system for the chronic toxicity of chemicals that can be used in risk characterization.
U.S. Environmental Protection Agency. 1985. *Toxic Substances Control Act Test Guidelines: Final Rules*.	Describes guidelines for performing tests of chemical fate and environmental and health effects.
U.S. Environmental Protection Agency. 1986c. "Guidelines for Carcinogen Risk Assessment."	Describes procedure for the performance of risk assessment on potential chemical carcinogens. (Soon to be revised.)
U.S. Environmental Protection Agency. 1986d. "Guidelines for Mutagenicity Risk Assessment."	Describes procedure for the performance of risk assessment on potential chemical mutagens.
U.S. Environmental Protection Agency. 1986e. "Guidelines for the Health Risk Assessment of Chemical Mixtures."	Describes procedure for the performance of risk assessment on mixtures of chemicals.
U.S. Environmental Protection Agency. 1988a. "Part II. Proposed Guidelines for Assessing Female Reproductive Risk and Request for Comments."	Proposed guidelines for the evaluation of potential toxicity of environmental agents to the human female reproductive system. Provides discussion of female reproductive organs and their functions, endpoints of toxicity in animal assays, human studies, and risk assessment.
U.S. Environmental Protection Agency. 1988b. "Part III. Proposed Guidelines for Assessing Male Reproductive Risk and Request for Comments."	Proposed guidelines for the evaluation of potential toxicity of environmental agents to the human male reproductive system. Provides discussion of male reproductive organs and their functions, endpoints of toxicity in animal assays, human studies, and risk assessment.

TABLE 5-10: PUBLISHED GUIDANCE ON HEALTH HAZARDS ASSESSMENT	
Reference	**Type of Guidance**
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual (Part A).*	Guidance for developing human health risk assessments at Superfund sites.
U.S. Environmental Protection Agency. 1991b. "Guidelines for Developmental Toxicity Risk Assessment."	Discusses basics of developmental toxicity and EPA's risk assessment process for developmental toxins.
U.S. Environmental Protection Agency. 1991c. *General Quantitative Risk Assessment Guidelines for Noncancer Health Effects*.	Discusses various aspects of risk assessment (hazard identification, dose-response assessment, risk characterization). A draft document to be used as guidance; not necessarily Agency policy at present.
U.S. Environmental Protection Agency. 1992a. "Guidelines for Exposure Assessment."	Provides a general approach and framework for carrying out human or nonhuman exposure assessments for specified pollutants. To be used for risk assessment in conjunction with toxicity/effects assessment.
U.S. Environmental Protection Agency. 1993b. "Draft Report: Principles of Neurotoxicity Risk Assessment."	Discusses basics of neurotoxicity and EPA's risk assessment process for neurotoxins. A draft document to be used as guidance; not necessarily Agency policy at present.
U.S. Environmental Protection Agency. 1994f. *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry*.	Describes procedure for the derivation of an inhalation reference dose.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 5-11 lists sources of health hazard data that should be readily available to most hazard assessors.

TABLE 5-11: SOURCES OF HUMAN HEALTH HAZARDS DATA	
Reference	**Type of Data**
Clayton, G.D. and F.E. Clayton. 1994. *Patty's Industrial Hygiene and Toxicology*.	Toxicology and properties of selected industrial chemicals and classes of chemicals.
Documentation of the Threshold Limit Values and Biological Exposure Indices. UNDATED.	Review of toxicity and rationale for selection of ACGIH exposure levels.

TABLE 5-11: SOURCES OF HUMAN HEALTH HAZARDS DATA

Reference	Type of Data
HSDB®. Hazardous Substances Data Bank (HSDB). Updated Periodically.	An on-line data base that contains information on a chemical's properties, human and environmental toxicity, environmental fate, regulations, and treatments.
International Agency for Research on Cancer (IARC). 1979. *IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man*.	Reviews the carcinogenicity of chemicals. Provides IARC classification.
International Agency for Research on Cancer (IARC). 1987. *IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man. Overall Evaluations of Carcinogenicity*.	Summary of IARC Monographs, Volumes 1 to 42. Contains rationale for IARC weight-of- evidence classifications.
International Programme on Chemical Safety (IPCS). UNDATED. *Environmental Health Criteria Documents*.	A series of chemical profiles that include information on exposure and toxicity.
National Institute for Occupational Safety and Health (NIOSH). UNDATEDa. *Health Effects Documents*.	Literature review of occupational exposure data, health effects data, and animal studies. Rationale for the derivation of NIOSH exposure levels.
National Institute for Occupational Safety and Health (NIOSH). 1992. *NIOSH Recommendations for Occupational Safety and Health. Compendium of Policy Documents and Statements*.	NIOSH occupational exposure limits.
National Toxicology Program (NTP). UNDATED. *NTP Toxicology and Carcinogenesis Studies*.	Reports results of NTP bioassays for carcinogenicity and chronic toxicity. Provides NTP classification.
U.S. Air Force. 1989. *The Installation Restoration Toxicology Guide, Vols. 1-5.*	Toxicological profiles of hazardous chemicals found at U.S. Air Force sites. In addition to health effects, these documents review properties, regulations, and exposure.
U.S. Department of Health and Human Services. UNDATEDa. *Toxicological Profiles*.	Toxicological profiles of hazardous chemicals most often found at facilities on CERCLA's National Priority List. In addition to health effects and risk levels, these documents review properties, regulations, and exposure.
U.S. Department of Labor, Occupational Safety and Health Administration. 1989a. "Table Z-2. Limits for Air Contaminants."	OSHA occupational exposure limits.

TABLE 5-11: SOURCES OF HUMAN HEALTH HAZARDS DATA	
Reference	**Type of Data**
U.S. Environmental Protection Agency. UNDATEDa. *Drinking Water Regulations and Health Advisories*.	Maximum Contaminant Levels for drinking water (MCLs), Maximum Contaminant Level Goal (MCLGs), drinking water health advisories, and ambient water quality criteria for the protection of human health. MCLs are promulgated pursuant to the Safe Drinking Water Act. MCLG is a non-enforceable concentration of a drinking water contaminant that is protective of adverse human health effects and allows an adequate margin of safety.
U.S. Environmental Protection Agency. UNDATEDb. *Health Assessment Documents (HAD)*.	Reviews of health effects of specific chemicals.
U.S. Environmental Protection Agency. UNDATEDc. *Integrated Risk Information System (IRIS®)*.	Agency position on selected substances, including reviews of selected studies used in the derivation of RfD, RfC, q_1*, and unit risk values. When appropriate data are available, provides EPA classification of carcinogenicity.
U.S. Environmental Protection Agency. 1991d. *Table 302.4. List of Hazardous Substances and Reportable Quantities.*	RQ values for selected hazardous chemicals.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

The following data bases (Table 5-12) are useful in the absence of other data, but information given should be checked against primary sources for accuracy. The TOXLINE and TOXLIT sources provide abstracts that sometimes contain useful data; most of these data bases are good sources of references to primary literature, such as journal articles.

TABLE 5-12: SUPPLEMENTAL SOURCES OF HUMAN HEALTH HAZARDS DATA	
Reference	**Types of Data**
CANCERLIT®. 1995.	Bibliographic on-line data base containing information on various aspects of cancer.
CCRIS®. Chemical Carcinogenesis Research Information System. 1995.	Factual data bank sponsored by National Cancer Institute. Contains evaluated data and information, derived from both short- and long-term bioassays on 1,200 chemicals.

TABLE 5-12: SUPPLEMENTAL SOURCES OF HUMAN HEALTH HAZARDS DATA

Reference	Types of Data
CHEMID®. Chemical Identification System. 1995.	A chemical dictionary file for over 184,000 compounds of regulatory and biomedical interest. Includes CAS RNs, molecular formulae, generic and trivial names, MeSH headings, and file locators for other files on the ELHILL® and TOXNET® systems. Also provides names and other data used to describe chemicals on over 20 key federal and state regulatory lists.
CHEMLINE®. Chemical Dictionary Online. 1995.	On-line data base that contains 1,142,000 records. Includes chemical names, synonyms, CAS RNs, molecular formulas, National Library of Medicine file locators and, where appropriate, ring structure information.
DART®. Developmental and Reproductive Toxicology. 1995.	Bibliographic data base covering teratology and developmental toxicology literature published since 1989.
EMICBACK®. Environmental Mutagen Information Center Backfile. 1995.	Contains references to chemical, biological, and physical agents that have been tested for genotoxic activity.
ETICBACK®. Environmental Teratology Information Center Backfile. 1995.	Contains references on agents that may cause birth defects.
GENE-TOX®. Genetic Toxicology. 1995.	An on-line data bank created by the EPA as a multi-phase effort to review and evaluate the existing literature and assay systems available in the field of genetic toxicology.
MEDLINE®. MEDLARS Online. 1995.	Bibliographic data base covering medicine, nursing, dentistry, veterinary medicine, and the preclinical sciences. Good source of epidemiological information.
RTECS®. Registry of Toxic Effects of Chemical Substances. 1995.	On-line data base that briefly summarizes the toxicity of a given chemical (not peer-reviewed).
TOXLINE®. 1995	Bibliographic toxicity data base. Abstracts are available.
TOXLIT®. 1995.	Bibliographic data base. Toxicity files from Chemical Abstracts. Abstracts are available.
U.S. Environmental Protection Agency. UNDATEDd. *Health Effects Assessment Summary Tables*.	RfD, RfC, unit risk, and q_1* values for selected chemicals.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

ENVIRONMENTAL HAZARDS SUMMARY

OVERVIEW: Environmental hazards assessment is the process of identifying the adverse effects that a chemical may have on organisms in the environment. Currently, the CTSA process for environmental hazards assessment focusses on aquatic toxicity. Other environmental hazards could include mammalian toxicity, avian toxicity, and habitat alteration or destruction (e.g., altering the temperature of a stream by discharging cooling water).

This module collects data on measured or predicted toxicity of chemicals to aquatic organisms to characterize the potential aquatic toxicity hazard of chemical discharges to receiving waters. Toxic chemical discharges can also affect the quality of water that may be a source of drinking water and can be a detriment to the human food chain. Aquatic toxicity data are combined with estimated water concentrations from the Exposure Assessment module to assess the risk of chemical exposure to aquatic organisms in the Risk Characterization module.

GOALS:

- Assess the toxicity of chemicals to the aquatic environment.
- Guide the selection and use of chemicals that are less toxic to aquatic organisms.
- Determine the aquatic toxicity concern concentration (CC) of chemicals.
- Provide the CCs to the Risk Characterization module.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Expertise in aquatic toxicology, including knowledge of standard aquatic toxicity test methods, relative sensitivity of aquatic species to chemical contamination, mechanisms of toxic action, and relationships of the molecular structure of chemicals to toxic action.
- Knowledge of molecular structure and fate of chemicals in the aquatic environment.

Within a business or a DfE project team, the people who might supply these skills include an aquatic toxicologist, an environmental scientist, a chemist, and/or an environmental engineer. DfE project teams that do not have people with the necessary expertise to complete this module should seek outside assistance.

Note: The analysis presented in this module should only be undertaken by someone with expertise in environmental hazards (toxicity) assessment. Furthermore, peer-review of the completed environmental hazards summary is recommended.

DEFINITION OF TERMS:

Analog: A chemical compound structurally similar to another but differing often by a single element of the same valence and group of the periodic table as the element it replaces.

Aquatic Toxicity Concern Concentration (CC): The concentration of a chemical in the aquatic environment below which no significant risk to aquatic organisms is expected.

Aquatic Toxicity Profile: A compilation of the effective concentrations (EC), either measured or predicted, for a range of species.

Assessment Factor (AsF): Adjustment value used in the calculation of a CC that incorporates the uncertainty associated with: (1) toxicity data (e.g., laboratory test versus field test; measured versus estimated data); (2) acute exposures versus chronic exposures; and (3) species sensitivity.

Chronic Value: (See No Effect Concentration.)

Daphnid: Water flea; an aquatic invertebrate (*Daphnia* spp.) frequently used as the test organism in aquatic toxicity testing.

Effects Concentration ($EC_{50)}$): The concentration of a chemical in water that causes 50 percent of the test organisms to show an adverse sublethal effect (such as growth inhibition) at the end of the specified exposure period. Typical units are mg/L.

Hydrolysis: A chemical transformation process in which a chemical reacts with water. In the process, a new carbon-oxygen bond is formed with oxygen derived from the water molecule, and a bond is cleaved within the chemical between carbon and some functional group.

Lethal Concentration ($LC_{50)}$): The concentration of a chemical in water (or air) that causes death or complete immobilization in 50 percent of the test organisms at the end of the specified exposure period. LC_{50} values typically represent acute exposure periods, usually 48 or 96 hours but up to 14 days for fish. Typical units are mg/L (mg/m^3 or ppm for air).

Lowest-Observed Effect Concentration (LOEC): The lowest concentration at which there are statistically significant increases in adverse effects in the exposed population over its appropriate control group.

Maximum Allowable Toxicant Concentration (MATC): The range of measured values in the range from the no-observed effect concentration (NOEC) to the LOEC.

Measured Concentrations: Chemical concentrations measured in the aqueous test solution at specified intervals and at the end of an aquatic toxicity test period. EPA aquatic toxicity test methods in the Code of Federal Regulations require test results to be reported based on mean measured concentrations. Many tests results are based on nominal concentrations, however, to avoid the cost of chemical laboratory analysis.

No-Effect Concentration (NEC): The concentration of a chemical that results in no significant effects on the test organisms following a prescribed (usually chronic) exposure period. NEC is the geometric mean of the NOEC and the LOEC and is used to represent the threshold concentration. This value may alternatively be called the geometric mean of the maximum allowable toxicant concentration (GMATC), or the Chronic Value. Typical units are mg/L.

No-Observed Effect Concentration (NOEC): A concentration at which there are no statistically significant increases in adverse effects in the exposed population over its appropriate control group.

Nominal Concentrations: Chemical concentrations added to the aqueous test solution at the beginning of an aquatic toxicity test. Nominal concentrations can be higher than the actual concentration causing a toxic effect, particularly if the chemical is volatile or was added to the test solution at a concentration greater than its water solubility limit.

Octanol/Water Partition Coefficient (K_{ow}): The equilibrium ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol/water system, typically expressed in log units (log K_{ow}). K_{ow} provides an indication of a chemical's water solubility, fat solubility (lipophilicity), its tendency to bioconcentrate in aquatic organisms, and to sorb to soil or sediment. It is often used in toxicity structure-activity relationships.

Structure-Activity Relationship (SAR): The relationship of the molecular structure and/or functional groups of a chemical with specific effects. SARs evaluate the molecular structure of a chemical and make qualitative or quantitative correlations of particular molecular structures and/or functional groups with specific effects.

Threshold Concentration: The concentration at which effects begin. (See No Effect Concentration.)

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for conducting an environmental hazards assessment focussing on aquatic toxicity. Methodology details for Steps 3, 4, 5, and 6 follow this section.

Step 1: Obtain the CAS RN and synonyms, chemical structure, and pertinent chemical properties information for each chemical from the Chemical Properties module.

Step 2: Obtain environmental fate parameter values and reactivity data from the Environmental Fate Summary module. (For example, a chemical's K_{ow} is required to predict effect concentrations.) If a chemical is highly water-reactive (for example, hydrolysis half-life less than one hour) consider collecting toxicity data for the hydrolysis product(s).

Step 3: Construct an aquatic toxicity profile for each chemical. The most frequently used toxicity profile for aquatic organisms consists of the following:

- Fish acute toxicity value (usually a fish 96-hour LC_{50} value).
- Aquatic invertebrate acute toxicity value (usually a daphnid 48-hour LC_{50} value).
- Green algal toxicity value (usually an algal 96-hour EC_{50} value).
- Fish chronic value (usually a fish 28-day early life stage NEC).
- Aquatic invertebrate chronic toxicity value (usually a daphnid 21-day NEC).
- Algal chronic toxicity value (usually an algal 96-hour NEC value for biomass).

Step 4: Use data quality checks to evaluate the validity of the data obtained in Step 3. Data that appear invalid (e.g., based on nominal concentrations instead of measured concentrations; inconsistent with the physical/chemical properties of the chemical, etc.) should be replaced with data of better quality or predicted data.

Step 5: Calculate the CC for each chemical in water. Concentrations in water below the CC are assumed to present low (acceptable) risk to aquatic species.

Step 6: Rank chemicals for aquatic toxicity according to the lowest of their acute or chronic values. This ranking can be based on scoring the chemicals as High, Moderate, or Low concern for aquatic toxicity.

Step 7: Provide the CCs to the Risk Characterization module.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 3, 4, 5, and 6. If necessary, additional information on this and other steps can be found in previously published guidance (Table 5-15: Published Guidance on Aquatic Toxicity Assessment).

Details: Step 3, Constructing the Aquatic Toxicity Profile

The aquatic toxicity profile may consist of only valid measured data, only predicted values, or a combination of both. Depending on the availability of valid measured data or SARs to estimate data, the toxicity profile may contain a minimum of one acute or chronic value to the full compliment of three acute values and three chronic values. Examples from the Screen Reclamation CTSA (EPA, 1994c) are shown in Table 5-13.

TABLE 5-13: EXAMPLE AQUATIC TOXICITY PROFILES (in mg/L)

Chemical	Fish Acute	Daphnid Acute	Algal Acute	Fish Chronic	Daphnid Chronic	Algal Chronic	CC[a]	Chronic Eco[b] Hazard Rank
Acetone	> 1000	> 1000	> 1000	490	100	76	7.6	Low
Sodium hypochlorite	< 1.7	< 2.0	< 2.0	< 0.17	< 0.2	< 0.2	< 0.02	Moderate
Solvent naphtha light aliphatic C^5 - C^{10}	0.64	0.86	0.23	0.05	0.05	0.11	0.005	High

a) CC is derived by dividing the lowest chronic value (in mg/L) by 10.
b) See Details: Step 6 for guidelines on ranking chemicals for aquatic toxicity.

Chemical Mixtures: Chemical mixtures, such as petroleum products (e.g., mineral spirits or solvent naphtha), do not lend themselves to the standard assessment process using SARs. The chemical constituents and the percentage of each in a mixture can vary. The toxicity of mixtures can be determined by estimating the toxicity of each individual constituent and then evaluating the potential toxicity of the product through a weighted average. If the concentration of each constituent in the mixture is not known, one approach is to assume that each component is present in an equal percentage in the product and the geometric mean of the range of like toxicity values provides the best estimate of the toxicity. The geometric mean of *n* positive numbers is $(a \times b \times c...)^{1/n}$. If the concentration of the constituents is known, then the sum of the weight fractions of each constituent multiplied by its toxicity provides an estimate of the toxicity of the product.

Discrete (Single) Organic Chemicals: The toxicity profile for single organic chemicals can be constructed using effective concentrations based on toxicity test data (measured) or estimated toxicity values based on SARs.

Inorganic Chemicals: The toxicity of inorganic chemicals typically cannot be as accurately estimated using SARs as for organic chemicals. The toxicity profile for inorganic chemicals should therefore be constructed using effective concentrations based on measured toxicity test data if possible. If no data are available, actual data from the nearest analog can be used.

To construct the toxicity profile:

(1) Collect valid measured data from peer-reviewed on-line data bases such as Hazardous Substance Data Bank (HSDB) or from peer-reviewed open literature sources.

(2) When valid measured data are not available, use SAR estimates if available for the chemical class. The use, application, development, and validation of SARs have been presented in a number of publications (see section on previously published guidance). Computer models that calculate toxicity values based on SARs are also

available (see section on analytical models). The following data hierarchy is preferred for SAR estimates (from lowest to highest):

a) Valid measured data from the nearest analog.

b) Predicted value based on valid measured data from two analogs that bracket the chemical of concern.

c) Predicted value based on regression equation developed from valid measured data for a similar class of compounds.

Details: Step 4, Evaluating Data Quality

The following are examples of data quality checks. An exhaustive data quality evaluation requires expert judgment and experience.

(1) Determine if the effective concentrations are based on mean measured concentrations or nominal concentrations. Data based on mean measured concentrations are preferred, especially for volatile compounds.

(2) Determine if a chemical's physical/chemical properties are consistent with one another and with the chemical's effective concentrations. For example, a chemical with a low K_{ow} value would be expected to have a high water solubility limit. A chemical's LC_{50} value should be less than or equal to its water solubility limit unless it is a self-dispersing compound such as a surfactant. Measured concentrations that significantly exceed the water solubility limit of a compound suggest that the test laboratory may have artificially enhanced the water solubility to a level that cannot be realized in the environment.

(3) Compare the test methods against the chemical's physical/chemical properties. For example, highly water reactive chemicals (as measured by the hydrolysis half-life) should be tested in a flow-through system instead of a static system where pure stock material is added directly to the system. With the static system the test organism may only be exposed to the hydrolysis products.

Details: Step 5, Calculating the CCs

The CC for each chemical in water is calculated using the general equation:

$$CC = \text{acute or chronic toxicity value} \div AsF$$

AsFs are dependent on the amount and type of toxicity data contained in a toxicity profile and reflect the amount of uncertainty about the potential effects associated with a toxicity value. In general, the more complete the hazard profile and the greater the quality of the toxicity data, the smaller the factor used.

One of the following specific equations is used, depending on the availability of data:

a) If the toxicity profile only contains one or two acute toxicity values (no chronic values):

CC = lowest acute value ÷ 1000

b) If the toxicity profile contains three acute values (no chronic values):

CC = lowest acute value ÷ 100

c) If the toxicity profile contains one chronic value:

CC = chronic value ÷ 10, if the value is for the most sensitive species.

Otherwise:

CC = acute value for the most sensitive species ÷ 100

d) If the toxicity profile contains three chronic values:

CC = lowest chronic value ÷ 10

e) If the toxicity profile contains a measured chronic value from a field study:

CC = measured chronic value ÷ 1

Examples from the Screen Reclamation CTSA (EPA, 1994c) are shown in Table 5-13.

Details: Step 6, Ranking Chemicals for Aquatic Toxicity

Chemicals can be ranked for aquatic toxicity according to the following criteria:

a) For chronic values:

≤ 0.1 mg/L ....High
> 0.1 to ≤ 10 mg/L ....Moderate
> 10 mg/L ....Low

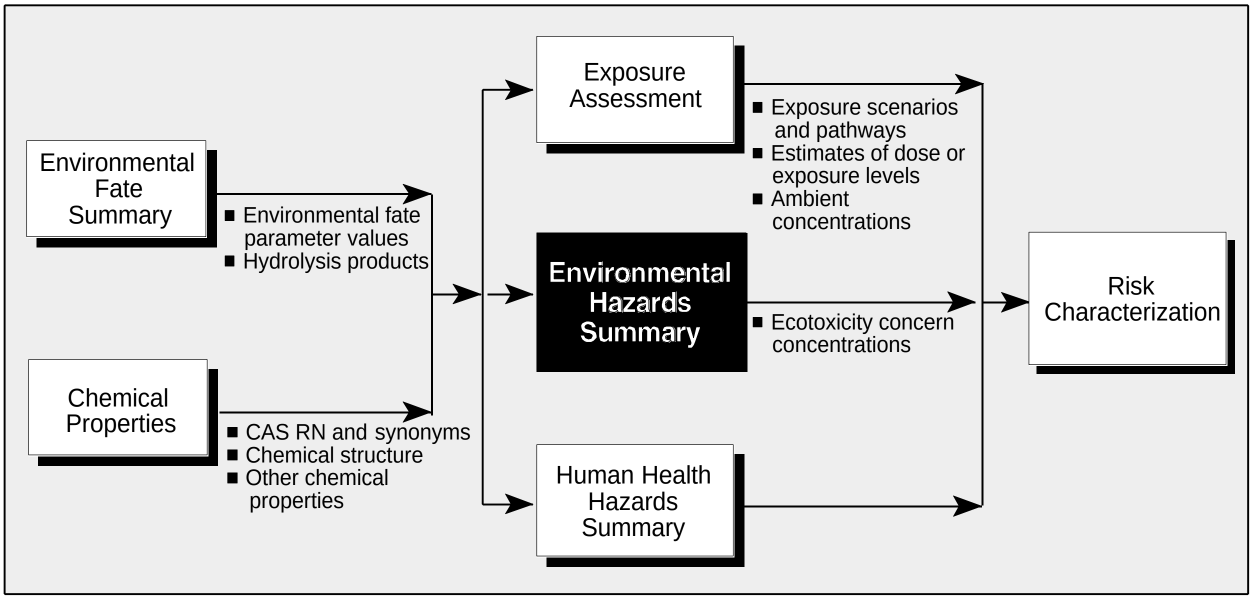
b) For acute values:

≤ 1 mg/L ....High
> 1 to ≤ 100 mg/L ....Moderate
> 100 mg/L ....Low

Chronic toxicity ranking takes precedent over the acute ranking. This relative ranking of toxicity can be used to guide the selection and use of chemicals that are less hazardous to aquatic organisms. Examples from the Screen Reclamation CTSA (EPA, 1994c) are shown in Table 5-13.

FLOW OF INFORMATION: This module can be used alone as a final data point to guide the selection and use of chemicals that are less toxic to aquatic organisms. In a CTSA, this module receives data from the Environmental Fate Summary and Chemical Properties modules and transfers data to the Risk Characterization module. Example information flows are shown in Figure 5-6.

FIGURE 5-6: ENVIRONMENTAL HAZARDS SUMMARY MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 5-14 presents references for SAR models that can be used to predict aquatic toxicity values. Since different SAR models may provide different or conflicting results, one model should be used consistently throughout a particular CTSA project.

TABLE 5-14: ANALYTICAL MODELS USED IN AQUATIC TOXICITY ASSESSMENT

Reference	Type of Model
Clements, R.G. and J.V. Nabholz. 1994. *ECOSAR: A Computer Program for Estimating the Ecotoxicity of Industrial Chemicals Based on Structure-Activity Relationships; User's Guide.*	PC format analytical model developed within the constraints of the regulatory program office of Office of Pollution Prevention and Toxics (OPPT). Uses SARs to predict acute and chronic ecotoxicity concentrations for daphnid, fish and algae. EPA uses this system exclusively for evaluating new and existing chemicals.

TABLE 5-14: ANALYTICAL MODELS USED IN AQUATIC TOXICITY ASSESSMENT	
Reference	**Type of Model**
Hunter, R.S. and F.D. Culver. 1992. *MicroQSAR Version 2.0: A Structure-Activity Based Chemical Modeling and Information System*.	Personal computer-based system of models. Uses quantitative SARs to estimate chemical properties and aquatic toxicity values.
QSAR: A Structure-Activity Based Chemical Modeling and Information System. 1986.	Available on-line and in PC format. Uses quantitative SARs to estimate chemical properties, environmental fate parameters, aquatic LC_{50} in 7 common test organisms, and NEC in fathead minnow.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 5-15 presents references for published guidance on environmental toxicity assessment and the use of SARs.

TABLE 5-15: PUBLISHED GUIDANCE ON AQUATIC TOXICITY ASSESSMENT	
Reference	**Type of Guidance**
Clements, R.G., Ed. 1988. *Estimating Toxicity of Industrial Chemicals to Aquatic Organisms Using Structure Activity Relationships*.	Describes the use of SARs by EPA OPPT.
Clements, R.G., et. al. 1993a. "The Use and Application of QSARs in the Office of Toxic Substances for Ecological Hazard Assessment of New Chemicals."	Describes the use and application of QSARs for the hazard assessment of new chemicals.
Clements, R.G., et. al. 1993b. "The Use of Quantitative Structure-Activity Relationships (QSARs) as Screening Tools in Environmental Assessment."	Describes the development, validation, and application of SARs in EPA OPPT.
Clements, R.G., Ed. 1994. *Estimating Toxicity of Industrial Chemicals to Aquatic Organisms Using Structure-Activity Relationships*.	Describes the use of SARs by EPA OPPT.
Lipnick, R.L. 1993. "Baseline Toxicity QSAR Models: A Means to Assess Mechanism of Toxicity for Aquatic Organisms and Mammals."	Describes the development, validation, and application of SARs in EPA OPPT.
Nabholz, J.V. 1991. "Environmental Hazard and Risk Assessment Under the United States Toxic Substances Control Act."	Detailed discussion of a comprehensive toxicity profile and risk assessment for existing chemicals.

TABLE 5-15: PUBLISHED GUIDANCE ON AQUATIC TOXICITY ASSESSMENT	
Reference	**Type of Guidance**
Nabholz, J.V., et. al. 1993a. "Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five."	Describes the toxicity profile outlined in Step 3.
Nabholz, J.V., et. al. 1993b. "Validation of Structure-Activity Relationships Used by the U.S. EPA's Office of Pollution Prevention and Toxics for the Environmental Hazard Assessment of Industrial Chemicals."	Describes the development, validation, and application of SARs in EPA OPPT.
U.S. Environmental Protection Agency. 1984b. *Estimating Concern Levels for Concentrations of Chemical Substances in the Environment*.	Describes the use of AsFs to determine the CC for a chemical.
Zeeman, M.G. and James Gilford. 1993. "Ecological Hazard Evaluation and Risk Assessment Under EPA's Toxic Substances Control Act (TSCA): An Introduction."	Provides an overview of the process used in the environmental toxicity assessment of chemicals.
Zeeman, M.G., et. al. 1993. "The Development of SAR/QSAR for Use Under EPA's Toxic Substances Control Act (TSCA): An Introduction."	Describes the development, validation, and application of SARs in EPA OPPT.
Zeeman, M.G. 1995a. "EPA's Framework for Ecological Effects Assessment."	Provides an overview of the process used in the environmental toxicity assessment of chemicals.
Zeeman. M.G. 1995b. "Ecotoxicity Testing and Estimation Methods Developed Under Section 5 of the Toxic Substances Control Act (TSCA)."	Describes the development, validation, and application of SARs in EPA OPPT.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 5-16 lists sources of aquatic toxicity data.

TABLE 5-16: SOURCES OF AQUATIC TOXICITY DATA	
Reference	**Type of Data**
Aquatic Information Retrieval (AQUIRE) Data Base. UNDATED.	Comprehensive data base of measured aquatic toxicity values derived from open literature. Some data not peer-reviewed. Data should be confirmed with original literature citation.

TABLE 5-16: SOURCES OF AQUATIC TOXICITY DATA

Reference	Type of Data
Brooke, L.T., et. al., Ed. 1984 - 1990. *Acute Toxicities of Organic Chemicals to Fathead Minnows (Pimephales promelas).*	Comprehensive source of measured fish toxicity values for a single species (fathead minnows), including fish LC_{50} data.
Call, D.J. and D.L. Geiger, Eds. 1992. *Sub-chronic Toxicities of Industrial and Agricultural Chemicals to Fathead Minnows (Pimephales promelas).*	Source of measured fish toxicity values for a single species (fathead minnows), including fish EC_{50} data.
HSDB®. Hazardous Substances Data Bank (HSDB). Updated Periodically.	Measured aquatic toxicity values derived from open literature. Peer-reviewed.
U.S. Atomic Energy Commission. 1973. *Toxicity of Power Plant Chemicals to Aquatic Life*.	Aquatic toxicity values for inorganic chemicals.
U.S. Environmental Protection Agency. UNDATEDe. *Ambient Water Quality Criteria Documents*.	Aquatic toxicity values for chemicals for which ambient water quality criteria have been developed. Useful for organic and inorganic compounds.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

CHEMISTRY OF USE & PROCESS DESCRIPTION

OVERVIEW: The Chemistry of Use & Process Description module identifies the chemical, physical, and mechanical properties which contribute to the effectiveness of the use cluster chemicals or technologies in an industry- or product-specific application. The module also details the process in which the chemicals are used through the creation of a process flow diagram that schematically describes the process operations, equipment, and material flows.

GOALS:

- Identify the characteristics of a chemical (e.g., low vapor pressure, high solvency, water solubility, ductility, and other chemical, physical, or mechanical chemical properties) that contribute to its effectiveness in achieving the desired function.
- Develop a process flow diagram that describes each operation performed in the application being evaluated.
- Utilize the chemistry of use and process flow diagram to identify potential substitute chemicals, processes, or technologies.
- Provide a basis for developing a survey instrument to evaluate workplace practices in the use cluster industry and to determine the possible sources of chemical release in the use cluster.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of basic chemical properties and reactions.
- Ability to create and use process flow diagrams.
- Knowledge of the manufacturing, commercial, or industrial process that is being evaluated.

Within a business or DfE project team, the people who might supply these skills include a chemist, process operator, process supervisor, or a chemical or mechanical engineer. Vendors of any process chemicals or equipment may also be a good resource.

DEFINITION OF TERMS:

<u>Flow Diagram</u>: A block diagram that depicts the equipment, material streams, and basic operations performed in a process.

Material Stream: A flow of material (e.g., water, chemicals, product outputs, air emissions, etc.) either into or out of a step in the process.

Unit Operation: A process step that achieves a desired function.

APPROACH/ METHODOLOGY: The following presents a summary of the approach or methodology for evaluating the chemistry of use and preparing a process description. If there are substantially different methods of performing the use cluster function within an industry, it may be necessary to define the chemistry of use and prepare a process description for each of the methods typically employed. Further methodology details for Step 4 follow this section.

Step 1: Obtain chemical data including CAS RNs, molecular structure, and chemical/physical properties from the Chemical Properties module.

Step 2: Identify the properties that contribute to the effectiveness of the use cluster chemicals or technologies in performing the desired function. The properties may be chemical properties (e.g., a solvent with the ability to dissolve many different types of resins may be required in a paint stripping product), physical properties (e.g., a printing ink may have to be white, thus requiring the ink to contain a white pigment, such as titanium dioxide), or mechanical properties (e.g., a material substrate may need to meet specific mechanical qualifications for yield strength or fracture toughness). These properties are important criteria when selecting alternatives for a particular use cluster and identifying performance characteristics for the Performance Assessment.

Step 3: Examine the industry- or product-specific application of the use cluster chemicals to identify the following:

- Unit Operations, or process steps, required to perform the desired function (e.g., cleaning, degreasing, plating, product assembly, drilling, painting, drying, etc.). Identify any chemical, physical, or mechanical agents used in conjunction with the use cluster chemicals (e.g., dilution with water, heat, pressure, mechanical agitation, etc.).
- Equipment used in the process steps (e.g., production machinery, reactors, heaters, waste stream control technologies, etc.).
- Material streams that flow into, out of, or between steps in the process (e.g., raw material inputs, product outputs, rinse water streams, solid waste disposal, air emissions, waste water discharges, etc.).
- The manner in which raw materials, chemicals, or products are stored and handled (e.g., chemical feedstock handling, methods of storage, etc.).
- Any other data that might be necessary to prepare a process description or process flow diagram.

Step 4: Construct a process flow diagram using the information collected in Step 3. An example flow diagram is shown in the Methodology Details section.

Step 5: Review the information obtained from Steps 1 through 4 with the objective of identifying alternative chemicals, processes, and/or technologies (i.e., substitutes) that could be used to accomplish the same function. One approach to identifying substitutes is to consult with other industries that have similar functional requirements at some stage in the manufacturing or commercial service process. Another approach is to consult with vendors of chemicals or equipment who may be able to suggest process improvements that reduce environmental releases. Also, consult technical assistance organizations that have a broad overview of chemical uses and substitutes in many different industries.

Step 6: Transfer a description of the unit operations and the process flow diagram to the following modules:

- Workplace Practices & Source Release Assessment.
- Process Safety Assessment.
- Exposure Assessment.
- Regulatory Status.
- Pollution Prevention Opportunities Assessment.
- Control Technologies Assessment.
- Performance Assessment.

Step 7: Provide data on material streams (e.g., water, raw materials, chemicals, etc.) to the Resource Conservation module, and a list of equipment used in the process to the Energy Impacts module.

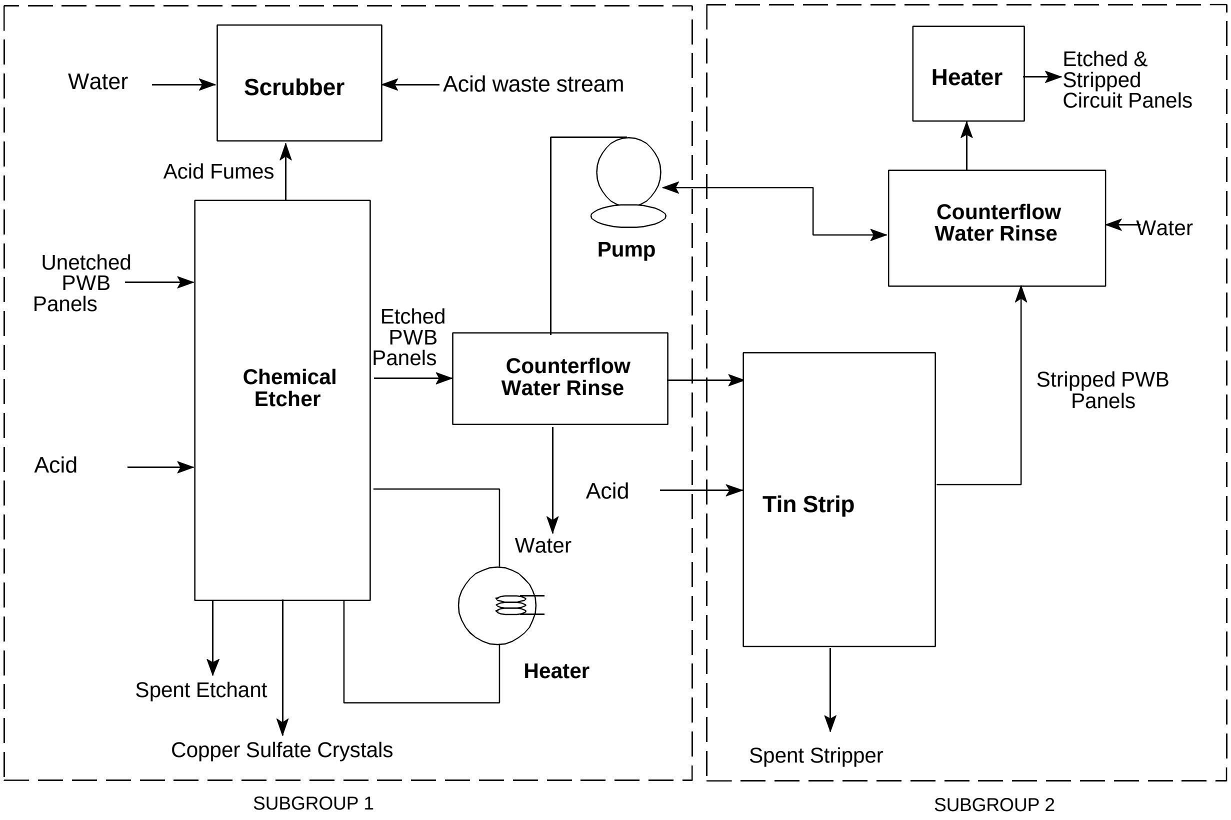
METHODOLOGY DETAILS: This section presents the methodology details for completing Step 4.

Details: Step 4, Process Flow Diagram Example

Figure 5-7 is an example of a process flow diagram for the pattern etching use cluster of the printed wiring board manufacturing process.

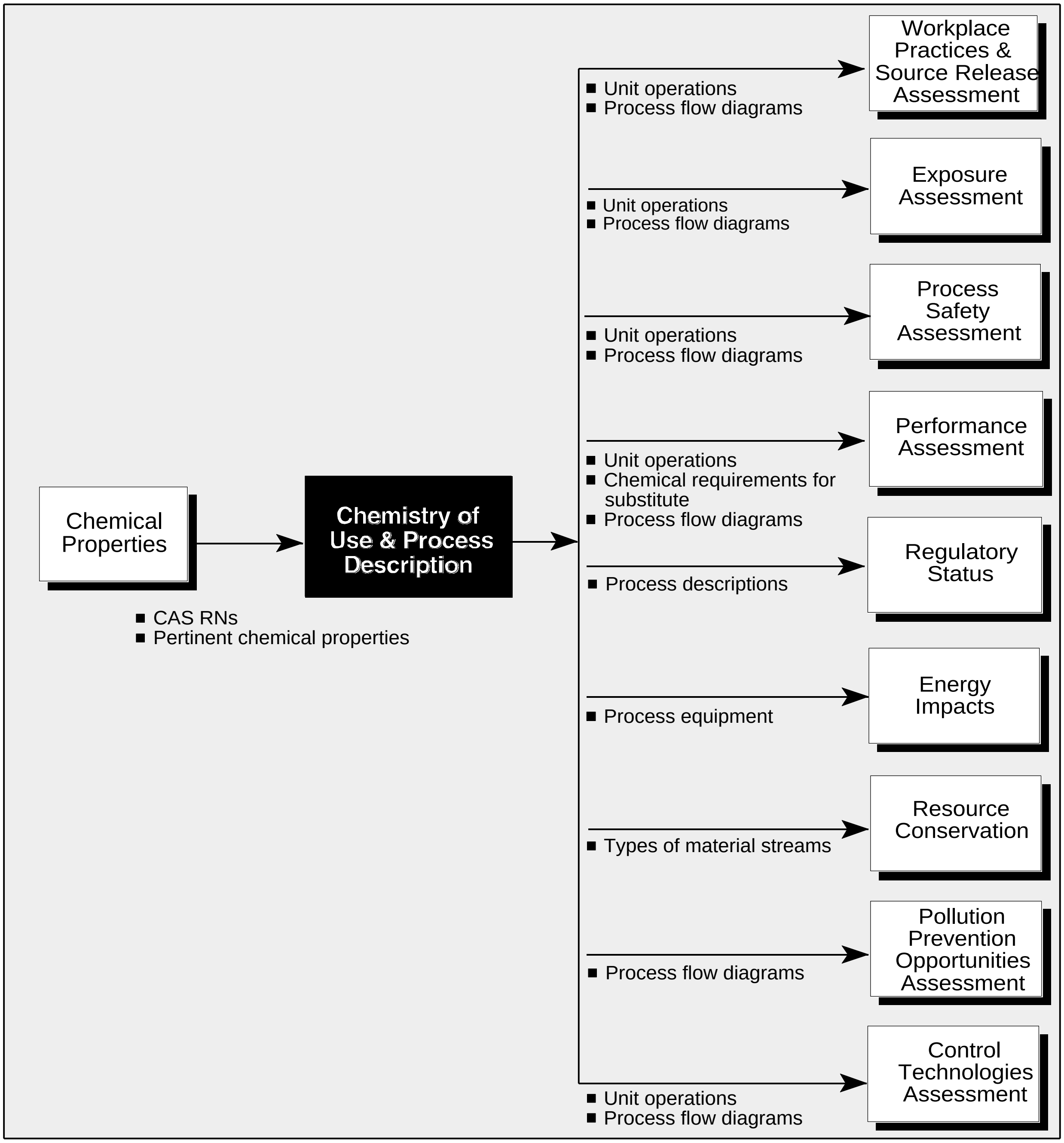
The pattern etching use cluster begins with the chemical etching of the unetched circuit panels and ends with the final drying of the etched panel. The use cluster shown here has the functional subgroups of chemical etching (Subgroup 1) and tin resist stripping (Subgroup 2). Subgroup 1 includes the actual etching step as well as a rinsing step to remove the excess etchant from the panels. Subgroup 2 includes the actual tin-resist stripping process step and a rinsing and drying step performed before the etched circuits can pass to the next step in the printed wiring board manufacturing process.

FIGURE 5-7: EXAMPLE PROCESS FLOW DIAGRAM OF A PATTERN ETCH PROCESS FOR PWB MANUFACTURING



FLOW OF INFORMATION: In a CTSA, this module receives information from the Chemical Properties module and transfers information to the Workplace Practices & Source Release Assessment, Exposure Assessment, Process Safety Assessment, Performance Assessment, Regulatory Status, Energy Impacts, Resource Conservation, Pollution Prevention Opportunities Assessment, and Control Technologies Assessment modules. Example information flows are shown in Figure 5-8.

FIGURE 5-8: CHEMISTRY OF USE & PROCESS DESCRIPTION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Although no publications were identified that provide guidance for this module, chemical engineering textbooks explain the basic concepts of process flow diagrams and provide numerous examples. Table 5-17 lists a few examples of chemical engineering textbooks.

TABLE 5-17: PUBLISHED GUIDANCE ON CHEMISTRY OF USE & PROCESS DESCRIPTION

Reference	Type of Guidance
Himmelblau, David M. 1990. *Basic Principles and Calculations in Chemical Engineering*.	Examples of process flow diagrams.
Luyben, William and L. Wenzel. 1988. *Chemical Process Analysis: Mass and Energy Balances*.	Examples of process flow diagrams.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

PROCESS SAFETY ASSESSMENT

OVERVIEW: The Process Safety Assessment module screens potential chemical substitutes to determine if they could potentially pose a safety hazard in the workplace. Process operating characteristics and workplace practices are combined with physical hazard data, precautions for safe handling and use, and other data to determine if implementing a chemical substitute might pose a safety hazard. Safe operating procedures for alternative technologies (equipment) are also considered.

GOALS:

- Obtain information on chemical hazards (reactivity, corrosivity, etc.), proper handling and storage precautions, and proper use guidelines for each chemical formulation or technology being evaluated.
- Compare physical hazard data to process operating conditions and workplace practices to determine if any of the chemical substitutes might pose a safety hazard in the workplace.
- Determine what special actions, if any, need to be taken when using substitute chemicals, formulations, or processes.
- Guide the selection and use of chemicals or processes that are less hazardous in the workplace.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of chemicals used and/or produced by the process as well as knowledge and understanding of the technologies and equipment used for the process.
- Knowledge of the workplace practices and operating procedures for the given process.
- Knowledge of process safety analysis, Occupational Safety and Health Administration (OSHA) regulations, and guidelines pertaining to hazardous chemicals and industrial safety.

Within a business or a DFE project team, the people who might supply these skills include a process engineer, safety engineer, safety specialist, or an industrial hygienist.

DEFINITION OF TERMS: The Process Safety Assessment module focuses on physical hazards such as flammability and explosivity rather than health hazards from toxic chemical exposure. Health hazards are characterized in other parts of the CTSA. The definitions of

OSHA established limits for worker exposure to toxic chemicals (e.g., Permissible Exposure Limit and Threshold Limit Value) are listed in this module, however, to assist the individual in interpreting material safety data sheet data.

<u>Combustible Liquid</u>: As defined by OSHA (29 CFR 1910.1200), any liquid having a flash point at or above 140 ^{o}F (37.6 ^{o}C), but below 200 ^{o}F (93.3 ^{o}C), except any mixture having components with flashpoints of 200 ^{o}F (93.3 ^{o}C), or higher, the total volume of which makes up 99 percent or more of the total volume of the mixture.

<u>Compressed Gas</u>: As defined by OSHA (29 CFR 1910.1200):

- A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 ^{o}F (21.1 ^{o}C).
- A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130 ^{o}F (54.4 ^{o}C) regardless of the pressure at 70 ^{o}F (21.1 ^{o}C).
- A liquid having a vapor pressure exceeding 40 psi at 100 ^{o}F (37.8 ^{o}C) as determined by ASTM D-323-72.

<u>Corrosive</u>: As defined by OSHA (29 CFR 1910.1200), a chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a chemical is considered to be corrosive if, when tested on the intact skin of albino rabbits by the method described by the U.S. Department of Transportation in Appendix A to 49 CFR 173, it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of four hours. According to the OSHA definition, this term shall not refer to action on inanimate surfaces.

<u>Explosive</u>: As defined by OSHA (29 CFR 1910.1200), a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

<u>Flammable</u>: As defined by OSHA (29 CFR 1910.1200), a chemical that falls into one of the following categories:

- <u>Flammable aerosol</u>: An aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening.
- <u>Flammable gas</u>:
  - A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less; or
  - A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than 12 percent by volume, regardless of the lower limit.
- <u>Flammable liquid</u>: Any liquid having a flashpoint below 100 ^{o}F (37.8 ^{o}C), except any mixture having components with flashpoints of 100 ^{o}F (37.8 ^{o}C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.
- <u>Flammable solid</u>: A solid, other than a blasting agent or explosive as defined in 29 CFR 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or

which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

Flash Point: As defined by OSHA (29 CFR 1910.1200), the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

- Tagliabue Closed Tester: (see American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24-1979 [ASTM D 56-79]) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 °F (37.8 °C), that do not contain suspended solids and do not have a tendency to form a surface film under test.
- Pensky-Martens Closed Tester: (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7-1979 [ASTM D 93-79]) for liquids with a viscosity equal to or greater than 45 SUS at 100 °F (37.8 °C), or that contain suspended solids, or that have a tendency to form a surface film under test.
- Setaflash Closed Tester: (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester [ASTM D 3278-78].) Typical units are °C or °F.

Hazard: A condition or changing set of circumstances that presents a potential for injury, illness, or property damage. The potential or inherent characteristics of an activity, condition, or circumstance which can produce adverse or harmful consequences. Hazards can be categorized into four groups: biological, chemical, mechanical, and physical.

Hazardous Chemical: As defined by OSHA (29 CFR 1910.1200), any chemical which is a physical hazard or a health hazard.

Hazardous Substance: Any substance which has the potential of causing injury by reason of its being explosive, flammable, toxic, corrosive, oxidizing, irritating, or otherwise harmful to personnel.

Immediately Dangerous to Life or Health (IDLH): The maximum inhalation level from which a worker could escape without any escape-impairing symptoms or any irreversible health effects.

Industrial Hygiene: The science and art devoted to the recognition, evaluation, and control of those environmental factors or stresses arising in or from work situations which may cause sickness, impaired health and well-being, or significant discomfort and inefficiency among workers or among the citizens of a community.

Irritant: As defined by OSHA (29 CFR 1910.1200), a chemical which is not corrosive but which causes a reversible, inflammatory effect on living tissue by chemical action at the site of contact. A chemical is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for four hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A chemical is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.

Lower Explosive Limit (LEL): The minimum concentration of combustible gas or vapor in air below which propagation of flame does not occur on contact with a source of ignition. The lower limit of flammability of a gas or vapor at ordinary ambient temperatures expressed in percent of the gas or vapor in air by volume.

Material Safety Data Sheet (MSDS): As defined by OSHA (29 CFR 1910.1200), written or printed material concerning a hazardous material which contains the following:

- The identity of the hazardous material (except as provided for materials that are trade secrets).
- The physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point).
- The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity.
- The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical.
- The primary route(s) of entry.
- The OSHA PEL, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the MSDS, where available.
- Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Annual Report on Carcinogens (latest edition) or has been identified as a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions) or by OSHA.
- Any generally applicable precautions for safe handling and use which are known to the chemical manufacturer, importer, or employer preparing the MSDS, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks.
- Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the MSDS, such as appropriate engineering controls, work practices, or personal protective equipment.
- Emergency and first aid procedures.
- The date of preparation of the MSDS or the last change to it.
- The name, address, and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the MSDS, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Mixture: As defined by OSHA (29 CFR 1910.1200), any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.

Occupational Safety and Health Act: Federal statute that governs workplace safety and the exposure of workers to chemicals in the workplace.

Occupational Safety and Health Administration (OSHA): A federal agency under the United States Department of Labor which develops and administers industrial safety and health standards.

Organic Peroxide: As defined by OSHA (29 CFR 1910.1200), an organic compound that contains the bivalent -O-O-structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

Oxidizer: As defined by OSHA (29 CFR 1910.1200), a chemical other than a blasting agent or explosive as defined in 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

Permissible Exposure Limit (PEL): An enforceable standard promulgated by OSHA. The PEL for a substance is the 8-hour TWA or ceiling concentration above which workers may not be exposed. Although personal protective equipment may not be required for exposures below the PEL, its use may be advisable where there is a potential for overexposure. In many cases, PELs are derived from TLVs published in 1968.

Personal Protective Equipment (PPE): Any material or device worn to protect a worker from exposure to or contact with any harmful substance or force.

Physical Hazard: As defined by OSHA (29 CFR 1910.1200), a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

Pyrophoric: As defined by OSHA (29CFR 1910.1200), a chemical that will ignite spontaneously in air at a temperature of 130 °F (54.4 °C) or below.

Reactive: Readily susceptible to chemical change and the possible release of energy; unstable. For example, as defined by OSHA (29 CFR 1910.1200), water-reactive means a chemical will react with water to release a gas that is either flammable or presents a health hazard.

Recommended Exposure Limit (REL): The workplace exposure concentration recommended by the National Institute for Occupational Safety and Health (NIOSH) for promulgation by OSHA as a PEL, but not enforceable as is the OSHA PEL. Typical units are parts per million (ppm).

Sensitizer: As defined by OSHA (29 CFR 1910.1200), a chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

Threshold Limit Value (TLV): The airborne concentration of a substance representing a condition under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect. Air at such a value may be breathed continually for 8 hours per day and 40 hours per week without harm. Because of wide variation in individual susceptibility, exposure of an occasional individual at or even below the TLV may not prevent discomfort, aggravation of a preexisting condition, or occupational illness. This is also referred to as the threshold limit value - time-weighted average (TLV-TWA). Typical units are ppm.

Threshold Limit Value - Ceiling (TLV-C): The concentration that should not be exceeded even instantaneously. Typical units are ppm.

Threshold Limit Value - Short-Term Exposure Limit (TLV-STEL): A 15-minute TWA exposure that should not be exceeded at any time during the work day. Typical units are ppm.

Upper Explosive Limit (UEL): The maximum proportion of vapor or gas in air above which propagation of flame does not occur. The upper limit of the flammable or explosive range. See also LEL.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for assessing the process safety of chemical substitutes, processes, and/or technologies. Methodology details for Steps 5, 6, 8, and 9 follow this section.

Step 1: Obtain a MSDS for the chemical products in the use cluster, noting properties of the products, fire and explosion hazard data, reactivity data, precautions for safe handling and use, and control measures. In DfE pilot projects, chemical suppliers have provided MSDSs for the chemical products evaluated in the Performance Assessment. If an MSDS is not available, or a MSDS has not yet been generated for a new substitute chemical product, the information contained within an MSDS should be developed to adequately assess the potential safety hazards of a substitute. (See the resources listed in the Published Guidance on Process Safety, Table 5-19, and Sources of Process Safety Data, Table 5-20.)

Step 2: If a MSDS is not available for a substitute, obtain chemical identities, including CAS RNs and synonyms, and chemical properties for individual chemicals, such as reactivity and flashpoint, from the Chemical Properties module.

Step 3: Obtain the process description and process flow diagram from the Chemistry of Use & Process Description module.

Step 4: Obtain a description of worker activities and workplace practices from the Workplace Practices & Source Release Assessment module.

Step 5: Compare MSDS data against the process description and workplace practices to determine if the substitute chemical might pose a safety hazard.

Step 6: Determine and list special precautions or actions that should be taken if a substitute is used that presents a safety hazard. This information could affect the feasibility or the cost of the process and therefore, whether or not to use that particular substitute.

Step 7: If a substitute is considered a hazardous chemical, refer to OSHA 29 CFR 1910.119 to determine the process safety management of that substitute. This would include using hazard evaluation techniques such as what-if scenarios, checklists, hazard and operability study (HAZOP), failure mode and effects analysis (FMEA), and other analyses. Appendix A to 1910.119 also contains a list of highly hazardous chemicals, toxics, and reactives. (Also refer to Table 5-10 for other sources of published guidance.)

Step 8: Review OSHA regulations to determine and list safe operating procedures, including safe start-up and shut-down procedures, that apply to the baseline or to the substitutes.

Step 9: Provide results of the Process Safety Assessment module to the Cost Analysis and the Risk, Competitiveness, & Conservation Data Summary modules.

METHODOLOGY DETAILS: This section presents the methodology details or examples for completing Steps 5, 6, 8, and 9 above.

Details: Step 5, Comparing MSDS Data with the Process Description and Workplace Practices

The following are examples of chemical properties that may be incompatible with certain operating conditions:

- Flammable chemicals used in an area where welding occurs.
- Flammable chemicals used in a process that operates at elevated temperatures near the chemical flashpoint.
- Water-reactive chemicals used in an area where aqueous spray washing occurs.
- Water-reactive chemicals used in a humid environment where water condenses on chilled equipment.

Details: Step 6, Determining or Listing Special Precautions or Actions to be Taken if Substitute is Used

Examples of special precautions include the following storage conditions:

- Flammable liquids, which should be stored in flammable liquid storage cabinets or refrigerators.
- Caustics, which should not be stored next to acids.

- Oxidizers, which should be stored separately from flammable and combustible materials as well as reducing agents (some oxidizers, such as perchloric acid, must be used only in a water wash-down fume hood made of stainless steel).
- Peroxide-forming compounds, which should be stored in airtight containers in a dark, cool, dry area.
- Compressed gases, which should be stored in a locked, upright position and contained within gas cylinders in a dry, cool location away from fumes, direct and indirect heat or flames.
- Chemicals that are highly flammable or corrosive (hazardous gases must be stored and used in fume hoods or ventilated cabinets and adequate PPE should be used).

Other examples of special precautions to be taken if a substitute presents a safety hazard are the use of chemical protective clothing and respirators. Specific examples warranting the use of chemical protective clothing include:

- Handling liquid chemicals during electronic component manufacture.
- Maintenance and quality assurance activities for chemical production.
- Application of pesticides and other agricultural chemicals.
- Chemical waste handling and emergency chemical spill response.

Specific examples warranting the use of respirators include:

- While engineering controls are being installed or tested.
- While engineering controls are being repaired or maintained; during fire fighting activities.
- During escape from suddenly occurring hazardous atmospheres.
- To eliminate hazardous conditions associated with emergencies.
- For operations where other controls are not feasible.
- For certain short-term operations where installing engineering controls would be economically impractical.

Details: Step 8, Reviewing OSHA Safe Operating Procedures

OSHA has established safe operating procedures that are either industry-specific or apply to the operation of equipment in numerous industry sectors. An example of a widely applicable OSHA standard is 29 CFR 1910.147, the OSHA standard entitled "The Control of Hazardous Energy (Lockout/Tagout)." This standard covers the servicing and maintenance of machines and equipment in which the unexpected energization or start-up of the machines or equipment, or release of stored energy could cause injury to employees. For some types of equipment the standard permits "tagout" or placement of a tagout device on an energy isolating device in accordance with established procedure to warn that equipment may not be operated if the employer can demonstrate that using the tagout will provide full employee protection.

Details: Step 9, Providing Results of the Process Safety Assessment to the Cost Analysis and the Risk, Competitiveness & Conservation Data Summary Modules

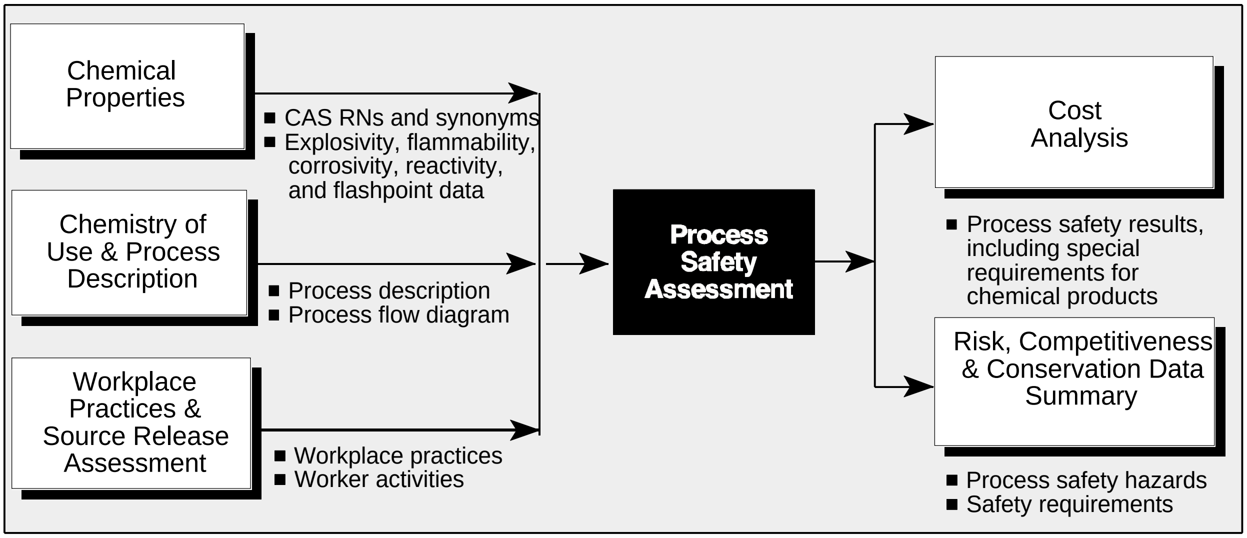
Table 5-18 indicates the type of information transferred from the Process Safety Assessment module.

TABLE 5-18: DATA TRANSFERRED FROM THE PROCESS SAFETY ASSESSMENT MODULE

Module	Data Transferred
Cost Analysis	Whether or not substitute requires special equipment which must be purchased. (Examples would include flammable liquid storage cabinets, fume hoods, ventilated cabinets, and PPE.)
Risk, Competitiveness & Conservation Data Summary	Corrosivity, explosivity, flammability possibilities and whether or not substitute is a hazardous chemical or substance, and a comparison of all substitutes to assess differences in physical or mechanical hazards.

FLOW OF INFORMATION: In a CTSA, this module receives data from the Chemical Properties, Chemistry of Use & Process Description, and Workplace Practices & Source Release Assessment modules. The Process Safety Assessment module transfers data to the Cost Analysis and the Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 5-9.

FIGURE 5-9: PROCESS SAFETY ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 5-19 presents references for published guidance on process safety.

TABLE 5-19: PUBLISHED GUIDANCE ON PROCESS SAFETY

Reference	Type of Guidance
American Petroleum Institute. UNDATED. *Management of Process Hazards.*	Describes recommended practices to prevent or minimize process hazards.
Dow Chemical Company. 1987. *Dow's Fire and Explosion Index Hazard Classification Guide.*	Helps the user quantify the expected damage of potential fire and explosion incidents; identifies equipment likely to contribute to the creation or escalation of an incident; and communicates fire and explosion risk potential to management.
National Safety Council. UNDATEDa. *Accident Prevention Manual for Industrial Operations.*	Three volumes containing accident prevention information concerning administration, engineering and technology, and environmental issues.
National Safety Council. UNDATEDb. *Fundamentals of Industrial Hygiene.*	Illustrated reference covers monitoring, evaluation, and control of workplace health hazards. It deals with OSHA regulations, professional standards, exposures, and worker's right to know laws.
National Safety Council. 1983. *Accident Investigation. . . A New Approach.*	Includes a seven-point program to cover environmental issues. Defines the components of a comprehensive program and of regulatory compliance.
Stull, D.R., Ed. UNDATED. *Fundamentals of Fire and Explosion.*	Reviews the fundamentals of fire and explosion. Topics include thermochemistry; kinetochemistry; ignition (gases, liquids, and solids); flames and dust explosions; thermal explosions; gas phase detonations; condensed phase detonations; evaluating reactivity hazard potential; blast effects, fragments and craters; and protection against explosions.
Texas Chemical Council. UNDATED. *Recommended Guidelines for Contractor Safety and Health.*	Includes a comprehensive model for a contractor safety and health program in the chemical industry. Describes responsibilities, safety requirements, safety and health training, safety program, substance abuse, safety audit, and accident reporting.

TABLE 5-19: PUBLISHED GUIDANCE ON PROCESS SAFETY

Reference	Type of Guidance
U.S. Department of Labor, Occupational Safety and Health Administration. UNDATEDa. *The Control of Hazardous Energy (Lockout/Tagout), 29 CFR 1910.147.*	Describes the OHSA regulations for the servicing and maintenance of machines and equipment in which the unexpected energization or start-up of the machines or equipment, or release of stored energy could cause injury to employees.
U.S. Department of Labor, Occupational Safety and Health Administration. UNDATEDb. *Process Safety Management of Highly Hazardous Chemicals, 29 CFR 1910.119.*	Describes the OSHA regulations for process safety management of highly hazardous chemicals.
U.S. Department of Labor, Occupational Safety and Health Administration. UNDATEDc. *Regulations Relating to Labor, 29 CFR 1926.64, Subpart D -- Occupational Health and Environmental Controls*.	Describes the OSHA regulations for preventing or minimizing the consequences of catastrophic releases of toxic, reactive, flammable, or explosive chemicals.
U.S. Department of Labor, Occupational Safety and Health Administration. UNDATEDd. *Regulations Relating to Labor, 29 CFR 1910, Subpart Z -- Toxic and Hazardous Substances*.	Describes the OSHA regulations for hazard communication.
U.S. Department of Labor, Occupational Safety and Health Administration. UNDATEDe. *Training Requirements in OSHA Standards and Training Guidelines*.	Describes OSHA training guidelines and requirements for general industry, maritime, construction, agricultural, and federal employees.
U.S. Department of Labor, Occupational Safety and Health Administration. 1970. *Occupational Safety and Health Act of 1970, Public Law No. 91-596.*	Describes original OSHA statute.
U.S. Department of Labor, Occupational Safety and Health Administration. 1986. *Safety & Health Guide for the Chemical Industry*.	Contains guidelines used by OSHA compliance officers to evaluate employer safety programs, particularly in the areas of disaster prevention and emergency response.
U.S. Department of Labor, Occupational Safety and Health Administration. 1989b. *Chemical Hazard Communication*.	Contains a summary of the OSHA Hazard Communication Standard.
U.S. Department of Labor, Occupational Safety and Health Administration. 1993. *Process Safety Management Guidelines for Compliance*.	Describes a systematic approach to designing a process safety management program.
U.S. Department of Transportation. UNDATED. *Hazardous Materials Transportation Regulations, 49 CFR 100 to 177.*	Lists and describes hazardous materials as well as requirements for shipping, labeling, and transporting hazardous materials.

TABLE 5-19: PUBLISHED GUIDANCE ON PROCESS SAFETY

Reference	Type of Guidance
U.S. Department of Transportation. 1994. *Emergency Response Guide.*	Lists chemicals which are health hazards and the emergency measures needed in the events of fire, explosion, injury, spills, and accidental releases.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 5-20 lists sources of process safety data.

TABLE 5-20: SOURCES OF PROCESS SAFETY DATA

Reference	Type of Data
Hazardous Chemicals Data Book. 1986.	Includes the following data on certain hazardous chemicals: chemical description, fire and explosion hazards, life hazards, personal protection needed, fire fighting measures, usual shipping containers, storage information, and special remarks regarding electrical installations and NFPA code numbers pertaining to the specified chemical.
Merck Index. 1989.	Handbook containing some caution and/or human toxicity statements for some substances.
National Fire Protection Association. 1995. *Fire Protection Guide on Hazardous Materials.*	Includes complete text of four different fire codes. Also includes chemical hazard data, quantitative health hazard rating based on recent research, and information needed on handling and storage of hazardous chemicals.
NIOSH/OSHA Pocket Guide to Chemical Hazards. 1995.	Lists known hazardous chemicals along with their health hazards, exposure limits, chemical and physical properties, incompatibilities, and suggested PPE, including recommended respirators.

TABLE 5-20: SOURCES OF PROCESS SAFETY DATA

Reference	Type of Data
Sax, N. Irving and Richard J. Lewis, Sr. 1989. *Dangerous Properties of Industrial Materials*.	A three-volume set containing hazard information. Volume I contains essays on selected topics relating to hazardous materials, a CAS RN cross-index, a synonym cross-index, and the list of CODEN bibliographic references given in the data section. Volumes II and III list and describe more than 20,000 materials in alphabetical order by entry name. Descriptions include physical and chemical properties, clinical data on experimental animals and humans, a material's hazard potential, IARC Cancer Review and the U.S. National Toxicology Program cancer testing program conclusions, OSHA PELs, ACGIH TLVs, and NIOSH RELs, DOT classifications, and Toxic and Hazardous Reviews (THRs). Fire and explosion hazards are briefly summarized.
Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment. UNDATED.	Lists TLVs for many chemicals found in the workplace.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

MARKET INFORMATION

OVERVIEW: The market information module contains economic data used to evaluate the importance of the target industry sector to the overall market for the alternatives under review, and conversely, the economic importance of the alternatives to the industry sector. Market information includes chemical/technology cost information, production and manufacturing volumes, chemical/technological use breakdowns, and an analysis of market trends that could affect future supply and demand.

GOALS:

- Evaluate the importance of the target industry sector to the overall market for the baseline and alternative chemicals and technologies.
- Compile price information for the baseline and alternatives to be used in the Cost Analysis module.
- Identify trends in the manufacturing and use of the baseline and alternatives that may influence future supply and demand.
- Compile information for the International Information module.

PEOPLE SKILLS: The following lists the types of skills or knowledge needed to complete this module.

- Knowledge of market information data sources and the capability to evaluate market trends.

Within a business or a DfE project team, the people who might supply these skills include a purchasing agent or an economist. Vendors of the chemicals or technologies may also be a good resource.

DEFINITION OF TERMS: Not applicable.

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for the Market Information module.

Step 1: Obtain chemical CAS RNs and synonyms from the Chemical Properties module.

Step 2: Using the most current data available, determine the total volumes of the chemicals and chemical products produced both in the U.S. and internationally, volumes imported and exported, volumes used by the target industry, and the names and locations of current producers (see Table 5-21: Sources of Market Information). Some of this information will have been collected in the Industry and Use Cluster Profile, but chemical use volumes may be unavailable or considered proprietary.

When data are unavailable, a project team may estimate information so that the transfer of information to other modules will occur. Appendix F gives a detailed example of how chemical volumes were estimated in the screen reclamation use cluster.

Step 3: For the baseline and/or alternative technologies and processes, identify the size of the market for the technology both in the U.S. and internationally, quantities exported and imported, quantities used by the target industry, and the names and locations of manufacturers within the U.S. and internationally.

Step 4: Transfer information on chemicals or technologies primarily supplied by manufacturers outside of the U.S. to the International Information module. Information on international trade issues, as well as source, availability, and cost data for these alternatives are compiled in the International Information module.

Step 5: Collect market price information for the baseline and alternative chemicals and technologies produced in the U.S. from the appropriate chemical or equipment vendors. Transfer market price information to the Cost Analysis module.

Step 6: Evaluate the importance of the target industry to the overall market for the baseline and alternatives in the use cluster. If the industry is a major market for an alternative (i.e., the amount of chemical produced fluctuates in response to the demand for the chemical in this industry; a technology was specifically developed and marketed for the target industry, etc.), consider evaluating the environmental impacts of upstream processes, such as the chemical manufacturing process, in the CTSA.

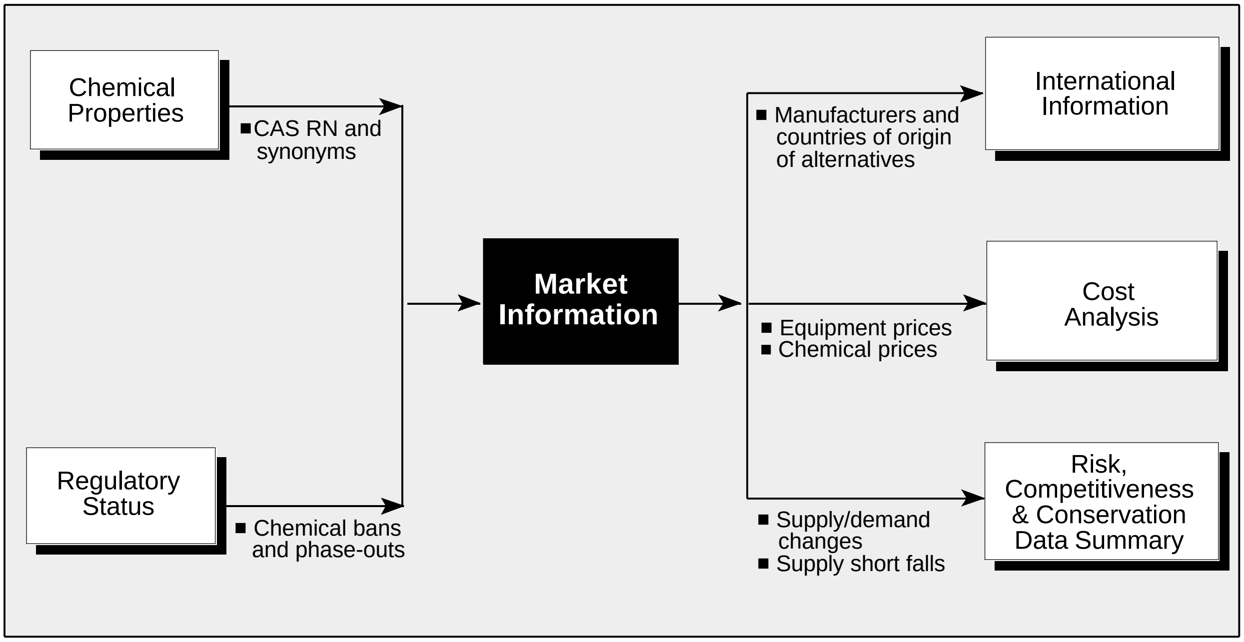
Step 7: Identify factors that could potentially affect the future supply or demand of the baseline or substitutes produced in the U.S. Possible factors include, but are not limited to:

- Proposed legislation on the manufacturing or use of a use cluster chemical, such as bans or phase-outs (see the Regulatory Status module).
- Any recent or expected improvements in technologies that could affect the future demand for a substitute in the target industry or in other industries.
- Resource or production limitations.

Step 8: Transfer any information about expected changes or shortfalls in the supply or demand for the baseline and alternative chemicals and technologies to the Risk, Competitiveness & Conservation Data Summary module.

FLOW OF INFORMATION: The Market Information module receives data from the Chemical Properties and Regulatory Status modules and transfers information to the International Information, Cost Analysis, and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 5-10.

FIGURE 5-10: MARKET INFORMATION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: None cited. EPA risk management documents (Preliminary Life-Cycle Analysis and Pollution Prevention Assessment reports) provide examples of the types of market information collected during the second phase of EPA risk management assessments.

DATA SOURCES: Table 5-21 lists sources of market information.

TABLE 5-21: SOURCES OF MARKET INFORMATION

Reference	Type of Data
Chemical Business News Data Base. Updated Periodically.	Data base containing chemical market trends.
Chemical Economics Handbook. Updated Periodically.	Chemical volume and consumption data.

TABLE 5-21: SOURCES OF MARKET INFORMATION

Reference	Type of Data
Chemical Industry Notes Data Base. Updated Periodically.	Data source for chemical industry production and trends.
Chemical Marketing Reporter. Updated Periodically.	Profiles of chemicals containing production data and market trend information.
Directory of Chemical Producers: United States Producers. Updated Periodically.	Chemical production information including manufacturers and production data.
Kirk-Othmer Encyclopedia of Chemical Technology. Updated Periodically.	Chemical production information including manufacturers and production data.
Mannsville Chemical Products Synopsis. Updated Periodically.	Chemical volume and consumption data.
Mines Data Base. Updated Periodically.	Data source for raw mineral and metal production.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

INTERNATIONAL INFORMATION

OVERVIEW: The International Information module collects data pertaining to the use or production of alternatives in other parts of the world, the impact of international trade on the selection of alternatives, and the impacts of switching to an alternative on international trade. Primarily, the international trade issues are driven by the source and availability of alternatives, and possible indirect costs (e.g., taxes, tariffs, or prohibitions) imposed on alternatives.

GOALS:

- Identify alternatives in use or attempted in other countries and the reasons for using or not using the alternatives.
- Identify the alternative chemicals and technologies in use in the U.S. that are primarily supplied by international sources.
- Identify possible trade implications concerning use of alternatives.
- Understand how trade implications impact availability and the relative social benefits/costs of alternatives.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Ability to search data bases, government agencies, trade association literature, government documents, international organizations, and trade agreements to identify alternative chemicals and technologies used in other countries and to determine the source of the alternatives.
- Knowledge of international trade regulations, agreements and treaties, and ability to determine the international trade implications of selections of particular alternatives.

Within a business or a DfE project team, the people who might supply these skills include a purchasing agent, an economist, or an attorney.

DEFINITION OF TERMS: Not applicable.

APPROACH/METHODOLOGY: The following presents a summary of the approach for collecting international data and identifying international issues that could influence the selection of a substitute. Methodology details for Steps 1, 2, and 5 follow this section.

Step 1: Identify the countries of interest that contain a large target industry sector. Service-oriented businesses such as the dry cleaning industry will most likely be present in almost all industrialized countries. Other industries, such as the printed wiring board industry, may be concentrated in certain regions of the world (i.e., in Asia, North America, etc.).

Step 2: Identify the alternatives that are being used or have been tried in the countries identified in Step 1. If these alternatives differ from those of the U.S., identify the conditions driving the choice of alternatives, such as the presence or absence of regulations. This information may be useful for planning for the future and for spotting trends, including treatment by a national government of chemicals of concern. If new alternatives are identified in this step, the project team will need to decide whether they should be quantitatively evaluated in the CTSA.

Step 3: Review the Market Information module to obtain data on the manufacturers/countries of origin of alternative chemicals, products, or technologies being evaluated in the CTSA.

Step 4: Investigate potential international sources of alternatives with particular attention to the following:

- Production capacity, the capability of producers of meeting market demand, and the stability of pricing structures.
- The price of chemicals and/or technologies supplied by foreign sources.
- Potential problems arising from reliance on foreign suppliers, including additional costs, such as taxes or tariffs, which may make imported alternatives more expensive than domestic.

Step 5: Investigate international trade regulations, agreements, and treaties for their impact on the chemicals or technologies. Examples of international trade agreements include the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA).

Step 6: Provide the price of chemicals and/or technologies primarily supplied by foreign sources to the Cost Analysis module. Market price information should reflect the suppliers price plus any additional costs, such as international taxes or tariffs or shipping costs.

Step 7: Based on the information collected in Steps 1 through 5, assess the relative social benefits and costs, including the potential indirect costs of selecting an alternative. Indirect costs of alternatives only supplied by international sources might include taxes, tariffs, or prohibitions in addition to foreign relations conflicts or loss of U.S. jobs. International bans or prohibitions on chemicals or technologies could affect a company's ability to market products made with that technology.

Alternatives that have been discontinued in some countries may have less stable pricing structures.

Step 8: Provide information on source, availability, and possible indirect costs of the alternatives to the Risk, Competitiveness & Conservation Data Summary module.

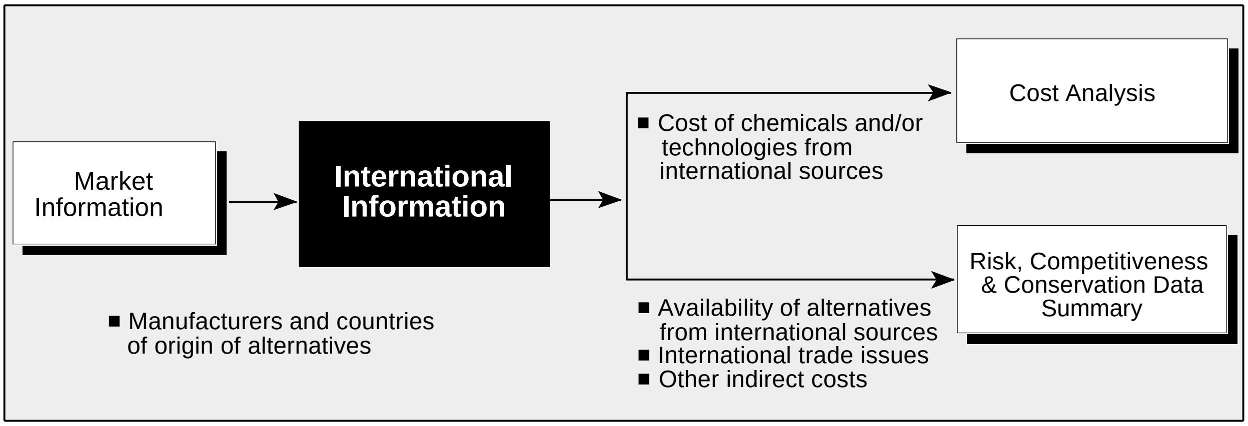
METHODOLOGY DETAILS: This section presents methodology details for completing Steps 1, 2, and 5.

Details: Steps 1, 2, and 5, Identifying Countries of Interest, Alternatives in Use, and International Trade Regulations, Treaties, or Agreements

Trade associations and chemical and equipment suppliers may be good resources for international manufacturing or market share data. Federal agencies and programs that may be able to provide information include the U.S. Department of Commerce, the U.S. Agency for International Development, the U.S. Trade and Development Program, and the U.S. Trade Representative. International organizations include the Organization of Economic Co-operation and Development, the United Nations Conference on Trade and Development, the United Nations Development Program, the United Nations Environment Program, the World Trade Organization, and the World Bank.

FLOW OF INFORMATION: The International Information module receives data from the Market Information module and transfers data to the Cost Analysis and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 5-11. If new alternatives are identified, the project team must decide whether to include them in the detailed analyses of the CTSA. If so, these alternatives must be returned to the beginning of the CTSA process.

FIGURE 5-11: INTERNATIONAL INFORMATION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: None cited.

DATA SOURCES: Table 5-22 presents references for data bases, published literature, and government contacts.

TABLE 5-22: SOURCES OF INTERNATIONAL INFORMATION

Reference	Type of Data
Brownson, Ann L., Ed. 1994. *Federal Staff Directory/1*.	Directory of federal programs, services and data bases such as the U.S. Department of Commerce Trade Data Services; U.S. Department of Commerce International Data Base, Census Information; and contacts within the U.S. International Trade Commission. Federal trade services and databases are useful for collecting international information, and for identifying addresses and telephone numbers of international organizations.
Russell, John J., Ed. 1994. *National Trade and Professional Associations of the United States*.	Directory of U.S. Trade Associations representing various industry sectors, including associations aimed at expanding international trade. (For example, the U.S. - ASEAN Council for Business and Technology strives to expand trade between the U.S. and Southeast Asia.)
U.S. Congress. 1992. *Trade and Environment: Conflict and Opportunities*.	Background paper describing the potential for conflict between trade and the environment, as reflected in disputes about the trade impacts of environmental laws and about the environmental impacts arising from efforts to liberalize trade and investment.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

Chapter 6

RISK

This chapter presents module descriptions for the risk-related component of a CTSA, including the following analytical modules:

- Workplace Practices & Source Release Assessment.
- Exposure Assessment.
- Risk Characterization.

Data from the Workplace Practices & Source Release Assessment module combine with data from the Chemical Properties and Environmental Fate Summary modules to provide the foundation for the Exposure Assessment module. Data from the Exposure Assessment module then combine with data from the Human Health Hazards Summary and Environmental Hazards Summary modules to characterize risks in the Risk Characterization module.

Data from all three of these modules flow into the final trade-off evaluations presented in Chapter 10. For example, the source and quantities of environmental releases from the Workplace Practices & Source Release Assessment module are qualitatively evaluated in the Social Benefits/Costs Assessment module for the effects of pollution on health, recreation, productivity, and other social welfare issues. The social benefits of reduced risk are considered more quantitatively using data from the Risk Characterization module.

The Exposure Assessment module provides the amounts of environmental releases that were not quantified in the Workplace Practices & Source Release Assessment module (e.g., solvent emissions from open containers that were modeled during the Exposure Assessment) to the Risk, Competitiveness & Conservation Data Summary module for evaluation with the other release data. It also provides an evaluation of the potential for exposure (e.g., high, medium, or low) by different pathways (e.g., ingestion, inhalation, dermal) to the Risk, Competitiveness & Conservation Data Summary module. Past CTSAs have used exposure levels as an indicator of the potential for risk when health and environmental hazard data are not available.

The Risk Characterization module provides human health and ecological risk data to the Risk, Competitiveness & Conservation Data Summary module for evaluation in the Social Benefits/Costs Assessment and Decision Information Summary modules. The former module considers the social benefits of reduced risk and folds these benefits into an overall evaluation of the net benefits (or costs) to society of a substitute. The Decision Information Summary module presents the risk data directly in the final trade-off evaluations where individual decision-makers consider all of the issues to choose the alternative that best fits their particular situation.

WORKPLACE PRACTICES & SOURCE RELEASE ASSESSMENT

OVERVIEW: The survey of workplace practices and source release assessment is the process of: (1) identifying and collecting data on workplace activities that may contribute to worker exposure; and (2) identifying the sources and amounts of environmental releases. The collected data are analyzed to determine the sources, nature, and quantity of both on-site releases (e.g., chemicals released to the sewer, evaporative, or fugitive emissions from the process, etc.) and off-site transfers (e.g., discharges to publicly owned treatment works).

GOALS:

- Collect workplace practices data through discussions with industry experts, review of existing information, the performance demonstration project, or the dissemination of a questionnaire to industry.
- Create a profile of a typical or model facility which can be used as the model for source release and exposure assessment calculations.
- Perform a source release assessment on the model facility to identify and characterize both on-site and off-site chemical releases and transfers.
- Provide data needed for the Exposure Assessment module which estimates possible exposure concentrations to human health and the environment.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- In-depth knowledge of the process under review, including waste streams and their point sources.
- Understanding of the concepts of material balances.
- Knowledge of the workplace activities associated with the operation of the process.
- Experience with exposure assessment guidance and methodology.
- Understanding of chemical fate, transport modeling and exposure modeling.
- Knowledge of chemistry or environmental science.
- Knowledge of surveying techniques and methodologies if a survey is utilized.

Within a business or DfE project team, the people who might supply these skills include a process engineer, a process operator or specialist, a statistician, an industrial hygienist, an environmental engineer, and a chemist or environmental scientist. Vendors of equipment or chemicals used in the process may also be a good resource.

DEFINITION OF TERMS:

Basis: The reference point chosen for the calculations made in any particular problem.

Material Balance: An accounting of the flow of material in and out of a system, derived from the generalized law that the mass of a material is conserved throughout a process. A material balance can be used to identify the sources and quantities of chemical released to the environment.

Mole: The weight of a substance, in kilograms, equal to that substance's molecular weight in atomic mass units.

Periodic Table: A list of elements in order of increasing atomic number, arranged in tabular form such that elements having similar properties appear in vertical columns.

Stoichiometry: The quantitative relationship between constituents in a chemical substance or reaction.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for collecting workplace practices data and conducting a source release assessment. Further methodology details for Steps 2, 3, 5, and 12 follow this section. Two examples of workplace practices questionnaires can be found in Appendix A.

Survey of Workplace Practices

Step 1: Obtain the unit operations and process flow diagram from the Chemistry of Use & Process Description module. The process flow diagram and unit operations provide the framework from which the workplace practices questionnaire can be generated.

Step 2: Identify the data needed to perform both the source release and exposure assessments. Information regarding industry pollution prevention practices should also be collected.

Step 3: Create a workplace practices questionnaire to obtain the information identified in Step 2 for this and subsequent modules. Existing information, such as industry literature, published studies and industry or scientific databases, should be checked and data used when applicable, to prevent the survey from becoming unduly long.

Step 4: If time and resources permit, conduct a test-run of the questionnaire by either distributing it to a small group of test facilities, or by performing site visits at selected facilities to assist them with the completion of the questionnaire. The goals of the test-run are to:

- Identify problems that may exist with the questionnaire (i.e., questions that are unclear, etc.).
- Verify that the data collected from the survey are reasonably representative and complete and that relevant data are not excluded from the results (i.e., all pertinent waste streams are included in the questionnaire, workplace practices that may contribute to worker exposure are represented, etc.).
- If site visits are performed, collect verified data that can be used as a guideline for identifying errant questionnaire data that may be collected during the survey.

Step 5: Collect industry data using the workplace practices questionnaire from the appropriate source(s). Typical sources of data include industry experts, performance demonstration sites, and/or individual industry facilities. The methods used to collect the data depend mostly on the source and include:

- Completing the questionnaire through discussions with a group of industry experts.
- Using the questionnaire as an observer data sheet to be completed during the performance demonstration (see the Performance Assessment module for more information on this process).
- Disseminating the questionnaire to a representative sample of industry facilities.

Step 6: Tabulate the data, preferably in a computer data base, so that it may be readily compared and analyzed. Data to be tabulated may include questionnaire responses, performance demonstration results, and any established data found to be relevant.

Step 7: Inspect the tabulated data for reasonableness and consistency using professional judgment. Collected data that appear unreasonable (i.e., outlying data that are inconsistent with the majority of the data) should be verified with the facility or person responsible for reporting the data point. Data generated from site visits performed in Step 4 may be used as a guide for evaluating the survey data.

Step 8: Provide a list of chemical names collected from the questionnaire data to the Chemical Properties module for comparison against the chemical substitutes list. If additional chemical substitutes are identified from the questionnaire results, they should be included in the entire CTSA process (e.g., collect chemical properties, hazard data, etc.).

Step 9: Create a profile of an average (model) facility from the tabulated data in Step 6. This is done by computing the average or other representative value of the appropriate survey data collected during the survey (i.e., number of workers employed, number of shifts operated, amount of chemical used, amount of chemical released to air, etc.). The profile will be used as the model facility for source release and exposure assessment calculations.

Source Release Assessment

Step 10: Using the data from the model facility, the process flow diagram, and the results of the site visits, identify the sources of chemical releases to the environment. The sources of some of the releases will be clearly identified in the questionnaire while others, such as open containers of volatile chemicals that result in air emissions, will have to be modeled using other data, such as chemical properties data from the Chemical Properties module, together with the workplace practices data. In a CTSA, the modeling of chemical releases or transfers that cannot be explicitly estimated from the survey data (i.e., volatization of volatile organic compounds [VOCs] from open containers, etc.) is usually done in the Exposure Assessment module.

Step 11: Characterize each of the chemical releases identified in Step 10 by determining the following attributes:

- Location of the release; on-site (i.e., fugitive or evaporative process releases to air, stack emissions, etc.) or off-site (i.e., air releases from contaminated rags that have been sent to a cleaning service, etc.).
- Media to which the release takes place (i.e., air, water, or land).
- Quantity of the release. (In some cases, such as evaporative losses of VOCs from open containers, the quantity of release will need to be estimated using mathematical models. See the Exposure Assessment module for information on models used by EPA.)
- Composition of the release (e.g., weight or volume percent), if known or reported.

Peer-Review and Data Transfer

Step 12: Verify the accuracy and consistency of the source release and exposure assessment profile created for the model facility by using any or all of the following methods:

- Perform a physical examination on one or more facilities with similar characteristics to the model facility.
- Have knowledgeable industry representatives review the profiles.

- Perform data quality checks such as checking that the reported value for the amount of chemical disposed does not exceed the amount of chemical purchased.
- Perform material balances on the model facility and check the model for reasonableness.

Step 13: Submit the survey and source release results for peer-review by industry experts. Clearly state all assumptions used in calculating the releases, as well as any sources of uncertainty.

Step 14: Provide source release and workplace practices data collected by the questionnaire to the Exposure Assessment and Pollution Prevention Opportunities Assessment modules; source release data to the Control Technologies Assessment module; chemical handling data and process operating practices to the Process Safety Assessment module; and source release data to the Risk, Competitiveness & Conservation Data Summary module.

METHODOLOGY DETAILS: This section presents the methodology details for completing Steps 2, 3, 5, and 12. If necessary, additional information on conducting a source release assessment can be found in the published guidance.

Details: Step 2, Identifying Data Requirements

An important step in the performance of both the source release and exposure assessments is the identification of the data that must be collected. Data types that are typically collected for use in this or other CTSA modules include, but are not limited to, the following:

<u>Facility and Employee Information</u>

- Total population of workers in the industry.
- Number of workers at the facility.
- Number of workers at the facility who are potentially exposed to the chemicals in the use cluster.
- Number of operating days per year.
- Number of shifts run per day.
- Number of hours per shift.
- Number of hours of worker exposure to use cluster chemicals per shift.
- Dimensions of the operating area in which chemical exposure may occur.

<u>Worker Exposure Information</u>

- Name of chemical.
- Concentration of chemical.
- Operations/activities leading to potential chemical exposure.

- Duration of potential chemical exposure.
- Frequency of potential chemical exposure.
- Personal protective equipment used.

Source Release Information

- Amount of chemical purchased per year.
- Amount of chemical used per day.
- Total chemical releases by facility per year.
- Location of release (on-site or off-site).
- Media of chemical release.
- Amount of chemical releases per site per day.
- Frequency of chemical releases.
- Duration of chemical releases.

Other Information

- Pretreatment standards and discharge permits.
- Types of in-process engineering controls used to reduce exposures.
- Types of end-of-pipe control technologies used to reduce releases and exposures.
- Types of pollution prevention practices used to reduce or prevent releases.
- Types of recycling used in waste streams or elsewhere to mitigate releases.

Details: Step 3, Creating a Workplace Practices Questionnaire

The workplace practices questionnaire is the primary tool in the CTSA process for gathering data from industry. Because the information to be collected is often case-specific, the ideal questionnaire is tailored to the selected industry, and it results from the collaborative efforts of individuals possessing the people skills listed in this module.

The required exposure and source release data may be obtained directly from the questionnaire, or indirectly through calculations using the questionnaire results, together with other information. Data should be collected and presented on a per unit production basis, or some other basis that allows a comparative evaluation of the baseline and alternatives. The workplace practices questionnaire should not be unduly lengthy, as this will influence the quality and quantity of the responses that will be received.

Details: Step 5, Disseminating the Workplace Practices Questionnaire to Industry

Surveys should be disseminated to facilities of various sizes and production levels in a manner that will ensure the confidentiality of the facilities responding. Trade associations can fulfill this role by providing a list of target facilities to participate in the survey, and by acting as an intermediate, assuring the confidentiality of those facilities that participate. Trade associations have been responsible for disseminating the questionnaires for all of the previously performed CTSAs.

Details: Step 12, Verifying Accuracy and Consistency: Material Balance Principles

A material balance is an accounting of the flows of a material into and out of a system. Performing a material balance involves the following steps:

(1) Define a system boundary around which the material balance will be calculated. The boundary of the system for the material balance can be chosen as the entire process or any portion of the process where material streams enter or leave the system. Typically, for this type of application, the entire process shown in the process flow diagram created in the Chemistry of Use & Process Description module is selected.

(2) Develop a set of material balance equations that include terms for all of the streams entering or leaving the system boundary. A material balance can be performed using a:

- Material or substance (e.g., lubricating oil, plastic pellets, etc.).
- Chemical compound (e.g., water [H_2O], hydrochloric acid [HCl], natural gas [CH_4], etc.).
- Individual chemical element (e.g., Hydrogen [H], Carbon [C], Sodium [Na], etc.).

The material balance equation states that the inputs of the material must equal the outputs of the material plus any accumulation. This condition holds true as long as there is not a chemical reaction taking place.

(3) Enter quantities for known input and output streams into the set of material balance equations. Stream data can come directly from questionnaire data that have been collected or from individual company records if the questionnaire data on a stream are inconclusive. Input stream data can be typically obtained from purchase or inventory information. Output stream data can be obtained from reported waste stream information or calculated from chemical properties together with chemical use data.

(4) Mathematically solve the set of equations for any unknown or unquantified terms that remain. Only one unknown term for each material balance equation can be quantified. Therefore, there must be at least as many different material balance equations as there are unknown streams in order to solve the equation set. If there are more unknown terms than equations, and the system boundary cannot be redrawn to correct the situation, then performing a material balance is not possible and the unknown release will have to be modeled. In cases where the equation cannot be made to balance because of inaccuracies in data, then the releases, again, will have to be modelled.

For cases in which a chemical reaction occurs within the system, a material balance must consider the rate of consumption or production of the chemical constituents (see combustion example below). The balanced chemical equation is used to determine the limiting reactant of the chemical reaction. The limiting reactant is the reactant that is consumed entirely as the chemical reaction occurs. Through the use of a properly balanced chemical equation and molar ratios, the unknown reactant and product streams can be quantified. For additional assistance with applications involving chemical reactions consult a chemical engineering text (see Published Guidance section).

Shown below are two examples of material balance equations. The first is an example of a situation where a chemical reaction is not present in the process. Finally, a typical combustion problem is used as an example of a situation involving a chemical reaction within the system boundary.

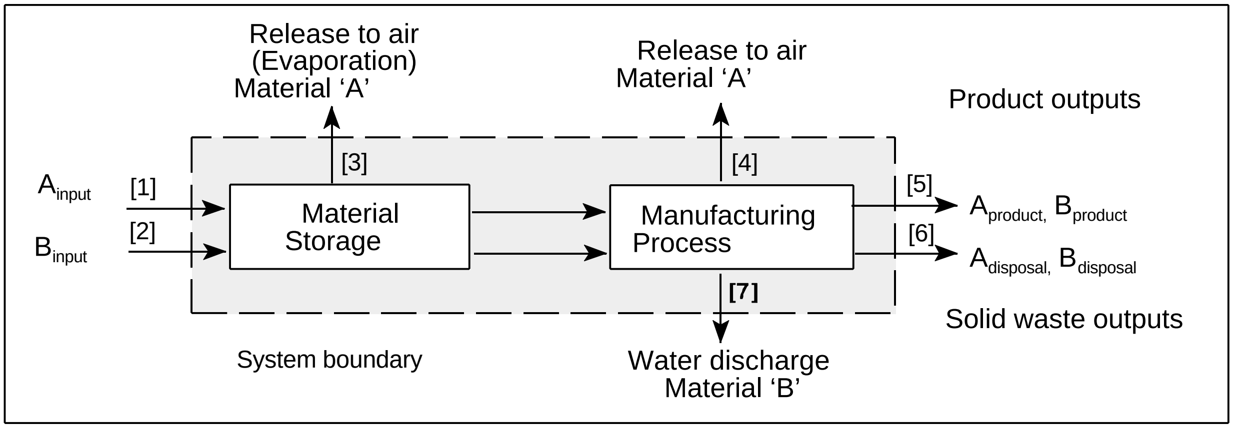
Example, Material Balance Without a Chemical Reaction Present

Figure 6-1 is an example of a material storage and component manufacturing process. The process is being run at steady-state so there is no accumulation of material within the system boundary. No chemical reaction occurs in the process.

Material Balance for Material 'A'
Mass In = Mass Out - Mass Accumulation
Mass In = Mass A_{Input} [1]
Mass Out = Mass A_{evap} [3]+ Mass A_{air} [4]+ Mass A_{prod} [5]+ Mass A_{disp} [6]
Mass A Accumulation = 0

Material Balance for Material 'B'
Mass In = Mass Out - Mass Accumulation
Mass In = Mass B_{Input} [2]
Mass Out = Mass B_{prod} [5] + Mass B_{disp} [6] + Mass B_{water} [7]
Mass B Accumulation = 0

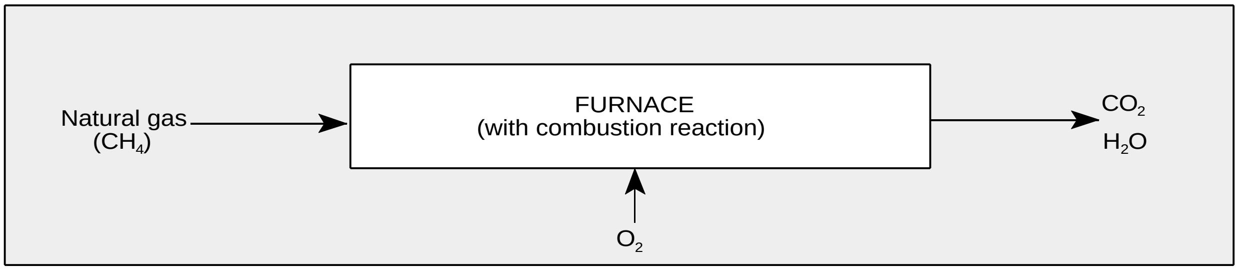
FIGURE 6-1: FLOW DIAGRAM OF MANUFACTURING PROCESS WITHOUT A CHEMICAL REACTION



Example, Chemical Reaction Present Within the System Boundary

In a material balance in which a chemical reaction is involved, the moles of a species (chemical compound) and the total moles of the reaction are not conserved. The mass balance must be made around the total mass and the mass or moles of each atomic species. In the example below, a total mass balance, and a carbon, hydrogen, and oxygen balance can be written. Figure 6-2 is an example of a furnace where the combustion of natural gas represents the reaction. The combustion of natural gas (CH_4) takes place in the presence of excess oxygen (O_2) which is typically supplied by air. Therefore, natural gas represents the limiting reactant and will be the basis for all calculations.

FIGURE 6-2: NATURAL GAS FURNACE PROCESS DIAGRAM



The combustion process is described by the following balanced chemical reaction:

Balanced Chemical Reaction: $CH_4 + 2\ O_2 \rightarrow CO_2 + 2\ H_2O$

This equation shows that for every one mole of CH_4 that reacts with two moles of O_2, one mole of carbon dioxide (CO_2) and two moles of water (H_2O) are produced. From this information, and using the basis of 100 kilograms (kg) per hour of CH_4, the following data can be calculated:

(1) Calculate the moles of natural gas (CH_4) consumed using the molecular weight for CH_4. The molecular weight can be found by consulting a periodic table and totaling the individual atomic weights of one carbon atom (C = 12) and four hydrogen atoms (H = 1).

Molecular weight of CH_4: 12 + 4 (1) = 16

Moles of CH_4: 100 kg ÷ 16 kg/mol = **6.25 moles of CH_4**

(2) Calculate the moles of reactant consumed and reaction products produced by using the molar ratios defined by the chemical equation. In this case, the equation shows that for every one mole of CH_4 consumed, two moles of O_2 are consumed, one mole of CO_2 is produced, and two moles of H_2O are produced.

Moles of CO_2 produced: moles of CH_4 = moles of CO_2
6.25 moles CH_4 = 6.25 moles CO_2
6.25 moles CO_2 produced

Moles of H_2O produced: 2 x moles of CH_4 = moles of H_2O produced
2 x 6.25 moles CH_4 = 12.5 moles H_2O produced
12.5 moles H_2O produced

Moles of O_2 reacted: 2 x moles of CH_4 = moles of O_2 reacted
2 x 6.25 moles CH_4 = 12.5 moles O_2 reacted
12.5 moles O_2 reacted

(3) Calculate the flow rates of unknown input and output streams using the molecular weights for each of remaining streams. The molecular weights for CO_2, H_2O, and O_2 were calculated using method of step 1 above. The input flow rate of oxygen is supplied by:

Molecular weights: CO_2 = 12 + 2 (16) = 44 kg/mol
H_2O = 2 (1) + 16 = 18 kg/mol
O_2 = 2 (16) = 32 kg/mol

kg of CO_2 produced: 6.25 moles CO_2 x 44 kg/mol = **275 kg CO_2**

kg of H_2O produced: 12.5 moles H_2O x 18 kg/mol = **225 kg H_2O produced**

kg of O_2 reacted: 12.5 moles O_2 x 32 kg/mol = **400 kg O_2 reacted**

(4) Calculate the input flow rate of air required to supply the needed oxygen. This quantity differs from the amount of O_2 reacted because air contains only 21 percent oxygen.

Composition of air: 21 percent Oxygen (O_2)
79 percent Nitrogen (N_2)

kg of air required: 400 kg O_2 ÷ 0.21 kg O_2/kg air = **1904.7 kg air**

(5) Verify that the mass balance calculation was performed correctly by checking that the total mass of the input streams is equivalent to the total mass of the output streams (i.e., total mass is conserved).

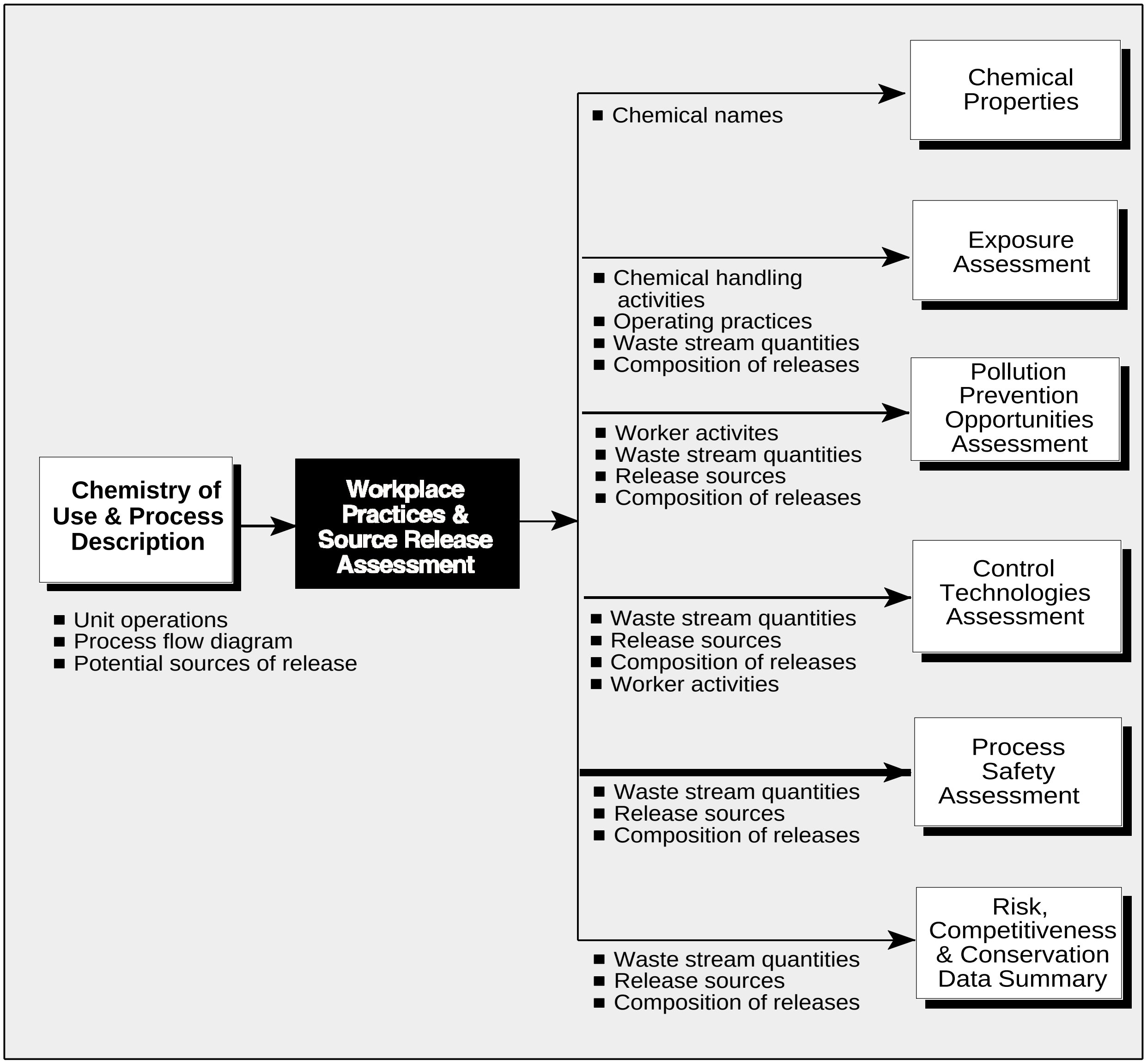
Total kg of input streams: 100 kg CH_4 + 400 kg O_2 = 500 kg input material

Total kg of output streams: 275 kg CO_2 + 225 kg H_2O = 500 kg output material

500 kg Input material = 500 kg Output material

FLOW OF INFORMATION: In a CTSA, this module receives information from the Chemistry of Use & Process Description module and transfers information to the Chemical Properties, Exposure Assessment, Pollution Prevention Opportunities Assessment, Control Technologies Assessment, Process Safety Assessment, and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 6-3.

FIGURE 6-3: WORKPLACE PRACTICES & SOURCE RELEASE ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 6-1 presents references for analytical models that can be used to perform a source release assessment.

TABLE 6-1: ANALYTICAL MODELS USED TO PERFORM A SOURCE RELEASE ASSESSMENT

Reference	Type of Model
U.S. Environmental Protection Agency. 1992b. *Strategic Waste Minimization Initiative (SWAMI) Version 2.0.*	Software tool for personal computers to aid in preparing a source release assessment.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 6-2 presents references for published guidance on source release assessments and the use of mass balances.

TABLE 6-2: PUBLISHED GUIDANCE ON SOURCE RELEASE ASSESSMENTS AND THE USE OF MASS BALANCES

Reference	Type of Guidance
Lorton, G.A., et. al. 1988. *Waste Minimization Opportunity Assessment Manual*.	Describes the EPA method for performing a source release assessment.
Luyben, William and L. Wenzel. 1988. *Chemical Process Analysis: Mass and Energy Balances*.	Describes the use of mass balances.
U.S. Environmental Protection Agency. 1987a. *Estimating Releases and Waste Treatment Efficiencies for the Toxic Chemical Release Inventory Form.*	Describes methods to determine waste streams by measurement, mass balance, or estimation.
U.S. Environmental Protection Agency. 1991e. *Chemical Engineering Branch Manual for the Preparation of Engineering Estimates.*	Describes various approaches and data sources for release estimation.
U.S. Environmental Protection Agency. 1992c. *User's Guide: Strategic Waste Minimization Initiative (SWAMI) Version 2.0.*	User's Manual for the SWAMI software package.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

EXPOSURE ASSESSMENT

OVERVIEW: An exposure assessment is the quantitative or qualitative evaluation of the contact an organism (human or environmental) may have with a chemical or physical agent, which describes the magnitude, frequency, duration, and route of contact.

GOALS:

- Estimate occupational exposure to workers.
- Estimate consumer exposure from product use (if applicable).
- Estimate exposure to humans and aquatic organisms from releases to the ambient environment.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of exposure assessment guidance and methodology, including in the context of an occupational setting.
- Understanding of chemical fate, transport modeling and exposure modeling.
- Background in chemistry and environmental science.
- Background in occupational health or industrial hygiene.

Within a business or a DfE project team, the people who might supply these skills include a chemist, environmental scientist, industrial hygienist, and/or chemical engineer.

Note: The analysis presented in this module should only be undertaken by someone with expertise in exposure assessment. Because of the complexity and multidisciplinary nature of exposure assessments, it may be necessary even for the experienced exposure assessor to seek assistance from others with expertise in certain areas of the assessment. Furthermore, peer-review of the completed exposure assessment is recommended.

DEFINITION OF TERMS:

Acute Exposure: Exposure occurring over a short period of time (e.g., 14 days or less for fish). The specific time period varies depending on the test method and test organism or the receptor of interest.

Acute Potential Dose Rate (APDR): The dose, usually expressed on a per day basis, averaged over a period of time corresponding to an acute exposure period.

Averaging Time (AT): The time period, usually expressed in units of days, over which exposure is averaged when calculating an average dose rate.

Bioconcentration Factor (BCF): The equilibrium ratio of the concentration of a chemical in an exposed organism to the concentration of the chemical in the surrounding water.

Chronic Exposure: Continuous or intermittent exposure occurring over an extended period of time, or a significant fraction of the animal's or the individual's lifetime (e.g., > 20 days for daphnids).

Contact Rate (CR): The amount of contaminated medium contacted per unit time or event (e.g., m^3 per day of air inhaled, liters per day of water ingested).

Dose: See Potential Dose Rate.

Exposure: The contact of an organism (human or environmental) with a chemical or physical agent, expressed in terms of concentration and time.

Exposure Concentration, Exposure Point Concentration: The chemical concentration, in its transport or carrier medium, at the location of contact with an organism. Also defined, typically for exological risk, as the *Expected Environmental Concentration* (EEC) or *Predicted Environmental Concentration* (PEC).

Exposure Descriptor: A term used to characterize the position an exposure estimate has in the distribution of possible exposures (e.g., high-end, central tendency) for the population of interest.

Exposure Duration (ED): The duration of exposure, typically expressed in terms of days or years.

Exposure Frequency (EF): The frequency of exposure, expressed in units of days per year, events per year, events per lifetime, etc.

Exposure Level: In general, a measure of the magnitude of exposure, or the amount of an agent available at the exchange boundaries (i.e., lungs, gastrointestinal tract, or skin), during some specified time. In the Exposure Assessment and Risk Characterization modules, "exposure level" is used specifically as a measure of exposure expressed as a concentration rather than as a potential dose rate.

Exposure Pathway: The physical course a chemical takes from the source to the organism exposed. An example of an exposure pathway might be inhalation by a worker of volatile organic compounds (VOCs) that have evaporated from a solvent to the air.

Exposure Point: The location of potential contact between an organism and a chemical or physical agent.

Exposure Route: The route by which a chemical (or physical agent) comes in contact with the body of a receptor (e.g., by inhalation, ingestion, or dermal contact).

Exposure Scenario: A description of the specific circumstances under which exposure might occur, consisting of facts, assumptions, and inferences about how exposure takes place. An exposure scenario may comprise one or more exposure pathways.

Exposure Setting: The time frame and location, including a facility and its surrounding environment, where exposure might occur.

Lifetime Average Daily Concentration (LADC): The estimated daily concentration (usually in air) during the exposure duration, averaged over a lifetime.

Lifetime Average Daily Dose (LADD): The estimated potential daily dose rate received during the exposure duration, averaged over a lifetime. LADD is typically expressed in units of mg/kg-day.

Peak Exposure Level or Dose: The maximum exposure level or maximum potential dose rate.

Potential Dose Rate (PDR): The amount of a chemical ingested, inhaled, or applied to the skin per unit time (e.g., in units of mg/day). PDR may also be expressed per unit body weight per unit time (e.g., in mg/kg-day). PDR is the amount of a chemical that is available at the body's exchange boundaries and potentially could be absorbed into the body. (Related terms used elsewhere include "intake" or simply "dose," although the term dose implies that absorption is taken into account while PDR does not. The concepts of intake, dose and potential dose are described in detail in "Guidelines for Exposure Assessment" [EPA, 1992a].)

Receptor: The organism of interest (human or non-human) involved in a particular exposure pathway.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for conducting an exposure assessment. Further details on Steps 2, 3, 5, 6, 7, 8, and 9 are presented in the next section of this module. It should be noted that this is intended as a simplified overview of the exposure assessment process, which will vary on a case-by-case basis. The reader is referred to guidance documents (see Table 6-8) for further information. The guidance documents alone, however, do not substitute for experience; professional judgement plays an important role in the exposure assessment process, as stated in "Guidelines for Exposure Assessment" (EPA, 1992a)*:*

> *"Exposure assessments are done for a variety of purposes and for that reason, cannot easily be regimented into a set format or protocol." ... "Professional judgement comes*

> *into play in virtually every aspect of the exposure assessment process, from defining the appropriate exposures scenarios, to selecting the proper environmental fate models, to determining representative environmental conditions, etc."*

With these caveats, the steps involved in exposure assessment are summarized below.

Step 1:	Identify the potentially exposed population(s), including any sensitive or highly exposed subpopulation(s). For example, populations may include workers in a facility and residents living near a facility; special subpopulations may include children, the elderly, or residents living especially close to a facility. Occupational and population exposures are evaluated separately.
Step 2:	Characterize the exposure setting. This includes characterizing the physical environment, all waste streams, and defining the exposure scenarios to be evaluated for the identified population(s). Collect information on the exposure setting from the Chemistry of Use & Process Description and the Workplace Practices & Source Release Assessment modules, and the Industry and Use Cluster Profile (see Chapter 2).
Step 3:	Based on the characterization from Step 2, evaluate any possible exposure pathways and select complete exposure pathways to evaluate. Collect information pertaining to exposure pathways from the Workplace Practices & Source Release Assessment and Environmental Fate Summary modules. The potential for population exposures should be evaluated for releases to water, releases to air, and releases to land.
Step 4:	Perform a literature search for available chemical concentration data, such as chemical concentrations in indoor air.
Step 5:	Estimate concentrations in all media where exposure could occur. (For the aquatic exposure assessment, estimate concentrations in water where exposure to aquatic organisms could occur.) Concentrations can be from measured data and/or estimated using chemical fate and transport models. Use information from the previous steps, the Industry and Use Cluster Profile, and the following modules to estimate concentrations: Chemical Properties, Environmental Fate Summary, Workplace Practices & Source Release Assessment, Performance Assessment, and Control Technologies Assessment.
Step 6:	Select values for exposure parameters used to estimate PDR for the population(s) of interest, clearly documenting the data sources and any assumptions made. Collect information pertaining to occupational exposure parameters from the Workplace Practices & Source Release Assessment module.
Step 7:	Quantify exposure either in terms of PDR or exposure level.

Step 8: Evaluate uncertainties.

Step 9: Provide exposure information to the Human Health Hazards Summary, Risk Characterization, and Risk, Competitiveness & Conservation Data Summary modules.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 2, 3, 5, 6, 7, 8, and 9. Additional information on these and other steps can be found in the previously published guidance (see Table 6-8: Published Guidance on Exposure Assessment). In addition, detailed examples of occupational exposure assessment and population exposure assessment are presented in Appendix B and C, respectively, from the Screen Reclamation CTSA (EPA, 1994c).

Details: Step 2, Characterizing the Exposure Setting

This involves characterizing the physical setting with regard to actual or potential exposure for the population(s) of interest (e.g., workers, consumers, persons exposed through releases to the ambient environment, and aquatic organisms). In a CTSA, some of this characterization is performed in other modules. An evaluation of the process flow or the unit operations involved in the use cluster is performed in the Chemistry of Use & Process Description module. The Workplace Practices & Source Release Assessment module provides information on the occupational setting and worker activities required to characterize worker population exposure (e.g., number of workers, job descriptions), the chemical release/emission points, and the quantity of chemical released for a "model" or "sample" facility, as well as the media to which the chemical is released.

Information on product use by consumers, and land use and demographic data for areas surrounding the facilities and other release points could be used to assess potential exposures to other human populations. Additional information on the location of aquatic environments might be used to assess exposure to aquatic organisms, and to humans through the food chain.

Characterizing the exposure setting leads to defining exposure scenarios to be evaluated. Some example scenarios include:

- Nearby residents using groundwater in their homes that has been contaminated by releases from a landfill.
- Consumers bringing dry-cleaned clothes into their homes, potentially exposing themselves to perchloroethylene.
- Workers in a facility using a specific piece of equipment or performing a specific process.

Many other exposure scenarios are possible, and are very case-specific. The definition of exposure scenarios leads to selection of the exposure pathways to be evaluated. An exposure scenario may comprise one or several pathways.

Example data elements that may be used to characterize the exposure setting and define the exposure scenarios are listed below, along with sources of those data.

- *Sizes for small and medium facilities:* from the Workplace Practices & Source Release Assessment module.
- *Average number of workers at a facility*: from the Workplace Practices & Source Release Assessment module.
- *Total population of workers in the industry*: from the Workplace Practices & Source Release Assessment module, the Industry and Use Cluster Profile, and other sources (e.g., industry sources, census data, National Institute for Occupational Safety and Health [NIOSH], Health Hazard Evaluations [HHE]).
- *Operations/activities in handling the chemicals*: from the Workplace Practices & Source Release Assessment module, professional judgement, and other sources (e.g., NIOSH HHE, industry sources).
- *Chemical fate in the environment*: from the Environmental Fate Summary module.

Details: Step 3, Selecting Exposure Pathways

Selection of exposure pathways involves professional judgement and is based on the characterization of the physical setting, potentially exposed populations, and exposure scenarios from Steps 1 and 2. All of the pathways considered should be documented, with reasons for selection or exclusion of each pathway. A complete exposure pathway consists of:

- A source of chemical and mechanism for release.
- An exposure point.
- A transport medium (if the exposure point differs from the source).
- An exposure route.

For example, an occupational exposure pathway in a printing shop could consist of volitization of lacquer thinner from an open container as the source and mechanism of release; a worker's breathing zone as the exposure point; air as the transport medium (transport from the container to the worker's breathing zone); and inhalation as the exposure route.

Typical exposure pathways evaluated for occupational exposure are inhalation of airborne chemicals and dermal contact. Typical exposure pathways evaluated for human exposures in the ambient environment are:

- Inhalation of chemicals in air.
- Ingestion of chemicals in drinking water, from either groundwater or surface water.
- Ingestion of fish that have been exposed to bioaccumulative chemicals. EPA's Exposure Assessment Branch generally assumes that chemicals with a BCF of > 100 will bioaccumulate. (BCF values come from the Environmental Fate Summary module.)

Other pathways are possible, and will vary on a case-by-case basis. Other possible pathways might include:

- Ingestion of mother's milk by an infant, where the mother has been exposed to the chemical(s) of interest.

- Incidental ingestion of soil by nearby residents where the soil has been contaminated by releases from a nearby facility.
- Inhalation of VOCs from household water use.

Additional data elements that may be used to select occupational exposure pathways, and sources of those data, are listed below.

- *Personal protective equipment used*: from the Workplace Practices & Source Release Assessment module, using professional judgement, and checked against other sources of information.
- *Types of engineering controls used to reduce exposures (e.g., ventilation)*: from the Workplace Practices and Source Release Assessment module, professional judgement, and other sources of information (e.g., NIOSH HHE, Material Safety Data Sheets [MSDSs]).

Details: Step 5, Estimating Concentrations

Exposure concentrations can be determined by measurements or by fate and transport models (see Table 6-7: Analytical Models Used in Exposure Assessment). Selection of fate and transport models depends in part on the available data and on the data needs for the exposure assessment. Typical data sources for exposure assessment, listed in order of preference, include:

- Actual monitoring data for the compound of interest at the location where exposure could occur.
- Monitoring data for a similar process.
- Models to estimate worker exposures and environmental releases.
- Administrative controls and permit requirements to roughly estimate exposure and/or releases.

Additional data elements that may be used to estimate exposure concentrations, and sources of those data, are listed below.

- *Chemical formulations*: from the Performance Assessment module.
- *Amount of chemical used per day*: from the Workplace Practices & Source Release Assessment module and professional judgement.
- *Media of release*: from the Workplace Practices & Source Release Assessment module and types of control technologies used to reduce releases/exposures.
- *Amount of releases per site-day*: data for waste streams that can be quantified are obtained from the Workplace Practices & Source Release Assessment module; other release rates are modeled in the exposure assessment using information on conditions for potential releases from the Workplace Practices & Source Release Assessment module.
- *Number of shifts run per day and number of operating days*: from the Workplace Practices & Source Release Assessment module.
- *Number of facilities in the industry*: from the Workplace Practices & Source Release Assessment module, the Industry and Use Cluster Profile, and other sources (e.g., industry sources, census data, NIOSH HHE).

- *Total industry releases per year*: determined from amount of releases per site-day, number of facilities in the industry, number of shifts run per day, and number of operating days.
- *Pretreatment standards and discharge permits*: from the Workplace Practices & Source Release Assessment module or other sources.
- *Types of control technologies used to reduce releases and subsequent exposures*: from the Control Technologies Assessment and Workplace Practices & Source Release Assessment modules.
- *Frequency and duration of releases*: determined from number of shifts run per day, number of operating days, and duration of potential exposures.
- *Chemical fate in the environment* (specifically, chemical/physical parameter values used for transport modeling/exposure determination): from the Chemical Properties and Environmental Fate Summary modules.

Below is an example format for documenting the point-of-contact concentrations used in the exposure assessment.

Population(s) of Interest/Pathways	Chemical	Exposure Concentration	Comments (e.g., Details, Assumptions)
Workers, inhalation of VOCs in air.	chemical *a* . . . chemical z	conc. *a* (mg/m^3) . . . conc. *z* (mg/m^3)	Concentrations estimated using a volatilization model and average measured concentrations in solution x.

Table 6-3 is an example of calculating and presenting surface water concentrations from releases to water from a single facility.

TABLE 6-3: EXAMPLE - ESTIMATED RELEASES TO WATER FROM TRADITIONAL FORMULATIONS FROM SCREEN RECLAMATION AT A SINGLE FACILITY[a]

Substance	Amount Released to Water From Facility (g/day)	Waste Water Treatment Removal Efficiency	Amount to Water After Waste Water Treatment (g/day)	Daily Stream Concentration, for 1,000 MLD Receiving Water (µg/l)[b]
Methyl ethyl ketone	363	84%	58	0.06
n-Butyl acetate	191	97%	5.7	0.006
Methanol	37	97%	1.1	0.001
Naptha, light aliphatic	257	94%	15.4	0.02
Toluene	251	92%	20	0.02
Isobutyl isobutyrate	132	98%	2.6	0.003

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) µg/l is micrograms per liter, which is parts per billion for a substance in water. MLD is million liters per day.

In some areas there may be several facilities connected to the same waste water treatment plant. The concentration in the stream would be the combined amounts of all the releases in the stream.

As an example, the combined effects of multiple screen printing facilities in St. Louis County, Missouri, were demonstrated in the Screen Reclamation CTSA. Dun and Bradstreet data showed 135 screen printing facilities in St. Louis County. It was assumed that the waste water from all of these facilities goes to the St. Louis County Sewer Company, which releases into the Meramec River. Table 6-4 presents the surface water concentrations for the combined facilities' releases.

TABLE 6-4: EXAMPLE - ESTIMATED CUMULATIVE RELEASES FOR ST. LOUIS COUNTY, MISSOURI, FROM 135 SCREEN PRINTING FACILITIES[a]

Substance	Total Amount Released to Water From All Facilities (kg/day)	Waste Water Treatment Removal Efficiency	Amount to Water After Waste Water Treatment (g/day)	Average Concentration in Meramec River, (µg/l)[b]
Methyl ethyl ketone	49	84%	7,800	1
n-Butyl acetate	26	97%	800	0.1
Methanol	5	97%	150	0.02
Naptha, light aliphatic	35	94%	2,100	0.3
Toluene	34	92%	2,700	0.3
Isobutyl isobutyrate	18	98%	360	0.04

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) µg/l is micrograms per liter, which is parts per billion for a substance in water. The mean flow of the river is 7,895 MLD (million liters per day).

Table 6-5 is an example of calculating and presenting air concentrations from releases to air.

TABLE 6-5: EXAMPLE - AIR RELEASES AND CONCENTRATIONS FROM A SINGLE MODEL SCREEN PRINTING FACILITY[a]

Substance	Amount of Releases per Day (g/day)	Highest Average Concentration at 100 Meters[b] (µg/m^3)
Methyl ethyl ketone	403	0.8
n-Butyl acetate	107	0.2
Methanol	101	0.2
Naptha, light aliphatic	222	0.4
Toluene	255	0.5
Isobutyl isobutyrate	19.7	0.04

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) This estimates air concentrations at 100 meters from a hypothetical facility. The actual number of people who would fall into this range can be determined from census data, if the facility location is known. The model used to calculate concentrations is explained in the Screen Reclamation CTSA, Overview by Media - Air Section in Appendix C.

Details: Step 6, Selecting Values for Exposure Parameters for the Population(s) of Interest

Typical required parameters include:

- Contact rate (CR) (e.g., water ingestion, inhalation, or dermal contact rates).
- Exposure frequency (EF).
- Exposure duration (ED).
- Body weight (BW).
- Averaging time (AT).

Additional data elements that may be used to determine parameter values for quantifying worker exposure are listed below, along with the appropriate sources.

- *Duration of potential exposures*: from the Workplace Practices & Source Release Assessment module.
- *Frequency of exposures*: from the Workplace Practices & Source Release Assessment module, with professional judgement required to interpret the applicability of survey information.
- *Number of shifts run per day and number of operating days:* from the Workplace Practices & Source Release Assessment module.

If data are not available, professional judgement may be used to select default parameter values. See Table 6-9: Sources of Data for Exposure Assessment, for documents containing measured or default values for exposure parameters.

Following is an example format for documenting the parameters and assumptions used in the exposure assessment.

Population/ Pathways	Parameter	Value, Units	Reference, Rationale
Workers in Ocupational Setting			
Inhalation of VOCs	inhalation rate exposure frequency exposure duration body weight averaging time	__ m^3/day __ days/year __ years __ kg __ days	Information from the Workplace Practices & Source Release Assessment module or default values from EPA guidance (e.g., EPA, 1990a; EPA, 1991f).
Adults in a Residential Setting			
Inhalation of VOCs Released from Site	inhalation rate exposure frequency exposure duration body weight averaging time	__ m^3/day __ days/year __ years __ kg __ days	Information from the Workplace Practices & Source Release Assessment module or default values from EPA guidance (e.g., EPA, 1990a; EPA, 1991f).

Note: Default values are not presented. Exposure frequency and exposure duration for workers are typically determined from the Workplace Practices & Source Release Assessment module.

Details: Step 7, Quantifying Exposure

The concentration and other parameter values selected in Steps 5 and 6 are used to quantify exposure in pathway-specific exposure equations. Equations for several pathways can be found in "Guidelines for Exposure Assessment" (EPA, 1992a), *Risk Assessment Guidance for Superfund* (EPA, 1989a), and in *Dermal Exposure Assessment: Principles and Applications* (EPA, 1992d). A generic equation for quantifying exposure is:

$$\mathrm{PDR} = (\mathrm{C})(\mathrm{CR})(\mathrm{EF})(\mathrm{ED})/[(\mathrm{BW})(\mathrm{AT})]$$

where:

PDR = potential dose rate (mg/kg-day) (LADD, APDR or other dose rate)
C = chemical concentration in exposure medium (average or peak concentration contacted during the exposure period)
CR = contact rate; the amount of contaminated medium contacted per unit time or exposure event (i.e., m^3/day of air inhaled, L/day of water ingested, etc.)
EF = exposure frequency (days/year)
ED = exposure duration (years); exposure frequency and duration may also be combined into one term, also called exposure frequency but expressed in units of days
BW = body weight; the average body weight over the exposure period (kg)
AT = averaging time; the time period, in days, over which exposure is averaged

For example:

> For a chemical concentration of 5 mg/L in water, 2 liters of water ingested per day, an exposure frequency of 365 days per year, an exposure duration of 9 years, a body weight for an adult of 70 kg, and an averaging time of 25,550 days (for a 70-year lifetime), the LADD for ingestion of drinking water is typically calculated as follows:

$$\begin{aligned}\mathrm{LADD} &= (5\ \mathrm{mg/L})(2\ \mathrm{L/day})(365\ \mathrm{days/year})(9\ \mathrm{years})/[(70\ \mathrm{kg})(25{,}550\ \mathrm{days})] \\ &= 0.018\ \mathrm{mg/kg\text{-}day}\end{aligned}$$

An acute PDR can also be calculated using an exposure frequency and duration, and an averaging time of one day:

$$\begin{aligned}\mathrm{APDR} &= (5\ \mathrm{mg/L})(2\ \mathrm{L/day})(1\ \mathrm{day})/[(70\ \mathrm{kg})(1\ \mathrm{day})] \\ &= 0.14\ \mathrm{mg/kg\text{-}day}\end{aligned}$$

An example of occupational exposure results is shown in Table 6-6.

TABLE 6-6: EXAMPLE - OCCUPATIONAL EXPOSURE ESTIMATES FOR SCREEN RECLAMATION, INK REMOVER SYSTEM[a]

Substance	Inhalation (mg/day)[b]				Dermal (mg/day)	
	I	II	III	IV	Routine	Immersion
Methyl ethyl ketone	165	5.3	3	20	468	2,180
n-Butyl acetate	44	1.3	1	5.3	234	1,090
Methanol	27	4.7	2	15	78	364
Naptha, light aliphatic	98	1.6	1	6.2	312	1,460
Toluene	110	2.3	1	9.2	312	1,460
Isobutyl isobutyrate	7	0.4	0	1.7	156	728

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) Scenario I = reclaiming 6 screens per day; each screen is approximately 2100 in^2; Scenario II = pouring 1 ounce of fluid for sampling; Scenario III = transferring chemicals from a 55 gallon drum to a 5 gallon pail; Scenario IV = storing waste rags in a drum and transferring them to a laundry.

Details: Step 8, Evaluating Uncertainties

A discussion of uncertainties in the overall risk assessment process is presented in the Risk Characterization module. Sources of uncertainty in the exposure assessment could include:

- Description of exposure setting - how well the typical facility used in the assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been evaluated, including minor ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgement.
- Uncertainty in combining pathways for an individual.

In a CTSA, uncertainty is typically addressed qualitatively. Because of the uncertainty inherent in the parameters and assumptions used in estimating exposure, and the variability that is possible within a population, there is no one number that can be used to describe exposure. Using exposure (or risk) descriptors is a method typically used to provide information about the position an exposure estimate has in the distribution of possible outcomes for a particular population. "Guidelines for Exposure Assessment" (EPA, 1992a), Habicht (1992), and others provide guidance on the use of risk descriptors, which include the following:

- *Central tendency*: represents either an *average estimate* (based on average values for the exposure parameters) or a *median estimate* (based on 50th percentile or geometric mean values) of the actual distribution.

- *High-end*: represents approximately the upper 10th percentile of the actual (measured or estimated) distribution. The high-end descriptor is a plausible estimate of individual risk for those persons at the upper end of the exposure distribution (i.e., a person exposed to an amount higher than 90 percent of the people who are exposed to the substance). It is also no higher than the individual in the population who has the highest exposure.
- *Bounding estimate*: an intentional overestimate of exposure used for screening purposes. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.
- *Worst case*: a combination of events and conditions such that, taken together, produces the highest conceivable risk.
- *What-if*: represents an exposure estimate based on postulated questions (e.g., what if the worker is exposed to the concentration predicted by a particular air dispersion model). The estimates based on these what-if scenarios do not give any indication as to the likelihood of the exposure actually occurring, but may be useful for decision-making or to add perspective to the risk assessment.

Two types of quantitative uncertainty analysis (discussed in EPA, 1990a and EPA, 1992a) are sensitivity analysis and probability analysis. Sensitivity analysis requires data on the range of exposure parameter values, and gives information on how the results are impacted by variation within the different parameters. Sensitivity analysis can be used to determine the percent contribution to the overall uncertainty and/or variability from specific exposure parameters. Probability analysis (e.g., Monte Carlo simulation) requires data on the range and probability function, or distribution, of the exposure parameters and yields a probability function that describes the range of possible results. (Although not generally recommended for a CTSA, the increasing use of Monte Carlo simulation and availability of software for performing this type of analysis warrants mention of the technique.)

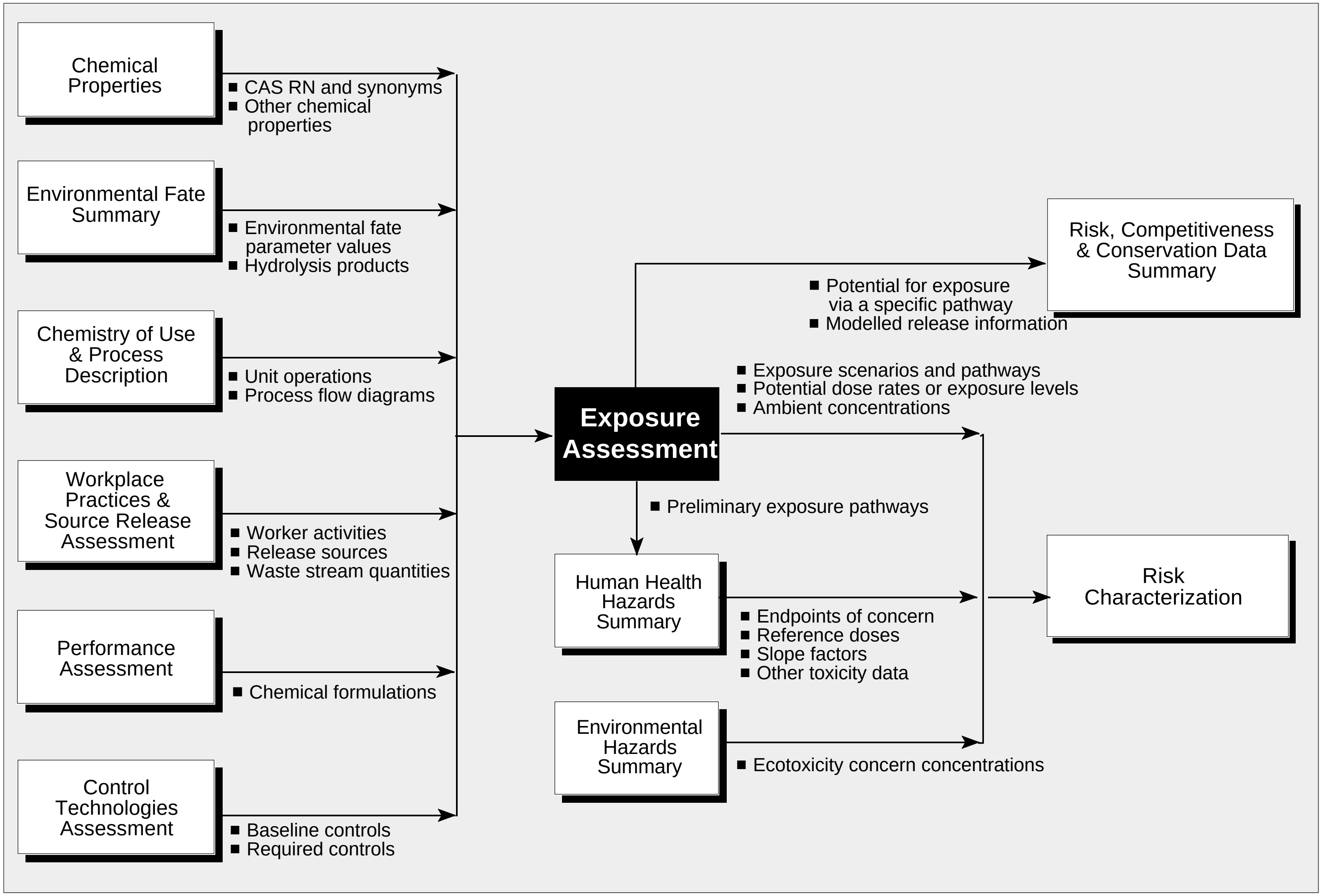
Details: Step 9, Transferring Information

Data elements that are transferred from the Exposure Assessment module are listed below:

- *Preliminary exposure pathways*: to the Human Health Hazards Summary module.
- *Exposure scenarios and pathways, ambient aquatic exposure concentrations, PDR, human exposure levels, and uncertainty information*: to the Risk Characterization module.
- *Modeled release information (i.e., releases not quantified in the Workplace Practices & Source Release Assessment module but modeled in the Exposure Assessment module instead, such as releases of VOCs from containers of solvent left open during operating hours) and potential for exposure (e.g., high, medium, low) via a particular pathway (e.g., inhalation, ingestion, dermal):* to the Risk, Competitiveness & Conservation Data Summary module.

To the extent possible, include "unit of production" information with the exposure assessment results. For example, report the square feet of printed wiring board produced during the time period corresponding to the PDR. This can be determined by multiplying ED (in years) by the production rate (in ft^2/year). This may not be possible in all cases, depending on the available data. This information is used in the Risk Characterization module to express risk on a "per unit of production" basis.

FLOW OF INFORMATION: The Exposure Assessment module receives information from the Chemical Properties, Environmental Fate Summary, Chemistry of Use & Process Description, Workplace Practices & Source Release Assessment, Performance Assessment, and Control Technologies Assessment modules. It transfers information to the Human Health Hazards Summary, Risk Characterization, and Risk, Competitiveness & Conservation Data Summary modules. Examples of information flows are shown in Figure 6-4.


Chemical Properties
■ CAS RN and synonyms
■ Other chemical properties
Environmental Fate Summary
■ Environmental fate parameter values
■ Hydrolysis products
Chemistry of Use & Process Description
■ Unit operations
■ Process flow diagrams
Workplace Practices & Source Release Assessment
■ Worker activities
■ Release sources
■ Waste stream quantities
Performance Assessment
■ Chemical formulations
Control Technologies Assessment
■ Baseline controls
■ Required controls
Exposure Assessment
Risk, Competitiveness & Conservation Data Summary
■ Potential for exposure via a specific pathway
■ Modelled release information
■ Exposure scenarios and pathways
■ Potential dose rates or exposure levels
■ Ambient concentrations
■ Preliminary exposure pathways
Human Health Hazards Summary
■ Endpoints of concern
■ Reference doses
■ Slope factors
■ Other toxicity data
Environmental Hazards Summary
■ Ecotoxicity concern concentrations
Risk Characterization

ANALYTICAL MODELS: Table 6-7 presents references for analytical models that can be used to estimate exposure concentrations. This list contains the major models used by the U.S. EPA Office of Pollution Prevention and Toxics, in the Exposure Assessment Branch, for their work, and is not all-inclusive.

Note: *Chemical fate and transport modeling is a highly technical undertaking, and should be performed only by someone with the appropriate technical background and experience with the particular models to be used. Additional sources of information on models includes the Integrated Model Evaluation System (IMES), developed by the Office of Research and Development within the U.S. EPA. IMES is currently undergoing review by EPA and is available to assist in the selection of appropriate fate models.*

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT

Reference	Type of Model
AMEM (A.D. Little Migration Estimation Model): A.D. Little, Inc. Lastest version, 1993.	Multimedia environmental fate; models migration of additives, monomers, and oligomers from polymeric material.
AT123D[a,b] (Analytical Transient One-, Two-, and Three-Dimensional Simulation model): Yeh, G.T. 1981. *AT123D: Analytical Transient One-, Two-, and Three-Dimensional Simulation of Waste Transport in an AQUIFER System.*	Groundwater model; estimates spread of contaminant plume through saturated zone, considers adsorption and degradation.
BOXMOD[a]: General Sciences Corporation. 1991a. *GEMS User's Guide.*	Air model; estimates exposure in urban areas with diffuse emissions. BOXMOD is implemented in the Graphical Exposure Modeling System (GEMS).
DERMAL: Versar, Inc. 1995a. *DERMAL User's Manual.*	Estimates consumer dermal exposure for a variety of product categories.
ENPART[a,b]: General Sciences Corporation. 1985a. *A User's Guide to Environmental Partitioning Model.*	Multimedia environmental fate model to screen for chemical partitioning in the environment.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT

Reference	Type of Model
EXAMS-II[a,b] (Exposure Analysis Modeling System): Burns, L.A., et al. 1982. *Exposure Analysis Modeling System (EXAMS) User Manual and System Documentation*. Burns, L.A., et. al. 1985. *Exposure Analysis Modeling System: User's Guide for EXAMS II*.	Surface water model; simulates fate, transport, and persistence of organic chemicals in surface water.
FLUSH: Versar, Inc. 1995b. *FLUSH User's Manual*.	Surface water model; estimates surface water concentrations from disposal of household products.
Fugacity models: For example: Mackay, D. 1993. *Multimedia Environmental Models, The Fugacity Approach*.	Multimedia fate and transport models.
GAMS[a] (GEMS Atmospheric Modeling Subsystem): General Sciences Corporation. 1990a. *Draft GAMS Version 3.0 User's Guide*.	Air exposure model; estimates average annual concentrations, LADD and risks; incorporates ISCLT and TOXBOX as the air fate and transport models.
GEMS/PCGEMS (Graphical Exposure Modeling System): General Sciences Corporation. 1988a. *PCGEMS User's Guide Release 1.0*. General Sciences Corporation. 1991b. *Graphical Exposure Modeling System, GEMS User's Guide*. Harrigan, P. and A. Battin. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in Surface Waters*. Harrigan, P. and A. Nold. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in Unsaturated Soil and Groundwater*. Harrigan, P. and S. Rheingrover. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in the Atmosphere*.	Modeling system for general population exposure assessment. Includes fate and transport models along with some relevant data needed to run those models, and where possible applies results to assess the population exposed. Includes many of the models listed below, as well as population data.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
INPUFF[a]: General Sciences Corporation. 1986. *INPUFF User's Guide*.	Air model; estimates air exposure from short term releases or continuous plume.
ISCLT[a,b] (Industrial Source Complex Long-Term), and ISCST[a] (Industrial Source Complex Short-Term): U.S. Environmental Protection Agency. 1992e. *Industrial Source Complex (ISC2) Dispersion Models User's Guide*.	Air model; ISCLT calculates average annual air concentrations and exposures. Air model; ISCST calculates short term air concentrations and exposures.
MCCEM (Multi-Chamber Concentration and Exposure Model): Geomet Technologies, Inc. 1991a. *MCCEM User's Manual, Version 2.3*. Geomet Technologies, Inc. 1991b. *MCCEM Documentation Model, Version 2.3*.	Air model; estimates consumer inhalation exposure.
PDM 3.1 (Probabilistic Dilution Model): Versar, Inc. UNDATED. *User's Guide to PDM 3.1*.	Surface water model; estimates frequency that concentration of concern is exceeded.
PRZM[a,c] (Pesticide Root Zone Model): Carsel, R.F., et. al. 1984. *Users Manual for the Pesticide Root Zone Model (PRZM) Release 1*.	Soil model; simulates vertical transport in the vadose zone, plant uptake, runoff, etc.
PTPLU[a,b] (Point Plume): General Sciences Corporation. 1988b. *User's Guide for PTPLU in GEMS*. Pierce, T.E. and D.B. Turner. 1982. *PTPLU - A Single Source Gaussian Dispersion Algorithm User's Guide*.	Air model; calculates maximum short term air concentrations.
ReachScan: Versar, Inc. 1992a. *ReachScan User's Manual*.	Surface water model; estimates downriver concentrations and exposures.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT

Reference	Type of Model
ReachScan/PDM: Versar, Inc. 1992b. *ReachScan/PDM User's Manual*.	Surface water model; combines downriver concentration estimates from REACHSCAN with the concentration of concern (COC) exceedance information from PDM.
SCIES (Screening Consumer Inhalation Exposure Software): Versar, Inc. 1994. *SCIES User's Manual, Version 3.0*.	Air model; estimates consumer inhalation exposure for a variety of product categories.
SEAS (Screening Exposure Assessment Software): U.S. Environmental Protection Agency. 1995e.	Surface water concentration estimation; simple dilution calculations from flow data. Calculates by single facility or by groupings of Standard Industrial Classifications (SICs). SIC-based stream information used to calculated mean and low flows for the industry.
SESOIL[a,b] (Seasonal Soil Compartment Model): Bonazountas, M. and J. Wagner. 1981. *SESOIL, a Seasonal Soil Compartment Model.*	Soil/vadose zone model; long-term fate simulations for organic and inorganic chemicals.
STP (Sewage Treatment Plant fugacity model): Clark, B., et al. 1995. "Fugacity Analysis and Model of Organic Chemical Fate in a Sewage Treatment Plant."	Estimates chemical fate in sewage treatment plants.
SWIP[a] (Survey Waste Injection Program): General Sciences Corporation. 1985b. *User's Guide to SWIP Model Execution Using Data Management Supporting System*. U.S. Geological Survey. UNDATEDa. "Detailed Model Description and Capabilities." U.S. Geological Survey. UNDATEDb. "Revised Documentation for the Enhanced Model."	Groundwater model; estimates chemical or thermal pollutant transport and transformation in groundwater systems.
TOXBOX[a]: General Sciences Corporation. 1990a. *Draft GAMS Version 3.0 User's Guide*.	Air model; estimates air exposure levels over large areas from diffuse sources. Available only within the GEMS Atmospheric Modeling Subsection.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
TOXSCREEN[a,b]: Hetrick, D.M. and L.M. McDowell-Boyer. 1983. *User's Manual for TOX-SCREEN: A MultiMedia Screening-Level Program for Assessing the Potential of Chemicals Released to the Environment.*	Multimedia environmental fate; models fate of chemicals released to air, water, soil, or a combination.
TRIAIR[a]: General Sciences Corporation. 1990b. *Draft TRIAIR User's Guide.*	Air model; models dose and air concentrations using TRI data and ISCLT model. Must be run by OPPT personnel.
TRIWATER: General Sciences Corporation. 1990c. *Implementation of the T.R.I. Regional Surface Water Modeling System in GEMS.* General Sciences Corporation. 1993. *Final Report, GEMS and RGDS Linkage III, EPA Contract 68-d0-0080, Work Assignment No. 3-4.*	Surface water model; estimates surface water concentrations and risks from point source releases. Must be run by OPPT personnel.
UTM-TOX[a] (Unified Transport Model for Toxicants): Browman, M.G., et. al. 1982. *Formulations of the Physicochemical Processes in the ORNL Unified Transport Model for Toxicants (UTM-TOX), Interim Report.* General Sciences Corporation. 1985c. *Characterization of Data Base Requirements for Implementation of UTM-TOX Under GEMS: Parameter Sensitivity Study.* Patterson, M.R., et. al. 1984. *A User's Manual for UTM-TOX, the Unified Transport Model.*	Multimedia environmental fate; simulates dispersion of chemicals in soil, air, and water.
Valley[a]: Burt, E. 1977. *VALLEY Model User's Guide.* General Sciences Corporation. 1989. *User's Guide for Valley in GEMS.*	Air model; estimates 24-hour average air concentrations in complex terrain.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
Other models as required; from various sources, for example: U.S. Environmental Protection Agency. 1988c. *Superfund Exposure Assessment Manual*.	

a) Model is implemented in GEMS.
b) Model is implemented in PCGEMS.
c) Model is available from other sources in a more recent version than the version implemented in GEMS.
Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 6-8 presents references for published guidance on exposure assessment. **Some of these documents may not have been published outside of EPA**.

TABLE 6-8: PUBLISHED GUIDANCE ON EXPOSURE ASSESSMENT	
Reference	**Type of Guidance**
Gilbert, R.O. 1987. *Statistical Methods for Environmental Pollution Monitoring*.	Guidance on statistical methods for summarizing and using environmental monitoring data.
Habicht, F.H. II. 1992. *Guidance on Risk Characterization for Risk Managers and Risk Assessors*.	Guidance for risk assessors on describing risk assessment results in EPA reports, presentations and decision packages; includes guidance on use of exposure descriptors.
Harrigan, P. 1994. *Guidelines for Completing the Initial Review Exposure Report*.	Information on models, assessing releases to various media, and environmental fate default values as well as guidance on assessing exposure to consumers from use of various products.
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*.	Detailed guidance for developing health risk information at Superfund sites; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1989b. *Toxic Chemical Release Inventory Risk Screening Guide*.	Guidance for risk screening for ranking and further evaluation.
U.S. Environmental Protection Agency. 1991e. *Chemical Engineering Branch Manual for the Preparation of Engineering Assessments.*	Describes various approaches and data sources for occupational exposure estimation.

TABLE 6-8: PUBLISHED GUIDANCE ON EXPOSURE ASSESSMENT

Reference	Type of Guidance
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Standard default values for exposure parameter to be used in the Superfund remedial investigation/feasibility study process; may also apply to exposure assessments in general.
U.S. Environmental Protection Agency. 1992a. "Guidelines for Exposure Assessment."	EPA guidance on exposure assessment.
U.S. Environmental Protection Agency. 1992d. *Dermal Exposure Assessment: Principles and Applications. Interim Report*.	Guidance on procedures for assessment of dermal exposure pathways.
U.S. Environmental Protection Agency. 1992f. *EPA Supplemental Guidance to RAGS: Calculating the Concentration Term.*	Calculating exposure point concentrations from environmental sample data.
U.S. Environmental Protection Agency. 1992g. *RM1/RM2 Process Manual, Version 1.0*.	Guidance for exposure assessors on performing RM1 and RM2 exposure assessments.
U.S. Environmental Protection Agency. 1994g. *Guidelines for Completing the Initial Review Exposure Report - Final Draft*.	Guidance for preparation of initial exposure assessments for substances submitted under the Pre-manufacture Notification Program.
U.S. Environmental Protection Agency. 1994h. *Guidelines for Statistical Analysis of Occupational Exposure Data*.	Guidance on using occupational exposure data.
Versar, Inc. 1988. *The Nonexposure Aspects of Risk Assessment, An Introduction for the Exposure Assessor*, Final Draft.	Guidance on interpreting results.
Wood, P. 1991. *Existing Chemical Assignment/RM1 Exposure Report*.	Information on chemical properties, production and use information, and consumer uses (if applicable).

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 6-9 lists sources of data for exposure assessment.

TABLE 6-9: SOURCES OF DATA FOR EXPOSURE ASSESSMENT

Reference	Type of Data
American Industrial Health Council. 1994. *Exposure Factors Sourcebook*.	Summary and evaluation of current scientific documentation and statistical data for various exposure factors used in risk assessments.

TABLE 6-9: SOURCES OF DATA FOR EXPOSURE ASSESSMENT

Reference	Type of Data
Chambers of Commerce.	Number of businesses of interest within a specified area.
Dun and Bradstreet, various sources.	Business census information.
Eastern Research Group, Inc. 1992. *Inventory of Exposure-Related Data Systems Sponsored by Federal Agencies*.	Description of and contacts for other sources of exposure data.
Environmental monitoring data from various sources.	Air, water, other environmental concentrations.
GEMS/PCGEMS models.	Contains census data, chemical properties for SARA Title III chemicals, and default model parameters (chemical, environmental, population, and site property data).
Industry, trade associations.	Chemical release information, controls used.
National Institute for Occupational Safety and Health (NIOSH). UNDATEDb. *Health Hazard Evaluations.*	Occupational exposure data.
Open literature.	Other exposure parameter data, other fate and transport models, etc.
U.S. Census Bureau.	Population, demographic data, some information on activity patterns (e.g., average time in a residence, average tenure for different occupations, etc.).
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A).*	Detailed guidance for developing health risk information at Superfund sites, including values for exposure parameters; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1990a. *Exposure Factors Handbook*.	Data on human physiological and behavioral parameters.
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Standard default values for exposure parameter to be used in the Superfund remedial investigation/feasibility study process; may also apply to exposure assessments in general.
U.S. Environmental Protection Agency. 1992d. *Dermal Exposure Assessment: Principles and Applications. Interim Report*.	Guidance on assessment of dermal exposure.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

RISK CHARACTERIZATION

OVERVIEW: Risk characterization (also referred to in the CTSA process as risk integration) is the integration of hazard and exposure information to quantitatively or qualitatively assess risk. Risk characterization typically includes a description of the assumptions, scientific judgments, and uncertainties that are part of this process.

The level of risk characterization necessary in a CTSA varies depending on the differences between the substitutes being assessed in the use cluster. The risk characterization identifies, in a manner that facilitates decision-making, the areas of concern as they differ among the substitutes. Risks may vary in terms of magnitude, type, or domain of application. If the differences in risk among the substitutes are great, then a detailed, quantitative characterization of risk may not be necessary. If the differences in risk associated with the substitutes are more subtle, then a quantitative analysis may be necessary. The methods outlined here describe a more detailed, quantitative risk characterization.

GOALS:

- Integrate chemical hazard and exposure information to assess and compare risks from ambient environment, consumer, and occupational exposures.
- Provide risk estimates to the Risk, Competitiveness & Conservation Data Summary module.
- Present risk information and discuss uncertainty in a manner that assists in decision-making.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of risk assessment guidance and methodology.
- Understanding of chemical exposures.
- Understanding of human, other mammalian, and aquatic toxicology.
- Ability to present and interpret the results of risk characterization for decision-making.

Within a business or a DfE project team, the people who might supply these skills include a risk assessment specialist.

Note: The analysis presented in this module should not be undertaken without the assistance of someone with expertise in human health and environmental risk assessment. Furthermore, peer-review of the completed risk characterization is recommended.

DEFINITION OF TERMS: Several terms from the Human Health Hazards Summary, Environmental Hazards Summary, and Exposure Assessment modules are used in the Risk Characterization module and are defined here as well.

Human Health Hazards Summary

Developmental Toxicity: Adverse effects produced prior to conception, during pregnancy, or during childhood. Exposure to agents affecting development can result in any one or more of the following manifestations of developmental toxicity: death, structural abnormality, growth alteration, and/or functional deficit. These manifestations encompass a wide array of adverse developmental end points, such as spontaneous abortion, stillbirths, malformations, early postnatal mortality, reduced birth weight, mental retardation, sensory loss and other adverse functional or physical changes that are manifested postnatally.

International Agency for Research on Cancer (IARC) Classification: A method for evaluating the strength of evidence supporting a potential human carcinogenicity judgment based on human data, animal data, and other supporting data. A summary of the IARC carcinogenicity classification system includes:

- Group 1: Carcinogenic to humans.
- Group 2A: Probably carcinogenic to humans.
- Group 2B: Possibly carcinogenic to humans.
- Group 3: Not classifiable as to human carcinogenicity.
- Group 4: Probably not carcinogenic to humans.

Lowest-Observed Adverse Effect Level (LOAEL): The lowest dose level in a toxicity test at which there are statistically or biologically significant increases in frequency or severity of adverse effects in the exposed population over its appropriate control group.

No-Observed Adverse Effect Level (NOAEL): The highest dose level in a toxicity test at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects in the exposed population over its appropriate control; some effects may be produced at this level, but they are not considered adverse, nor precursors to adverse effects.

Pharmacokinetics: The dynamic behavior of chemicals within biological systems. Pharmacokinetic processes include uptake, distribution, metabolism, and excretion of chemicals.

Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of the daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. RfCs are generally reported as a concentration in air (mg/m^3).

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of the daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. RfDs are reported as mg/kg-day.

Risk: In general, risk pertains to the probability and severity of adverse effects (e.g., injury, disease, or death) under specific circumstances. In the context of a CTSA, risk is an expression of the likelihood of adverse health or environmental effects from a specific level of exposure; only cancer risk is estimated as a probability. (Also see Cancer Risk, Individual Risk and Population Risk.)

Slope Factor (q_1*): A measure of an individual's excess risk or increased likelihood of developing cancer if exposed to a chemical. It is determined from the upperbound of the slope of the dose-response curve in the low-dose region of the curve. More specifically, q_1* is an approximation of the upper bound of the slope when using the linearized multistage procedure at low doses. The units of the slope factor are usually expressed as 1/(mg/kg-day) or $(\text{mg/kg-day})^{-1}$.

Unit Risk: The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water or 1 $\mu g/m^3$ in air (with units of risk per $\mu g/m^3$ air or risk per µg/L water).

Weight-of-Evidence Classification (EPA): In assessing the carcinogenic potential of a chemical, EPA classifies the chemical into one of the following groups, according to the weight-of-evidence from epidemiologic and animal studies:

- Group A: Human Carcinogen (sufficient evidence of carcinogenicity in humans).
- Group B: Probable Human Carcinogen (B1 - limited evidence of carcinogenicity in humans; B2 - sufficient evidence of carcinogenicity in animals with inadequate or lack of evidence in humans).
- Group C: Possible Human Carcinogen (limited evidence of carcinogenicity in animals and inadequate or lack of human data).
- Group D: Not Classifiable as to Human Carcinogenicity (inadequate or no evidence).
- Group E: Evidence of Noncarcinogenicity for Humans (no evidence of carcinogenicity in adequate studies).

(The "Proposed Guidelines for Carcinogen Risk Assessment" [EPA, 1996b] propose use of weight-of-evidence descriptors, such as "Likely" or "Known," "Cannot be determined," and "Not likely," in combination with a hazard narrative, to characterize a chemical's human carcinogenic potential - rather than the classification system described above.)

Environmental Hazards Summary

Aquatic Toxicity Concern Concentration (CC): The concentration of a chemical in the aquatic environment below which no significant risk to aquatic organisms is expected.

Exposure Assessment

Acute Potential Dose Rate (APDR): The dose, usually expressed on a per day basis, averaged over a period of time corresponding to an acute exposure period.

Exposure Concentration, Exposure Point Concentration: The chemical concentration, in its transport or carrier medium, at the location of contact with an organism. Also defined, typically for ecological risk, as the *Expected Environmental Concentration* (EEC), or *Predicted Environmental Concentration* (PEC).

Exposure Level: In general, a measure of the magnitude of exposure, or the amount of an agent available at the exchange boundaries (i.e., lungs, gastrointestinal tract, or skin), during some specified time. In the Exposure Assessment and Risk Characterization modules, "exposure level" is used specifically as a measure of exposure expressed as a concentration rather than as a potential dose rate.

Exposure Pathway: The physical course a chemical takes from the source to the organism exposed. An example of an exposure pathway might be inhalation by a worker of volatile organic compounds (VOCs) that have evaporated from a solvent to the air.

Exposure Scenario: A description of the specific circumstances under which exposure might occur, consisting of facts, assumptions, and inferences about how exposure takes place. An exposure scenario may comprise one or more exposure pathways.

Lifetime Average Daily Concentration (LADC): The estimated daily concentration (usually in air) during the exposure duration, averaged over a lifetime.

Lifetime Average Daily Dose (LADD): The estimated potential daily dose rate received during the exposure duration, averaged over a lifetime. LADD is typically expressed in units of mg/kg-day.

Peak Exposure Level or Dose: The maximum exposure level or maximum potential dose rate.

Potential Dose Rate (PDR): The amount of a chemical ingested, inhaled, or applied to the skin per unit time (e.g., in units of mg/day). PDR may also be expressed per unit body weight per unit time (e.g., in mg/kg-day). PDR is the amount of a chemical that is available at the body's exchange boundaries and potentially could be absorbed into the body. (Related terms used elsewhere include "intake" or simply "dose," although the term dose implies that absorption is taken into account while PDR does not. The concepts of intake, dose, and potential dose are described in detail in "Guidelines for Exposure Assessment" [EPA, 1992a].)

Receptor: The organism of interest (human or non-human) involved in a particular exposure pathway.

Risk Characterization

Cancer Risk: The probability of developing cancer over a lifetime as a result of exposure to a potential carcinogen. Cancer risk could be estimated for an individual or a population (see Individual Risk and Population Risk). The cancer risk estimated in a CTSA is the upper bound excess lifetime cancer risk.

Ecological Risk Indicator: The ratio of the exposure concentration (EEC or PEC) to the CC. In ecological risk characterization this approach is typically referred to as the ecological quotient method.

Hazard Index (HI): The sum of more than one hazard quotient for multiple chemicals and/or multiple exposure pathways. Calculation of HI assumes additivity of the chemical effects. This is valid only where the chemicals elicit the same effect by the same exposure route and mechanism of action.

Hazard Quotient (HQ): The ratio of potential rate (PDR) or exposure level for a single chemical over a specified time period to the RfD or RfC for that chemical derived from a similar exposure period.

Individual Risk: An estimate of the probability of an exposed individual experiencing an adverse effect, such as "1 in 1,000" (or 10^{-3}) risk of cancer.

Margin of Exposure (MOE): The ratio of the NOAEL or LOAEL to a PDR or exposure level.

Population Risk: An aggregate measure of the projected frequency of effects among all exposed people, such as "four cancer cases per year."

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for conducting a risk characterization. Further details for Steps 1 through 9 are presented in the next section of this module. This summary is intended as an overview of the process, and may vary on a case-by-case basis. The reader is referred to guidance documents (see Table 6-11 for further information).

Step 1: Collect and organize information from the Exposure Assessment, Human Health Hazards Summary, and Environmental Hazards Summary modules.

Human Health Risk (occupational, consumer, etc.)

Step 2: For each chemical in a pathway, calculate the indicator of cancer risk and/or noncancer risk.

- For each chemical that is classified in the hazard summary as a carcinogen, estimate cancer risk.

- For each chemical that exhibits noncancer health effects and for which an RfD or RfC is available (note: this may include chemicals that are also classified as carcinogens), calculate the indicator of noncancer risk, expressed as an HQ.
- For chemicals without a RfD or RfC, calculate the indicator of noncancer risk, expressed as a MOE.

Step 3: For multiple chemicals (e.g., exposure to a formulation made up of a mixture of chemicals), calculate total cancer risk and the noncancer HI for each pathway, using the information from Step 2.

Step 4: If applicable, and exposure is possible via more than one pathway, combine risks across pathways that affect the same individual(s) over the same time periods by summing cancer risks and summing HQs or HIs.

Step 5: If applicable, calculate population cancer risk.

Step 6: Discuss and assess sources of uncertainty and variability of risk characterization results.

Step 7: Summarize and present the risk characterization results. The chemical- and pathway-specific results from Step 2 as well as totals from Steps 3 and 4 (if applicable) and population cancer risk from Step 5 (if applicable) should all be presented. (Large tables of data may be more appropriately included as an appendix to the Risk Characterization module.)

Environmental (aquatic) Receptors

Step 8: Compare CC for each chemical to the exposure concentration (EEC or PEC). Typically, this is done for the aquatic environment. A numerical indicator of ecological risk may also be calculated as the ratio of the exposure concentration to the CC. This approach is typically referred to as the ecological quotient method.

Transfer Information

Step 9: Provide human health and environmental risk information to the Risk, Competitiveness & Conservation Data Summary module. Express risk characterization information on a "per unit of production" basis, if applicable.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 1 through 9. Additional information on these and other steps can be found in the published guidance (see Table 6-11: Published Guidance on Risk Characterization). In addition, an example of background information on risk assessment is presented in Appendix D, from the Screen Reclamation CTSA (EPA, 1994c).

Details: Step 1, Collecting and Organizing Data

Data to be provided by the Human Health Hazards Summary module include:

- Characterization of chemicals by hazard type: carcinogenicity, acute or chronic toxicity, developmental toxicity, etc.
- q_1* or unit risk, and weight-of-evidence for chemicals classified as carcinogens.
- RfD and/or RfC for chemicals that exhibit noncancer toxicity.
- LOAEL or NOAEL for chemicals where an RfD or RfC is not available.
- Pharmacokinetic data (e.g., chemical absorption factors).

Data to be provided by the Environmental Hazards Summary module include the CC.

Data to be provided by the Exposure Assessment module include:

- Outline of exposure scenarios, population(s) of interest, and pathways to be evaluated (these are described in the Exposure Assessment module).
- Potential dose rates (e.g., the PDR, LADD, and APDR).
- Exposure levels (e.g., the lifetime average exposure level, and the peak exposure level [expressed as concentrations]).
- Modeled or measured ambient environmental (water) concentrations.

Details: Step 2, Calculating Chemical Risk

Cancer Risk

For chemicals classified as carcinogens, upper bound excess lifetime cancer risk, expressed as a unitless probability, is typically estimated by the linear low-dose cancer risk equation, where:

$$\text{cancer risk} = \text{LADD} \times q_1^*$$

For example:

for an LADD of 0.3 mg/kg-day and a q_1^* of 0.02 (mg/kg-day)$^{-1}$:

$$\begin{aligned}\text{cancer risk} &= (0.3) \times (0.02) \\ &= 0.006\end{aligned}$$

This cancer risk (on an individual basis) would mean a 6 in 1,000 risk of developing cancer from exposure to this particular chemical, in addition to baseline cancer risk.

Alternatively, cancer risk can be calculated by the lifetime average exposure level (in air or water) x unit risk factor (this is a variant of the linear low-dose equation).

For example:

for a lifetime average exposure level of 0.4 µg/m^3 and a unit risk of 0.0002 (µg/m^3)$^{-1}$:

$$\begin{aligned}\text{cancer risk} &= (0.4) \times (0.0002) \\ &= 0.00008 \text{ (or } 8 \times 10^{-5}\text{)}\end{aligned}$$

For higher doses (cancer risks above approximately 0.01), this linear equation is not considered valid. In this case the results should state "risks are above 0.01 but cannot be estimated more exactly." Cancer risk numbers are typically presented to one significant figure.

Noncancer Risk

For chemicals that exhibit noncancer toxicity, an HQ is calculated by:

$$HQ = PDR / RfD$$

For example:

for a PDR of 0.4 mg/kg-day and an RfD of 0.05 mg/kg-day:

$$HQ = (0.4) / (0.05)$$
$$= 8$$

Chemicals that exhibit developmental toxicity are evaluated separately, using an RfD for developmental effects (RfD_{DT}). Short-term exposure can be of concern for developmental effects (because of the window of fetal vulnerability) so a peak exposure is used rather than a PDR for the entire duration of exposure:

$$HQ_{DT} = \text{peak exposure} / RfD_{DT}$$

Alternatively, if an RfC (typically for air) or RfC for developmental effects (RfC_{DT}) and corresponding exposure level is available, the HQ can be calculated by:

$$HQ = \text{lifetime average exposure level} / RfC$$

or:

$$HQ_{DT} = \text{peak exposure level} / RfC_{DT}$$

HQs (non-developmental) are typically calculated for long-term (chronic) exposure periods. They can also be calculated for subchronic or acute (shorter-term) exposure periods if subchronic or acute RfD (or RfC) and dose rates (or exposure levels) are determined in the Human Health Hazards Summary and Exposure Assessment modules. It is important to keep the exposure durations consistent; for example, subchronic RfDs combined with subchronic dose rates.

The HQ is based on the assumption that there is a level of exposure (i.e., the RfD) below which it is unlikely, even for sensitive subgroups, to experience adverse health effects. Unlike cancer risk, the HQ does not express *probability* (only the ratio of the estimated dose to the RfD or RfC) and it is not linear; i.e., an HQ of 10 does not mean that adverse health effects are 10 times more likely to occur than for an HQ of 1.

For chemicals where an RfD or RfC is not available, MOE is calculated by:

$$MOE = NOAEL / PDR \quad \text{or} \quad LOAEL / PDR$$

Alternatively, MOE can be calculated with an exposure level rather than a dose rate:

MOE = NOAEL or LOAEL / lifetime average exposure level

As with the HQ, the MOE is not a probabilistic statement of risk. Very high MOE values, such as values greater than 100 for a NOAEL-based MOE or 1,000 for a LOAEL-based MOE, imply a very low level of concern. As the MOE decreases, the level of concern increases.

Details: Step 3, Calculating Pathway Risk for Multiple Chemicals

For pathways where exposure to more than one chemical is being assessed, the cancer risk results for each chemical are typically summed for each pathway:

$$\text{cancer risk}_{TOT} = \Sigma \text{ cancer risk for each chemical}$$

It should be noted that summing cancer risks assumes additivity of the chemical effects. Risks from exposures to more than one carcinogen are typically assumed to be additive, unless available information suggests otherwise.

The HQs can also be summed to calculate an HI:

$$\text{HI} = \Sigma \text{ HQ for each chemical}$$

Alternatively, HI can be calculated by:

$$\text{HI} = \text{PDR}_1/\text{RfD}_1 + \text{PDR}_2/\text{RfD}_2 + \ldots + \text{PDR}_i/\text{RfD}_i$$

Calculation of an HI also assumes additivity of the chemical effects. This is valid only where the chemicals elicit the same effect by the same mechanism of action. Typically, if an HI exceeds unity, the chemicals are segregated by effect and mechanism and segregated HIs recalculated. This segregation by mechanism of action and type of effect is not a simple exercise and should only be performed by an experienced toxicologist.

Details: Step 4, Summing Pathway Risks, if Applicable

In some situations, a receptor may be exposed to a chemical, or a mixture of chemicals, through more than one pathway (for example, a worker may be inhaling volatile chemicals from a solution and at the same time be exposed through the skin). In this case the total risk is equal to the risks from all relevant pathways. Cancer risks can be summed across pathways, where:

$$\text{total exposure cancer risk} = \text{cancer risk (pathway}_1\text{)} + \text{cancer risk (pathway}_2\text{)} + \ldots \text{ cancer risk (pathway}_i\text{)}$$

HI should be summed separately for different exposure durations (e.g., chronic, subchronic, shorter term durations); an HI for multiple pathways and similar exposure durations can be calculated by:

$$\text{total exposure HI} = \text{HI}(\text{pathway}_1) + \text{HI}(\text{pathway}_2) + \ldots \text{HI}(\text{pathway}_i)$$

Results are typically presented for each pathway separately (Step 3) as well as combined across pathways.

Details: Step 5, Calculating Population Cancer Risk, if Applicable

Cancer risks may be characterized in terms of individual or population risk. Risk to a population is typically calculated by:

$$\text{cancer risk} = \text{individual cancer risk} \times \text{number in exposed population}$$

Population risks may also be calculated separately for areas with different levels of exposure. Population data sources may include the number in the exposed population from the Exposure Assessment module, census data, or other demographic data or work place surveys.

Details: Step 6, Assessing Uncertainty and Variability

Because information for risk characterization comes from the Environmental Hazards Summary, Human Health Hazards Summary, and Exposure Assessment modules, an assessment of uncertainty should include those uncertainties in the hazard and exposure data. There is also the issue of compounded uncertainty; as uncertain data are combined in the assessment, uncertainties may be magnified in the process. EPA guidance (e.g., *Risk Assessment Guidance for Superfund* [EPA, 1989a]; "Guidelines for Exposure Assessment" [EPA, 1992a]) contains detailed descriptions of uncertainty assessment, and the reader is referred to these for further information.

Uncertainties in the hazard data could include:

- Uncertainties from use of quantitative structure-activity relationships (QSARs) for aquatic toxicity.
- Using dose-response data from high dose studies to predict effects that may occur at low levels.
- Using data from short-term studies to predict the effects of long-term exposures.
- Using dose-response data from laboratory animals to predict effects in humans.
- Using data from homogeneous populations of laboratory animals or healthy human populations to predict the effects on the general human population, with a wide range of sensitivities.
- Assuming 100 percent absorption of a dose when the actual absorption rate may be significantly lower.
- Using toxicological potency factors from studies with a different route of exposure than the one under evaluation.

- Effects of chemical mixtures (effects may be independent, additive, synergistic or antagonistic).
- Possible effects of substances not included because of a lack of toxicity data.
- Carcinogen weight-of-evidence classifications; for any chemicals assessed as carcinogens (described in the Human Health Hazards Summary module), the weight-of-evidence classification should be presented with any cancer risk results.

Uncertainties in the exposure data could include:

- Description of exposure setting - how well the typical facility used in the exposure assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been included because they are minor or proprietary ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgment.
- Uncertainty in combining pathways for an individual.

In the CTSA, uncertainty is typically addressed qualitatively. Variability in the exposure assessment is typically addressed through the use of "exposure descriptors," which are discussed in the Exposure Assessment module.

Details: Step 7, Summarizing and Presenting Results

The risk characterization results are typically presented in tables, with the cancer risk, HQ and/or HI, and MOE calculated for each chemical. The results are also explained and summarized in the text along with the tables. The actual format of the tables can vary greatly, depending on the complexity of the analysis (the number of chemicals, scenarios, and pathways being assessed). A typical format is shown in Table 6-10.

TABLE 6-10: TYPICAL FORMAT FOR RISK CHARACTERIZATION RESULTS			
(e.g., Dermal Contact with Solution X in Occupational Setting Performing Task Y)			
Chemical	**Cancer Risk [weight-of-evidence classification]**	**HQ**	**MOE**
chemical *a* . . . **chemical *z***	result for *a* [B2] . . . result for *z* [B1]	result for *a* . . . result for *z*	result for *a* . . . result for *z*
sum of cancer risk, or HI, for pathway:	sum of cancer risks	sum of HQs (when appropriate)	(not summed)

Details: Step 8, Comparing CC to Aquatic Concentrations

Exposure concentrations below the CC are assumed to present low risk to aquatic species. Exposures that exceed the Cc indicate a potential for adverse impact on aquatic species. The level of concern increases as the ratio of exposure concentration to CC increases.

An ecological risk indicator may be calculated as a unitless ratio, for example:

> With a daily stream concentration of 2 mg/l and a CC of 1 mg/l, the ecological risk indicator = (2) / (1) = 2

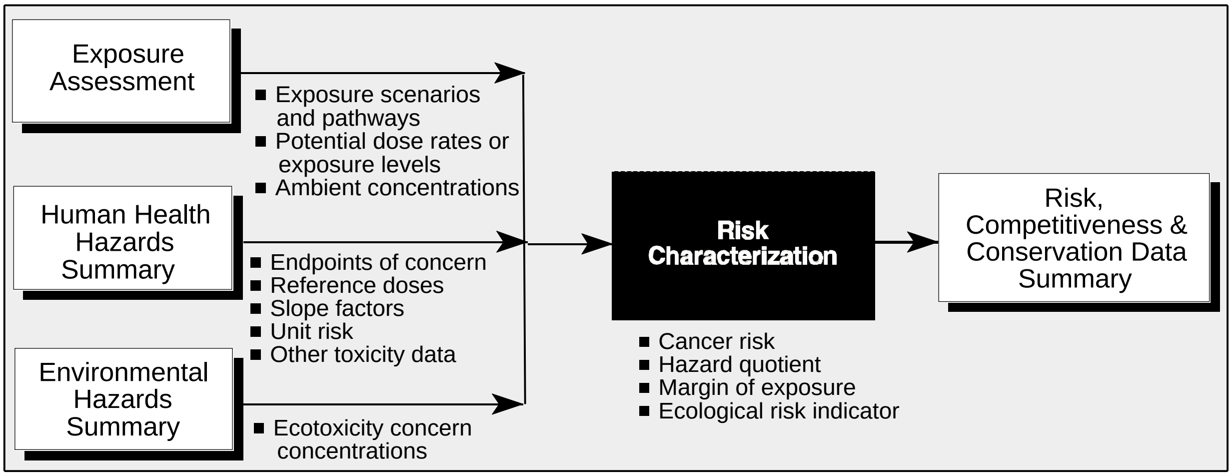
An ecological risk indicator greater than 1 indicates that the estimated or measured chemical concentration exceeds the concentration of concern for the aquatic environment based on chemical toxicity to aquatic organisms. The greater the number of days the CC is exceeded, the greater the potential risk.

Details: Step 9, Expressing Risk on a "Per Unit of Production" Basis

Where possible, also express risk characterization results on a "per unit of production" basis using an amount that is produced during the corresponding exposure period. For example, cancer risk can be expressed as risk/amount produced. This information will facilitate evaluating tradeoffs among alternatives in the Social Benefits/Costs Assessment and Risk, Competitiveness & Conservation Data Summary modules.

FLOW OF INFORMATION: The Risk Characterization module receives information from the Exposure Assessment, Human Health Hazards Summary, and Environmental Hazards Summary modules and transfers information to the Risk, Competitiveness & Conservation Data Summary module. Examples of information flows are shown in Figure 6-5.

FIGURE 6-5: RISK CHARACTERIZATION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 6-11 presents references for published guidance on risk characterization.

TABLE 6-11: PUBLISHED GUIDANCE ON RISK CHARACTERIZATION

Reference	Type of Guidance
Barnes, D.G. and M. Dourson. 1988. "Reference Dose (RfD): Description and Uses in Health Risk Assessments."	EPA's principal approach to assessing risk for health effects, other than cancer and gene mutations, from chronic chemical exposure.
Habicht, F.H. II. 1992. *Guidance on Risk Characterization for Risk Managers and Risk Assessors.*	Guidance for managers and assessors on describing risk assessment results in EPA reports, presentations, and decision packages with respect to reliability and uncertainty of the results of risk characterization.
Nabholz, J.V. 1991. "Environmental Hazard and Risk Assessment Under the United States Toxic Substances Control Act."	Discussion of environmental risk assessment procedures (as practiced under TSCA).
Nabholz, J.V., et. al. 1993a. "Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five."	Discussion of environmental risk assessment procedures (as practiced under TSCA).
U.S. Environmental Protection Agency. 1987b. *The Risk Assessment Guidelines of 1986*.	Guidance on risk assessment methods; includes *Guidelines for Mutagenicity Risk Assessment, Guidelines for Carcinogen Risk Assessment*, and *Guidelines for the Health Risk Assessment of Chemical Mixtures*, originally published in the September 24, 1986 *Federal Register*, FR 51(185).
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*.	Detailed guidance for developing health risk information at Superfund sites; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1990a. *Exposure Factors Handbook*.	Data related to exposure frequency and duration, and other human physiological and activity parameters.
U.S. Environmental Protection Agency. 1991b. "Guidelines for Developmental Toxicity Risk Assessment."	Guidance on assessing developmental toxicity risks; a revision of the *Guidelines for the Health Risk Assessment of Suspect Developmental Toxicants*, FR 51(185), September 24, 1986.

TABLE 6-11: PUBLISHED GUIDANCE ON RISK CHARACTERIZATION	
Reference	**Type of Guidance**
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Exposure factors guidance to be used in the Superfund remedial investigation/feasibility study process.
U.S. Environmental Protection Agency. 1992a. "Guidelines for Exposure Assessment."	EPA guidance on exposure assessment; assessing uncertainty and variability in exposure data.
U.S. Environmental Protection Agency. 1994i. *Guidelines for Reproductive Toxicity Assessment.*	Guidance on assessing reproductive toxicity risks.
U.S. Environmental Protection Agency. 1994j. *Pesticide Occupational and Residential Cancer Risk Policy Statement*.	EPA's risk management policy with regard to occupational and residential (not dietary) cancer risks resulting from the use of pesticides. (Reflects Assistant Administrator's policy direction on risk which may be applicable to OPPT programs.)
U.S. Environmental Protection Agency. 1994k. "Final Report: Principles of Neurotoxicity Risk Assessment."	Guidance on assessing neurotoxic risks.
U.S. Environmental Protection Agency. 1994l. *OPPT Risk Assessment SOPs.*	A collection of guidance documents on various EPA exposure and risk characterization procedures.
U.S. Environmental Protection Agency. 1996b. "Proposed Guidelines for Carcinogen Risk Assessment."	Guidance on assessing carcinogenic risks; a revision of the *Guidelines for Carcinogen Risk Assessment,* FR 51(185), September 24, 1986.
Zeeman, M.G. 1995a. "EPA's Framework for Ecological Effects Assessment."	Provides an overview of the process used in the environmental toxicity assessment of chemicals
Zeeman, M.G. 1995b. "Ecotoxicity Testing and Estimation Methods Developed under Section 5 of the Toxic Substances Control Act (TSCA)."	Describes the developoment, validation, and application of SARs in the EPA OPPT.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Hazard and exposure data are provided by the Human Health Hazards Summary, Environmental Hazards Summary, and Exposure Assessment modules.

Chapter 7

COMPETITIVENESS

This chapter presents module descriptions for the competitiveness component of a CTSA, including the following modules:

- Regulatory Status.
- Performance Assessment.
- Cost Analysis.

Each of these modules provides information on basic issues traditionally important to the competitiveness of a business: its need or ability to comply with environmental regulations; the performance characteristics of its products relative to industry standards; and the direct and indirect costs of manufacturing its products. A CTSA weighs these traditional competitiveness issues against a new generation of competitiveness issues: the health and environmental impacts of alternative products, processes, and technologies.

Data from all three of these modules are considered in the Social Benefits/Costs Assessment and Decision Information Summary modules along with risk data, conservation issues, and other information. In addition, the Regulatory Status and Performance Assessment modules transfer data to other modules of a CTSA. For example, the Regulatory Status module determines if control technologies are required for a particular alternative and transfers that information to the Control Technologies Assessment module.

The Performance Assessment module is one of the most important data gathering modules of a CTSA. A DfE project team typically conducts a performance demonstration project during this module where performance data are collected together with data on capital, operating, and maintenance costs; energy and other resource consumption rates; waste generation rates; and worker exposure (particularly for new or novel alternatives not evaluated in the Workplace Practices & Source Release Assessment module). These data are then transferred to the appropriate modules. For example, cost data from the Performance Assessment module can be used to perform a comparative cost analysis of alternatives in the Cost Analysis module.

REGULATORY STATUS

OVERVIEW: The Regulatory Status module determines the statutes and regulations that govern the chemicals and industrial processes in the use cluster. Although federal environmental regulations are typically assessed in a CTSA, this module also provides guidance in conducting searches of other Federal regulations and state and local regulations that may be pertinent to the use cluster being assessed or the group performing the evaluation.

GOALS:

- Determine the pertinent laws and regulations, including those governing use and release to the workplace or environment, affecting the chemicals, processes, and technologies in the use cluster or the use cluster industry.

- Assist in the evaluation of economic and social costs and benefits of the use of a particular chemical, process, or technology by determining the regulatory requirements that lead to costs of compliance (such as treatment costs, permit costs, and reporting costs) and public disclosure of environmental information, possibly affecting public relations.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Ability to identify laws and regulations affecting the chemicals and technologies in the use cluster or the target industry, including environmental, consumer product safety, and occupational safety and health laws and regulations.

- Ability to do legal research and search legal data bases.

- Legal expertise required to interpret laws and regulations and their application in a particular jurisdiction or particular situation.

Within a business or DFE project team the people who might supply these skills include environmental compliance managers and corporate attorneys, particularly those specializing in environmental compliance. Environmental consultants and law firms can also provide the skills and knowledge necessary.

DEFINITION OF TERMS:

Code of Federal Regulations (CFR): The official codification of federal regulations that were originally published in the daily *Federal Register*. *Citation note:* In a citation to the CFR (e.g., 40 CFR 129), the first number is the number of the title on a particular topic (Title 40 covers "Protection of Environment"), and the second number indicates the "part" or the section number (part 129 regulates "Toxic Pollutant Effluent Standards"). *Updating:* If the CFR part or section has been repealed or amended, the List of CFR Sections Affected (LSA) will provide a citation for the current material in the *Federal Register*.

Federal Register (Fed. Reg.): A daily publication of proposed and final federal regulations. *Citation note:* In a citation to the *Fed. Reg.*, the first number indicates the volume and the second number indicates the page. A complete citation also includes the date of publication. For example, 60 *Fed. Reg*. 5320 (Jan. 27, 1995) is Volume 60, page 5320, published on January 27, 1995.

Regulation: A rule or order having the force of law issued by the executive branch of government (e.g., by a federal administrative agency) to implement a statute.

Statute: A law enacted by the legislative department of government, whether federal, state, city, or county.

United States Code (U.S.C.): The official text of federal statutes. *Citation note:* In a citation to the Code (e.g., 49 U.S.C. 1261), the first number is the number of the title for a particular topic (Title 49 covers "Transportation"), and the second number is the section number of the statute. The United States Code Annotated (U.S.C.A.) and the United States Code Service (U.S.C.S.) follow the same numbering system and include annotations to federal regulations implementing the particular Code section. *Updating:* All of these texts are updated regularly by pocket parts at the end of each volume and/or supplementary volumes.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for identifying regulations affecting substitute chemicals, processes, or technologies. Further methodology details for Steps 2, 3, and 4 follow this Section.

Step 1: Obtain chemical identities including CAS RNs and synonyms from the Chemical Properties module. Identify the industry sector and specific process type (e.g., printing - lithographic) from the Chemistry of Use & Process Description module.

Step 2: Search secondary materials to preliminarily determine the statutes and regulations that apply to a particular chemical, process, or technology.

Step 3: Review federal statutes by reviewing codifications (e.g., *United States Code*) or looseleaf services (e.g., *Environment Reporter*).

Step 4: Review the federal regulations by original publication, codification, looseleaf service, or computer data base.

Step 5: Search case law for court interpretations of federal statues and regulations. In order to perform a thorough and comprehensive regulatory analysis, if time and resources permit, an environmental attorney, qualified law student, or paralegal should conduct an up-to-date search of case law from the federal courts to determine if there have been any court interpretations of statutes and regulations applicable to the chemical, process, or technology, and to determine the status of challenged regulations. Official case reporters can be used, such as *U.S. Reports*, or unofficial reporters, such as *United States Law Week*, *Supreme Court Reports*, *Federal Reporter*, and *Federal Supplements*. Other sources include *Environment Reporter Cases* and WESTLAW® or LEXIS® computer data bases.

Step 6: Review state statutes, regulations, and case law. Most states are administering federal environmental and occupational health and safety regulatory programs with federal approval and may have stricter and/or different requirements than federal statutes and regulations. Therefore, for a specific facility location it may be desirable to research state law as part of the regulatory analysis. In addition to official codifications of the state statues and regulations that may be available in a major law library, the *Environment Reporter* is a valuable resource for locating state environmental statutes and regulations. For completeness, state court decisions should also be reviewed for interpretations of state statutes and regulations. State statutes and case law can also be searched using WESTLAW® or LEXIS® computer data bases.

Step 7: Review local statutes and regulations. In some states, local governments also administer environmental statutes and regulations and may have different and stricter requirements than federal and state statutes and regulations. For a specific location, it may be desirable to review these local requirements, which can be obtained by consulting the local government, by visiting a local law library, or by consulting a local industrial development office which may have special packets concerning local regulations. For completeness, state court decisions should be reviewed for interpretation of local statutes and regulations.

Step 8: Provide the results of the search to the Risk, Competitiveness & Conservation Data Summary module. If a control technology would be required for one of the substitute chemicals in the application being evaluated, provide these requirements to the Control Technologies Assessment module. Additional regulatory information, such as specific disposal requirements, should be provided to the Regulatory Status module. If a chemical is planned for a ban or phase-out, provide this information to the Market Information module.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 2, 3, and 4. If necessary, additional information on these and other steps can be found in the published guidance.

Details: Step 2, Searching Secondary Sources

There are several commercial sources that can be used to preliminarily determine the statutes and regulations that apply to a particular chemical. *These sources will provide only a brief summary of the major regulations governing a chemical, however. They are not official sources and are not updated as often as the federal regulations. Even sources that are updated frequently (e.g., by supplements or a looseleaf service) cannot be relied upon as authoritative law.*

Examples of secondary sources include:

- EPA *Registry of Lists*: A data base of federal regulations applicable to specific chemicals that can be searched by chemical. It is maintained and updated by EPA for its own use and is not generally available to the public.
- The *Suspect Chemicals Sourcebook*: This reference shows what regulations apply to any given chemical. It directs the researcher to a Source List (e.g., Clean Water Act Section 311) which provides capsule descriptions of each chemical and complete chemical listings for each regulation. In many cases, the original regulation is reprinted (e.g., from the *Code of Federal Regulations* or the *Federal Register*).
- *Law of Chemical Regulation and Hazardous Waste*: This source is a legal treatise with an update service that keeps it fairly current. It analyzes not only environmental laws, but also occupational safety and health regulations, food additive regulations, and consumer product regulations with footnotes to key statutory and regulatory texts. Since it is not organized by chemical name, there is no simple way to find all the regulations governing a particular chemical. The treatise is organized by broader topic, such as "Regulation of the Generation, Transportation, Storage, and Disposal of Hazardous Waste."
- Regulatory Profiles: Profiles developed by EPA listing pertinent environmental regulations affecting specific industries. See the section on data sources for examples of EPA regulatory profiles that are currently available.
- Topical Material: Treatises and looseleaf services exist for specific federal statutes. See the section on data sources for some examples of guides to the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Toxic Substances Control Act (TSCA). These can be searched for applicability to the chemicals of interest.

Details: Steps 3 and 4, Searching Federal Statutes and Regulations

Identifying Applicable Statutes and Regulations

Federal statutes that may apply include laws governing releases of pollutants to air, land, or water, as well as laws governing the shipment of hazardous materials, the safety of consumer products containing hazardous chemical ingredients, and the exposure of workers to chemicals in the workplace. The discussion that follows identifies some of the key provisions of several federal statutes. It does not attempt an in-depth analysis nor does it list all the provisions that may apply.

The Clean Air Act (CAA) (42 U.S.C. 7401-7671q): Governs emissions of air pollutants to the environment. In addition to the *Code of Federal Regulations*, federal air regulations can be located easily in the *Environment Reporter (ER) Federal Regulations Binders*. Examples of key provisions include:

- National Ambient Air Quality Standards (NAAQS): EPA has established NAAQS for six criteria pollutants:
  (1) Sulfur dioxide (SO_2).
  (2) Nitrogen dioxide (NO_2).
  (3) Carbon monoxide (CO).
  (4) Ozone.
  (5) Lead.
  (6) Particulate matter (PM-10).
- Hazardous Air Pollutants (HAPs): The National Emissions Standards for Hazardous Air Pollutants (NESHAPs) control 189 pollutants listed at 42 U.S.C. 7412. The regulatory standards for these substances are spelled out at 40 CFR 61. Sources must also prepare and implement risk management plans with the Chemical Safety and Hazard Investigation Board.
- State Implementation Plans (SIPs): The states are authorized to establish programs for implementing the CAA. Regulations for each SIP can be found at 40 CFR 52. These can also be found in the *ER Federal Regulations Binder* at Tab 125.
- Chlorofluorocarbons (CFCs) or halons will be phased-out under Title VI of the CAA Amendments, at 42 U.S.C. 7671.

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9601-9675): Governs the cleanup of sites where hazardous substances have been released or disposed. Examples of key provisions include:

- A list of "hazardous substances" (see 42 U.S.C. 9601 for definition; see 40 CFR 302.4 for list of chemicals).
- Reportable Quantity (RQ) for releases of chemicals (see 40 CFR 302.4). If there is a release of the substance greater than the RQ, any person in charge of the facility must notify the National Response Center.

T**he Clean Water Act (CWA)** (33 U.S.C. 1251-1387): Governs the discharge of pollutants to United States waters, but does not cover ground water. Federal water pollution regulations can be found in the *ER Federal Regulations Binder* and the *Code of Federal Regulations*. Examples of key provisions include:

- The National Pollutant Discharge Elimination System (NPDES). NPDES permits are needed for point source discharges into surface waters (see 33 U.S.C. 1342 & 40 CFR 122.2). Permits include limits on discharge of specific chemicals as required by regulations for specific industry categories.
- "Priority pollutants" are listed at 40 CFR 122, Appendix D.
- National effluent standards source categories. The CWA has a system of minimum national effluent standards for several industry categories (see 33 U.S.C. 1316 for the categories and 40 CFR 400-460 for effluent guidelines and standards; toxic pollutants regulated under these standards are found at 40 CFR 401.15).

The Emergency Planning and Community Right-To-Know Act (EPCRA) (42 U.S.C. 11001-11050; also known as Superfund Amendments and Reauthorization Act [SARA] Title III): Requires reporting to EPA for toxic chemical releases to the environment and off-site transfer of chemicals. Reports are publicly available. Facilities must file an annual Toxic Release Inventory for each chemical listed at 40 CFR 372.65 if the facility has more than 10 employees and manufactures, processes, or otherwise uses amounts of chemicals in excess of the threshold reporting amount (see 40 CFR 372.25).

The Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301-395): Governs chemicals used as food additives or in cosmetics.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
(7 U.S.C. 136-136y): Governs chemicals used as active ingredients in pesticides.

The Hazardous Materials Transportation Act (HMTA) (49 U.S.C. 1801-1812): Governs shipments of hazardous materials in commerce by road, air, rail, and water. Examples of key provisions include:

- The listing of materials that are hazardous to transport in the Hazardous Materials Table (49 CFR 172.101), which also contains regulations for packaging, labeling, and transportation.

The Consumer Product Safety Act (CPSA) (15 U.S.C. 2051-2084) and **The Hazardous Substances Act (HSA)** (15 U.S.C. 1261-1277): Governs the safety of consumer products, including hazardous chemical ingredients. "Hazardous substances" defined by 15 U.S.C. 1261(f)(1)(A) or by any regulation issued by the Consumer Product Safety Commission are subject to labeling requirements, and the Commission may ban a product through regulation.

The Occupational Safety & Health Act (OSHA) (29 U.S.C. 651-678): Governs the exposure of workers to chemicals in the workplace. Examples of key provisions include:

- The Hazard Communication Standard, explained in 29 CFR 1910.1200, mandates notice requirements, labeling requirements, and the availability of Material Safety Data Sheets (MSDSs). Requires employers to inform and train employees about hazardous chemicals.
- Hazardous air contaminants in the workplace are controlled by Permissible Exposure Limits (PELs). These are found in 29 CFR 1910.1000 Table Z-1-A.

The Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6901- 6991): Governs the generation, transport, treatment, storage and disposal of hazardous chemical waste. In addition to the *Code of Federal Regulations*, the *ER Federal Regulations Binder* is a good resource to locate regulations on hazardous waste. Key provisions include:

- Definition of hazardous waste:
  Solid waste as defined by RCRA that fits any category below is hazardous waste subject to RCRA regulation:

  - Listed wastes (see 40 CFR 261 - four lists).
  - Characteristic wastes (e.g., ignitable, corrosive, reactive, or toxic wastes. See 40 CFR 261.2).
  - Substances derived from listed wastes.
  - Substances mixed with either listed or characteristic wastes.
- Treatment, Storage, and Disposal Facility (TSDF) regulations: Permitting requirements are found at 40 CFR 264-265, 270).

The Toxic Substances Control Act (TSCA) (15 U.S.C. 2601-2692): Governs manufacturing, use, and disposal of toxic chemicals; requires premanufacturing notices for new chemicals, and comprehensive reporting for certain existing chemicals. In addition to the *Code of Federal Regulations,* the *ER Federal Regulations Binder* is a good resource to locate TSCA regulations. TSCA regulates "chemical substances and mixtures" as defined in the act and regulations (40 CFR 710). Substances regulated under FIFRA and FFDCA are exempt.

Codifications of Federal Statutes

Codifications of federal statutes include:
- *United States Code* (U.S.C.).
- *United States Code Annotated* (U.S.C.A.).
- *United States Code Service* (U.S.C.S.).

Other publications which are useful tools for locating the text of environmental statutes include:
- *Environmental Law Reporter Statutes Binder.*
- *ER Federal Laws Binder* (published by the Bureau of National Affairs [BNA]).

These publications do not contain other federal laws, such as the Occupational Safety and Health Act (OSHA), which may apply to the chemical being researched. Other looseleaf services specialize in a particular area, such as:
- *Chemical Regulations Reporter* (published by BNA).
- *Occupational Safety and Health Reporter* (published by BNA).
- *Food and Drug Law Reporter* (several publishers).

Locating Federal Regulations

Sources that can be used to access the regulations in text form include:
- Annotations to the U.S.C.A. or U.S.C.S., which cite regulations that implement particular statutory provisions.
- Index to the *Code of Federal Regulations*.
- *ER Federal Regulations Binder*.
- *Federal Register* where the regulation was originally published (also contains explanatory materials not codified in the CFR).
- Computer data bases.

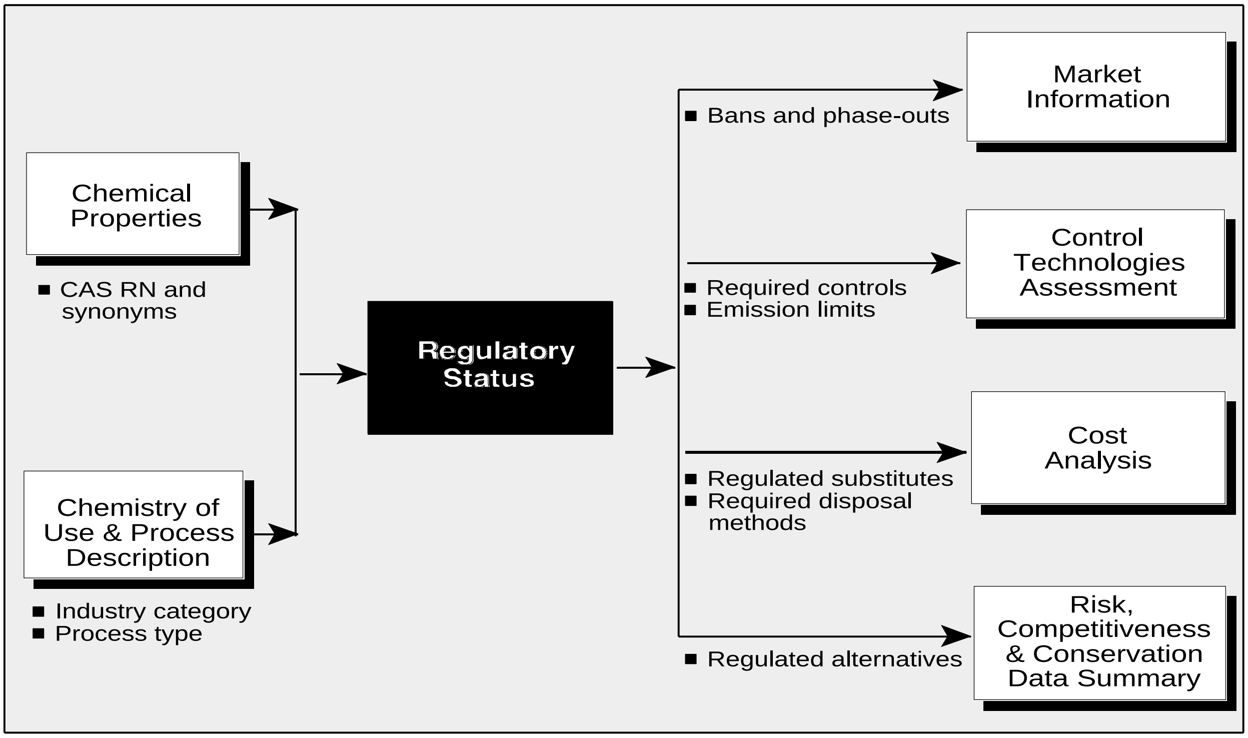
Searching Computer Data Bases

The WESTLAW® network has data bases for both the *Code of Federal Regulations* (FENV-CFR) and the *Federal Register* (FENV-FR). Within these data bases, it is possible to search by chemical name (e.g.,"benzene"). However, the search may produce hundreds of citations because the computer will pull up any document within the data base where the term appears. Thus, it will be necessary to review the text of the retrieved documents to determine whether each regulation specifically regulates the substance in question or merely mentions it in passing.

The LEXIS® network can also search for federal regulations. LEXIS® is organized by libraries and files. For a general search, enter the CODES library and then choose either the CFR file for citations to the *Code of Federal Regulations* or the FEDREG file for citations to the *Federal Register*. Again, relevant citations may also appear. Both of these on-line data bases charge for the use of their service, including on-line time changes and charges for documents downloaded.

FLOW OF INFORMATION: The Regulatory Status module receives information from the Chemical Properties and Chemistry of Use & Process Description modules and transfers information to the Market Information, Control Technologies Assessment, Cost Analysis, and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 7-1.

FIGURE 7-1: REGULATORY STATUS MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 7-1 lists published guidance and sources of regulatory data.

TABLE 7-1: PUBLISHED GUIDANCE AND DATA SOURCES

Reference	Type of Guidance
Chemical Regulations Reporter. Updated Periodically.	Looseleaf service for regulations regarding toxic chemicals.
Code of Federal Regulations Index. Updated Periodically.	Index to CFR providing guide to updates in Federal Register.
Environment Reporter. Updated Periodically.	Looseleaf service: text of federal and state laws and regulations.
Environmental Law Reporter. Updated Periodically.	Looseleaf service: news, statute texts.
Food and Drug Law Reporter. Updated Periodically.	Looseleaf service.
Index to the Code of Federal Regulations. Updated Periodically.	Index to CFR.
LEXIS® Network.	On-line data base of federal and state regulations and court opinions.
Occupational Safety & Health Reporter. Updated Periodically.	Looseleaf service.
Orloff, Neil, et. al. Updated Periodically. *Community Right-To-Know Handbook*.	Compliance guide to EPCRA.
Stever, Donald W. Updated Periodically. *Law of Chemical Regulation & Hazardous Waste*.	Comprehensive legal treatise.
Suspect Chemicals Sourcebook. Updated Periodically.	Regulatory analysis by chemical.
United States Code. Updated Periodically.	Official text of federal statutes.
United States Code Annotated. Updated Periodically.	Text of federal statutes with annotations.
*United States Code Servic*e. Updated Periodically.	Text of federal statutes with annotations.
U.S. Environmental Protection Agency. 1994b. *Federal Environmental Regulations Potentially Affecting the Commercial Printing Industry*.	Regulatory profile of the commercial printing industry.

TABLE 7-1: PUBLISHED GUIDANCE AND DATA SOURCES	
Reference	**Type of Guidance**
WESTLAW® Network.	On-line data base of federal and state regulations and court opinions.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

PERFORMANCE ASSESSMENT

OVERVIEW: The Performance Assessment module measures how well a product or process performs to meet the functional requirements of the use cluster. Performance data are collected for both the baseline and the substitute processes and used as a basis for a comparative evaluation. The amount of effort required to perform a useful performance assessment may vary depending on the thoroughness of the study and the specific nature of the process under consideration. The performance assessment can involve an actual operating trial of the baseline and substitutes during a performance demonstration project or, if both the baseline and substitutes are well known and documented, the compiling of performance information from literature sources. This module provides assistance in developing methodologies for collecting comparative performance data and conducting a performance assessment. The focus of this module is on the design of an actual operating trial rather than compiling performance information from literature sources.

GOALS:

- Design accurate and reliable performance measures.
- Select and use protocols for measuring performance to achieve reproducible testing results, and to remove bias from the interpretation of results.
- Develop a supplier data sheet to facilitate collection of required data from vendors and suppliers.
- Develop an observer data sheet to ensure that consistent and complete data are collected during performance testing.
- Evaluate relative performance of substitutes.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Familiarity with the required characteristics of the baseline and substitutes and the factors affecting performance.
- Knowledge of measuring techniques and quality control testing procedures.
- Familiarity with the details of the operation of the baseline and substitutes under review.
- Ability to analyze variability of results using qualitative or statistical techniques.

Within a business or DfE project team, the people who might supply these skills include a process engineer, process operator, industrial engineer, or statistician. Vendors of equipment or chemicals used in the process may also be a good resource.

DEFINITION OF TERMS:

American Society for Testing and Materials (ASTM): An independent group that sets standard testing procedures for a variety of materials (e.g., environmental effects on galvanized metal surfaces, light bulb life testing).

Bias: Testing error caused by systematically favoring some outcomes over others.

Blind Testing: An experimental method in which the material or process under study is not known to an operator to avoid influence on performance/results testing.

Generic Formulation: A generic classification into which a group of similar chemicals or chemical formulations can be grouped, in order to be evaluated, protecting the proprietary nature of a formulation.

Objective Characteristics: Characteristics which when measured are independent of the measurer's influence (e.g., weight, size).

Reproducibility: The ability of a test to give consistent results.

Subjective Characteristics: Characteristics which when measured and assigned a value are influenced by the perceptions of the measurer (e.g., color, sound, taste).

Test Vehicle: A standardized unit that can be used as a basis for testing different processes (e.g., a standard circuit board design that can be used to test the ability of several different processes to plate a conductive material into the holes on the board).

Underwriters Laboratory (U.L.): An independent group that tests and certifies the safety of electrical appliances (e.g., toasters, electric hand drills, lamps).

Variability: The measured difference in certain characteristics of similar items (e.g., paint thickness, color consistency, part cleanliness).

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for designing and conducting a performance demonstration. Further methodological details for Steps 4, 5, 6, 9, 12, and 13 are included in the Methodology Details section. In the procedure described below, the example of the use of a liquid cleaning agent applied to the surface of an ink-coated printing screen is used. Examples of an observer data sheet, and the testing methodology protocol for the screen printing industry are included in Appendix E.

Performance Protocol

Step 1: Obtain chemical properties data relevant to performance from the Chemical Properties module. Relevant properties for the example of a liquid cleaning agent to remove ink from a printing screen include vapor pressure (reflects tendency for evaporation), boiling point (indicates usable temperature range), and flashpoint (indicates fire ignition temperature level).

Step 2: Review the functional requirements of the use cluster listed in the Chemistry of Use & Process Description module. For the cited example, a minimal amount of residual ink on the screen after cleaning may be a specified requirement. A performance criteria may be that the screen must be cleaned until no visible ink residue remains on the screen surface.

Step 3: Identify relevant performance characteristics that could be qualitatively or quantitatively evaluated during the performance demonstration. These might include the ease of use (e.g., the physical effort required to clean the screens), the time required to accomplish the desired function (e.g., cleaning), the effectiveness of the substitute in achieving the function, or the effect of the substitute on the quality of the finished product (e.g., will use of the cleaner reduce the life of the screen).

Step 4: Identify variables which could significantly influence the results of the performance demonstration if not properly controlled. These might include process variables outside of the use cluster such as upstream process chemistry that must be adjusted to be compatible with the substitutes.

Step 5: Define methods of measuring each of the performance characteristics identified in Step 3. These methods, which may include laboratory testing as well as on-site analysis during the demonstration, should minimize the effect on results of the variables identified in Step 4. If applicable, the design and use of a test vehicle can help accomplish the above objectives.

Step 6: Define the parameters or conditions under which the demonstration of the baseline and substitutes will be performed. These parameters include when and where the demonstration will take place, along with who will observe the demonstration. Performance demonstration conditions should simulate real operating conditions as much as possible.

Step 7: Establish a procedure to quantitatively or qualitatively analyze each of the performance measures identified in Step 5. Analysis may be required on-site during the performance demonstration (e.g., how many cycles a screen will process before failure, testing to what extent a part is dried, etc.) or after the demonstration at a special test facility (e.g., the amount of light transmitted through a cleaned screen). Suppliers of chemicals and equipment should be consulted to ensure that the analysis methods are unbiased and do not favor a particular product or technology.

Step 8: Establish a performance scale for each of the performance measures to facilitate a comparative evaluation of the substitutes. The scale should consider both subjective and objective characteristics. (For example, visual inspection could be used to assign a high, medium or low level of cleanliness. A quantitative test, such as light transmission through cleaned screens, could be used to quantitatively measure the amount of residual ink left on a screen after cleaning.) Some objective characteristics can be evaluated using standard product specifications, such as military specifications.

Step 9: Develop a performance demonstration protocol based on the information developed in Steps 3 through 8.

Step 10: Review the Energy Impacts, Resource Conservation, and Cost Analysis modules to determine what data are required from the performance demonstration to complete those modules. Include in the protocol methods for collecting energy use, resources consumption and cost data, if required. The following data are typically gathered by the performance assessment:

- Energy Impact data: Collect data on energy consumed by motors, pumps, air fans, and other energy consuming process equipment. Data may include power rating, average duty, and average load.
- Resource Conservation data: Collect data on quantities of resources used in the process. Use direct measurement or examine historical records to determine rates of resources consumption (e.g., the amount of spent cleaner generated in the cleaning of screens).
- Cost Analysis data: Collect information on costs, such as operating and maintenance costs, process equipment costs, raw materials, utilities, as well as applicable indirect costs (e.g., waste management expenditures).

Step 11: If time and resources allow, perform test runs to evaluate the performance demonstration protocol for factors such as reproducibility. Performing trial runs will ensure that all important variables have been identified and controlled, and will highlight significant errors or impracticalities in the protocol.

Supplier and Observer Data Sheets

Step 12: Develop a supplier data sheet to collect consistent data from suppliers and vendors of the use cluster chemicals or technologies. One important purpose of the supplier data sheet is to collect information regarding the proprietary formulations of chemical products, which is necessary for the risk characterization component of a CTSA. The same data sheet should be disseminated to each of the vendors or suppliers of the chemicals or technologies being employed in the demonstration.

Step 13: Develop an observer data sheet to facilitate the collection and recording of consistent data at the time of the performance demonstrations. Because similar types of data must be collected, it may be helpful to use the questionnaire developed in the Workplace Practices & Source Release Assessment module as a basis for developing the observer data sheet. The data sheet should be completed by the observer for each test run at each performance demonstration site. In order to ensure an efficient on-site performance demonstration, it may be useful to distribute portions of the observer data sheet to participating test facilities prior to the demonstration. To minimize the variation in data recording, it is preferable to have the same observer complete the on-site portion of each data sheet.

Performance Results

Step 14: Conduct performance demonstrations for each of the alternatives using the performance protocol developed in Step 9. The demonstrations should be carried out in the presence of a neutral observer who can record the process conditions and complete the observer data sheet.

Step 15: If the test vehicle is to be shipped to an off-site laboratory for analysis, the observer should record the identification code of the test vehicle, package it according to a standard protocol and ship it to this laboratory. Only reporting the identification code to the off-site laboratory, and not the type of substitute demonstrated on the test vehicle, ensures blind testing by the off-site laboratory.

Step 16: Compare the performance results with the previously-defined performance characteristics to evaluate the comparative efficacy of the substitutes (e.g., substitute 1 failed to clean the screen effectively and was time-consuming, but substitute 2 cleaned the surface effectively and quickly). It is important to note that results from the performance demonstration may not be easily comparable, particularly if all key variables are not identified or able to be controlled.

Step 17: Transfer energy use, resource consumption and cost data to the appropriate modules. Transfer chemical formulation data to the Exposure Assessment module. Transfer performance assessment results from Step 14 to the Risk, Competitiveness & Conservation Data Summary module.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 4, 5, 6, 9, 12, and 13. If necessary, additional information on these and other steps can be found in the published guidance.

Details: Step 4, Identifying Variables

Given the screen cleaning example, the types of variables that could significantly influence the results of the performance demonstration, if not properly controlled, include the following:

- Environmental:
  - Ambient light levels needed for operator to judge screen cleanliness after cleaning operations.
  - Ambient air temperature can affect cleaning agent efficiency.
- Human Operator:
  - Different operators may handle and clean screens with different speeds and thoroughness.
- Process System:
  - Ink type and viscosity may affect cleaner action.
  - Design of screens may affect ease of cleaning along edges and in corners.

Details: Step 5, Measurement Methods and Test Vehicle Design

To reduce the potential for variation in the test results and thus improve the reproducibility of the test protocol, the performance demonstration should be designed to:

- Minimize the influence of secondary parameters (e.g., room temperature variation) to isolate the effect of the chemical/process on the performance results.
- Consider the different application methods or operational characteristics that may be required with one or more of the substitutes (e.g., spray application in lieu of hand wipe-on of screen cleaning agent).
- Use blind testing to minimize operator influence on the test outcome (e.g., different screen cleaning agents being evaluated could be provided to a worker in containers labeled with a number of different codes, several of which could be for the same cleaning agent).
- Minimize the potential for compounded effects caused by lack of control over several process variables. In this regard, it is important to identify all key variables so that all but a single performance measure can be controlled to the extent possible or practical.

A test vehicle can be developed and used to standardize the conditions and minimize the variables that can occur when testing several different processes. The use of a test vehicle is not always possible and should only be used when it is applicable and makes sense (e.g., a test vehicle may not be needed to test the efficacy of different chemical agents removing ink from a silkscreen). A test vehicle should not be used unless it can be designed to test all of the alternatives being considered. The design of the test vehicle should be done using input from manufacturers, DfE project team members, and suppliers of chemicals or technologies to ensure that the test vehicle performs its function without favoring a particular process being tested. The test vehicle should be designed to:

- Facilitate the testing of the performance characteristics listed in Step 3 for all of the alternatives being evaluated.
- Minimize the effect on results of the variables identified in Step 4 (e.g., use a screen with a consistent amount of stencil coverage and intricacy).

- Be broadly applicable to the range of products being evaluated (e.g., the variation of hole sizes on a circuit board test vehicle should be representative of the range of hole sizes used for a circuit board).

In addition, to minimize variation, test vehicles used at different demonstration sites should be manufactured under identical conditions at a single facility prior to shipment to the demonstration sites. This will minimize the variation in the test vehicles themselves.

Test vehicles that will be shipped to an off-site laboratory following processing at the demonstration site should be labeled with an identification code. The laboratory should use the same test methods to analyze all of the test vehicles, regardless of whether the test methods are qualitative or quantitative.

Standard ASTM or U.L. methods and military or other product specifications are available for some manufacturing processes and products and may be useful in designing the performance demonstration. Trade associations may have developed standard testing procedures for other processes or products. However, unique tests may need to be developed for many processes or products.

Details: Step 6, Selecting the Demonstration Sites

The performance demonstration may be carried out at any of the following facility types:
- Current operating facility.
- Operating facility that acts as a supplier test site.
- Supplier or trade association test site or demonstration facility.

Details: Step 9, Developing the Performance Demonstration Protocol

The performance demonstration protocol may include:
- A description of the test vehicle, if applicable, including specifications for manufacturing the test vehicle.
- The performance characteristics to be reported from the performance demonstrations.
- The processing or testing methodology (a step-by-step description of how the on-site performance demonstrations will be conducted, including any processing or testing requirements).
- The processing or testing parameters (the conditions under which the demonstration should be performed).
- The analysis procedures that will measure the performance characteristics.
- The performance scale that will be used to compare the results of the performance assessment.
- The number of times each test or analysis should be run.

Details: Step 12, Preparing a Supplier Data Sheet

The supplier data sheet can be used to collect the following types of data:

- Process operating parameters (e.g., compatibility with other process steps, product life, limitations, etc.).
- Material safety data sheets.
- Product formulation data.
- Equipment operating and maintenance procedures.
- Waste disposal requirements.
- Energy, cost, or resource data listed in Step 10 that are best supplied by vendors or suppliers (e.g., equipment power rating, equipment costs, maintenance costs, etc.).
- Any other data that are best supplied by the vendors or suppliers.

When proprietary chemical products are being used, the use of generic formulations may be necessary to obtain proprietary chemical formulation data from the supplier. A generic formulation allows the chemical formulation data to be evaluated in the process while protecting the proprietary nature of the chemical product. The generic formula is typically developed through the combined efforts of the suppliers and vendors of the chemical products along with members of the DfE project team, especially persons involved in the Exposure Assessment and Risk Characterization components of a CTSA (see Chapter 2: Preparing for a CTSA). An example method for preparing a generic formula is shown below.

(1) Group similar chemicals into categories. The categories can either be by chemical name or by similar chemical compound (e.g., alcohols).

(2) Provide a range of concentrations for the actual quantity of a chemical within the product formulation (e.g., 50-60 percent toluene).

(3) Exclude quantities of specific chemicals that are under a concentration agreed upon by the project team (e.g., one percent), such as surfactants or salts. Do not exclude potentially hazardous materials or chemicals that are regulated.

This method can be used to group formulations with specific chemicals in a range of concentrations (e.g., Product A: 20-40 percent methyl ethyl ketone, 15-25 percent butyl acetate, 10-20 percent methanol, 20-40 percent toluene), or to specify the actual concentrations of a chemical group (e.g., 40 percent propylene glycol series ethers, which can represent a number of different, but structurally similar, chemicals).

Details: Step 13, Developing an Observer Data Sheet

The observer data sheet should collect the following types of data:

- Personnel (e.g., facility contact, individuals performing demonstration, etc.).
- Demonstration conditions (e.g., ambient air temperature, air ventilation rate, humidity, etc.).

- Process description (e.g., equipment used, process steps, chemical product compositions, etc.).
- Type and identification code of test vehicle, if applicable.
- Observed operating procedures (e.g., time a panel is immersed in a chemical bath, process cycle time, amount of chemical used to clean a screen, etc.).
- Exposure data (e.g., chemical handling procedures, worker activities, personal protective equipment worn by workers, etc.).
- Process variables (e.g., temperature of chemical baths, worker operation inconsistencies).
- Energy, cost, and raw materials data listed in Step 10 (e.g., average energy load and duty, utility costs, water consumption rates, etc.).
- Any other data that are best collected by a neutral observer at the time of the performance demonstration.

In order to ensure an efficient on-site performance demonstration, it may be useful to distribute portions of the observer data sheet to participating demonstration sites prior to the demonstration. The partial observer data sheet should include:

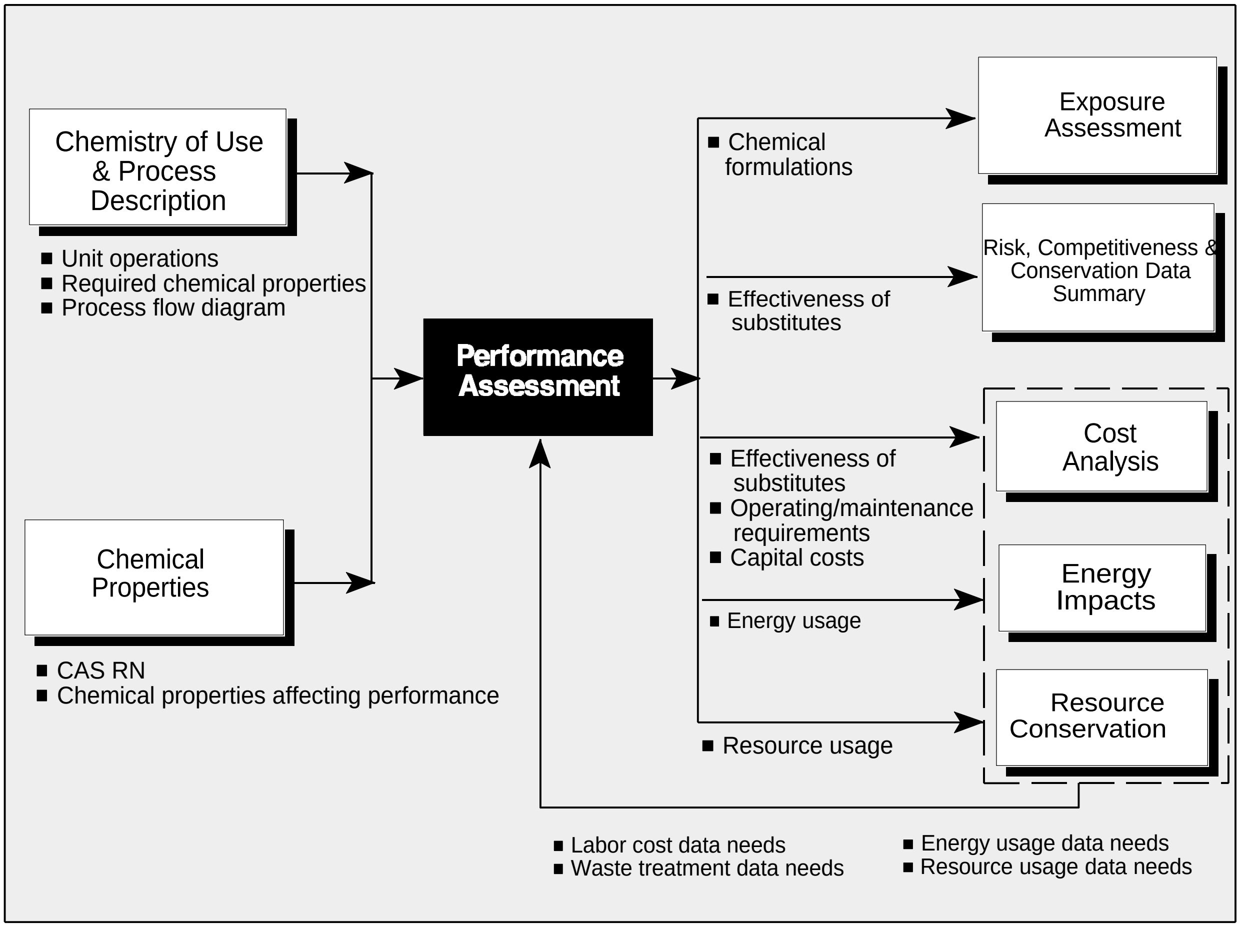
- A description of the process as it is performed at the specific test facility.
- Data that are difficult or time consuming to obtain (e.g., annual sludge volumes, data from company purchase records, equipment reliability data).
- Process history data (e.g., recent changes in equipment or operating practices that could effect the validity of data collected).
- Employee data (e.g., number of employees per shift, hours per shift).
- Any other data that can be collected by the facility that will help prepare observers for the demonstration or that are not readily available on-site.

By collecting and reviewing the facility completed portion of the observer data sheet prior to the facility test, the performance demonstration will be facilitated by allowing:

- Observers to become familiar with important process information prior to the performance demonstration.
- Data to be collected that are difficult or time consuming to obtain during a short on-site visit (e.g., annual chemical consumption, utility costs).
- The demonstration site to obtain the particular chemical products or technologies that are to be tested.

FLOW OF INFORMATION: The Performance Assessment module receives data requirements from the Energy Impacts, Resource Conservation, and Cost Analysis modules. It receives chemical and process information from the Chemistry of Use & Process Description and Chemical Properties modules. Performance data are transferred to the Exposure Assessment, Risk, Competitiveness & Conservation Data Summary, Cost Analysis, Energy Impacts, and Resource Conservation modules. Example information flows are shown in Figure 7-2.

-FIGURE 7-2: PERFORMANCE ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 7-2 presents references for published guidance relevant to the design of a performance demonstration project.

TABLE 7-2: PUBLISHED GUIDANCE ON PERFORMANCE ASSESSMENT

Reference	Type of Guidance
Kume, Hitoshi. 1987. *Statistical Methods for Quality Improvement.*	Methods for using statistics to measure performance, specifically quality, for the baseline and alternative chemicals or processes.
Montgomery, Douglas C. 1991. *Design and Analysis of Experiments*.	Information on designing non-biased experiments and statistical analysis of the results.

TABLE 7-2: PUBLISHED GUIDANCE ON PERFORMANCE ASSESSMENT

Reference	Type of Guidance
Ray, Martyn S. 1988. *Engineering Experimentation: Ideas, Techniques, and Presentation*.	In-depth coverage of experimental techniques and equipment for measuring performance.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

COST ANALYSIS

OVERVIEW: The Cost Analysis module identifies the costs associated with the baseline and alternatives, and calculates comparative costs between them. As a minimum, the cost analysis should identify and compare the direct and indirect costs of the baseline and the substitutes. If time and resources permit, data are also collected on future liability costs and less-tangible benefits that occur through the implementation of a substitute.

GOALS:

- Categorize and determine the costs that are incurred by the baseline and the substitutes.
- Identify less-tangible benefits that can result from the implementation of a substitute.
- Perform a comparative cost analysis of the baseline versus the substitutes.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of current bookkeeping and accounting practices.
- Knowledge of, and ability to perform, cost analysis practices and procedures.
- Knowledge of product and customer buying base to identify less-tangible benefits.
- Knowledge of costs incurred by the baseline and substitutes and other aspects of direct cost allocation.

Within a business or a DfE project team, the people who might supply these skills include a purchasing agent, marketing specialist, floor manager, an accountant, or an economist. Vendors of process equipment or chemicals may also be a good resource.

DEFINITION OF TERMS:

Cost Allocation: The method of assigning costs that have been incurred to the products and processes that generated the costs.

Direct Costs: Costs that are readily assignable to a specific process or product. These costs include capital expenditures, and operating and maintenance costs (e.g., labor, materials, utilities, etc.).

Discounting: Economic analysis procedure by which monetary valuations of benefits and/or costs occurring at different times are converted into present values which can be directly compared to one another.

Expanded Time Horizon: The concept of evaluating an economic analysis over an extended period of time (e.g., 10-20 years) as opposed to the traditional 3-5 year period. This concept is important to identifying the pollution prevention benefits of a substitute, because many of the liability costs and less-tangible benefits occur over a longer period of time.

Indirect Costs: Costs that are incurred by the operation of a business but not typically allocated to a specific process or product. Administrative costs, regulatory compliance costs, and workman's compensation costs are all examples of indirect costs.

Internal Rate of Return (IRR): The discount rate at which the net savings or net present value of an investment are equal to zero. An investment is economically justifiable when the IRR equals or exceeds a company's desired rate of return.

Less-Tangible Benefits: Benefits that may occur but cannot be readily quantified (e.g., reduced health maintenance costs due to a safer work environment, or increased product sales due to better product performance, etc.).

Liability Costs: Difficult to quantify costs incurred as a consequence of uncertain future liability for clean-up of hazardous substance releases or for liabilities from personal injury claims stemming from environmental releases or product use.

Net Present Value (NPV): The present value of future cash flows of an investment less the current cost of the investment.

Present Value (PV): A concept which specifically recognizes the time value of money, i.e., the fact that $1 received today is not the same as $1 received in ten years. Even if there is no inflation, $1 received today can be invested at a positive interest rate (say 5 percent), and can yield $1.63 in ten years. Present value refers to the value in today's terms of a sum of money received in the future. In the example above, the PV of $1.63 received in ten years is $1, i.e., $1 received today is the same as $1.63 ten years in the future. Alternately, the PV of $1 received in ten years is $0.61. The rate at which future receipts are converted into PV terms is called the discount rate (analogous to the interest rate given above). The formulation for calculating PV is given in the Methodology Details section.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for performing a cost analysis. Further methodology details for Steps 1, 2, 4, 5, 6, 7, and 8 follow this section.

Step 1: Determine data requirements for the cost analysis and provide them to the Performance Assessment module so that cost data can be collected during the performance demonstration project. Data should be collected on a per unit production basis, or some other basis that allows a comparative evaluation of the trade-off issues (e.g., energy impacts, resource conservation, risk, etc.).

Step 2: Obtain the data identified in Step 1 from the Performance Assessment module. Obtain additional cost-related data from the Energy Impacts, Resource Conservation, Control Technologies Assessment, Regulatory Status, Process Safety, Market Information and International Information modules. Energy, chemical, and resource consumption data are usually collected in the Performance Assessment module and compiled in the Energy Impacts and Resource Conservation modules, respectively.

Step 3: Review the Workplace Practices & Source Release Assessment module to determine if resource consumption rates, waste generation rates, and worker activities reported for the baseline and alternatives are consistent with the data obtained in Step 2. If the data are not consistent, it may be necessary to have knowledgeable industry personnel review and resolve any inconsistencies.

Note: To ensure that the cost analyses for alternatives are comparable, data from the Workplace Practices & Source Release Assessment module should be used in actual cost calculations only if the data are available for all of the alternatives being evaluated. The Workplace Practices & Source Release Assessment module may not contain information on new or novel alternatives that are not widely used.

Step 4: Calculate the direct costs associated with the operation of the baseline and the alternatives using the data gathered in Step 2 and checked in Step 3. Direct costs include capital expenditures, operating costs, and maintenance costs. Waste management costs are also examples of direct costs, but many businesses allocate these costs to overhead.

Step 5: Calculate indirect costs for the baseline and alternatives. The data gathered in Step 2 will determine many indirect costs, while other indirect costs can be estimated from other sources. Indirect costs are considered hidden costs because they are often allocated to overhead rather than their source, or are omitted altogether from a cost analysis.

Step 6: If time and resources permit, identify future liability costs associated with the operation of the baseline and alternatives. In most instances, the estimation of future liability cost is subject to a high degree of uncertainty. Therefore, the need to quantify the future liability may be less important than recognizing that the future liability exists.

Step 7:	If time and resources permit, identify any less-tangible benefits that could result from the implementation of a substitute. The benefits of a cleaner product, process, or technology can be substantial and should not be overlooked when performing a cost analysis.
Step 8:	Perform cost analyses of the baseline and alternatives using the cost data collected in Steps 3 through 6. The cost analyses should be performed using a traditional cost accounting method or an alternative cost method. An example of a cost analysis can be found in Appendix G.
Step 9:	Provide the results of the cost analysis to the Risk, Competitiveness & Conservation Data Summary module.

METHODOLOGY DETAILS: This section presents the methodology details for completing Steps 1, 2, 4, 5, 6, 7, and 8. If necessary, additional information on conducting a cost analysis can be found in the published guidance. Appendix G contains the cost analysis from the Lithography CTSA.

Details: Step 1, Collecting Cost Data

The following information may be needed for the cost analysis:

- Labor requirements (e.g., cycle time to produce a product unit, ease of use, number of employees to operate process, maintenance labor costs).
- Waste generation rates (e.g., waste water discharges, solid wastes generated).

Equipment and/or chemical costs may also be collected from suppliers during the performance demonstration if this information was not compiled in the Market Information (cost of U.S. supplied equipment and /or chemicals) and International Information modules (cost of foreign supplied equipment and/or chemicals).

If an actual performance demonstration is not planned during the CTSA (e.g., if performance data are being collected from existing sources instead of tests performed as part of the CTSA), cost estimates can be obtained using standard cost estimating techniques and/or cost estimation software combined with data from equipment vendors or other sources.

Details: Step 2, Obtaining Cost-Related Data From Other Modules

Cost-related data are obtained from the following modules:

- Chemical and other resource consumption rates (e.g., water, raw stock, etc.) should be obtained from the Resource Conservation module.
- Energy consumption rates should be obtained from the Energy Impacts module.
- Control technology equipment requirements should be obtained from the Control Technologies Assessment module. Costs of controls can be estimated using information contained in regulatory background documents or obtained from vendors and suppliers.

- Regulations requiring specific disposal methods for process wastes (e.g., processes that generate listed hazardous wastes) should be obtained from the Regulatory Status module. Costs of these disposal methods can be estimated using information contained in regulatory background documents or obtained from suppliers or disposal companies.
- OSHA requirements for special conditions or equipment needed to ensure process safety should be obtained from the Process Safety module. Costs of these requirements can be estimated using information contained in regulatory background documents or obtained from vendors and suppliers.
- Chemical and process equipment costs should be obtained from the Market Information module (U.S. supplied), International Information module (foreign supplied), and/or from supplier information provided to the performance demonstration, as noted in Step 1.

Details: Step 4, Calculating Direct Costs

Direct costs include the following:

- Capital expenditures (e.g., process equipment, control technologies, installation, project engineering, etc.).
- Operating costs (e.g., direct labor, raw materials, utilities, quality assurance testing, etc.).
- Maintenance costs (e.g., equipment cleaning and repair).

The details for Step 8, below, discuss how to calculate present value for costs that are incurred over time.

Details: Step 5, Calculating Indirect Costs

Indirect costs are hidden costs obscured in a cost category of overhead, or omitted completely. They include:

- Supervision and administrative costs.
- Regulatory compliance costs (e.g., permitting, monitoring, manifesting, employee training, etc.).
- Waste management expenditures (e.g., on-site pollution control costs, waste disposal charges, etc.).
- Insurance, rent, taxes, etc.

Not all indirect costs will be relevant to the cost analysis. For example, costs that are constant for both the baseline and the alternative may be excluded from the analysis.

The details for Step 8, below, discuss how to calculate present value for costs that are incurred over time. The following is a discussion of two methods for determining indirect costs.

Traditional Estimation Method: This method determines and allocates indirect costs to a process or product based on some measurable parameter (e.g., labor hours, capital investment). For example, maintenance costs for a piece of equipment can be estimated based on the capital cost of that equipment, where maintenance costs equal some function of capital cost. This method is the most common accounting method used throughout industry.

Activity-Based Costing (ABC) Method: This method of accounting allocates indirect costs to products or processes, based on how the products or processes actually incur these costs. This allocation is done using a series of cost drivers that are keyed to the activities required to produce the products. For example, the operating costs of an ion exchange bed used to treat liquid waste streams from various sources would be divided and attributed directly to each individual source in proportion to the percentage of its overall use.

Traditional Estimation Method vs. ABC Method: Traditional estimation methods are less complicated and time consuming than ABC methods. Little or no change to the current financial accounting methods are typically required. In contrast, ABC provides for a more accurate picture of costs by evaluating the actual activities of each process. ABC allows managers to cite specific problem areas in a process that would otherwise go undetected. As a result, the direct benefits of a substitute that addresses these problems are more easily identified. ABC, however, is time consuming because of the considerable effort needed to track each activity in the process. Therefore, additional administrative costs may be incurred to set up an ABC system, but the opportunities for cost savings identified by the ABC method probably would more than offset this cost.

In many cases it may be difficult to determine all indirect costs for substitutes that are not in widespread use. In these cases, ABC methods can be supplemented with the traditional estimation methods for the unavailable data. For example, determining if a waste stream is hazardous as defined by RCRA may not be possible until an alternative is fully implemented and the nature of the waste realized. Assumptions that are made about the applicability of environmental regulations and the associated costs should be explicitly stated. The Regulatory Status module helps to identify potential compliance issues.

Details: Step 6, Identifying Liability Costs

Liability costs include the following:

- Penalties and fines (e.g., penalties stemming from non-compliance with current or future environmental regulations).
- Personal injury (e.g., liability claims stemming from environmental releases of chemicals or consumer use of a product).
- Property damage (e.g., liability claims stemming from environmental releases from disposal sites).
- Clean-up costs (e.g., Superfund mandated corrective action).
- Natural resource damages (e.g., Superfund mandated damages).

Details: Step 7, Identifying Less-Tangible Benefits

Less-tangible benefits include:

- Increased sales due to improved product quality, enhanced public image, consumer trust in green products, or other effects.
- Reduced health maintenance costs due to a safer work environment.

- Improved worker productivity due to cleaner working conditions (e.g., fewer volatile solvents in cleaning area, less dizziness).
- Increased worker productivity due to improved employee relations.

Details: Step 8, Conducting a Cost Analysis

When conducting the cost analysis, the project team should select long-term financial indicators that account for the time value of money and all cash flows from implementing the baseline or a substitute. Two commonly used financial indicators include NPV and IRR. Formulas for calculating PV and NPV are discussed below. Discussions on IRR and other financial indicators may be found in economic analysis textbooks.

Calculating Present Value and Net Present Value

For a one-time cost or benefit, PV is given by the formula:

$$PV = \frac{CF_t}{(1 + r)^t}$$

where:

CF_t represents the value of a one-time cash flow, CF, received in year t, and r represents the discount rate

For a series of benefits to be received over several years, present value is given by the formula:

$$PV = \sum_{I=1}^{T} \frac{CF_t}{(1 + r)^t}$$

where:

∑ represents the summation of benefits in the time period which ranges from year 1 to year T

NPV is given by the formula:

$$NPV = PV - I$$

where:

I is the initial outlay or investment cost

Costing Methods

Traditional costing methods or Total Cost Assessment (TCA) can be used to perform the cost analysis. Both methods allow for the calculation of a net cash flow, IRR, or NPV. The methods differ in which costs are calculated and how costs are allocated. The following is a discussion of the advantages and disadvantages of different costing methods.

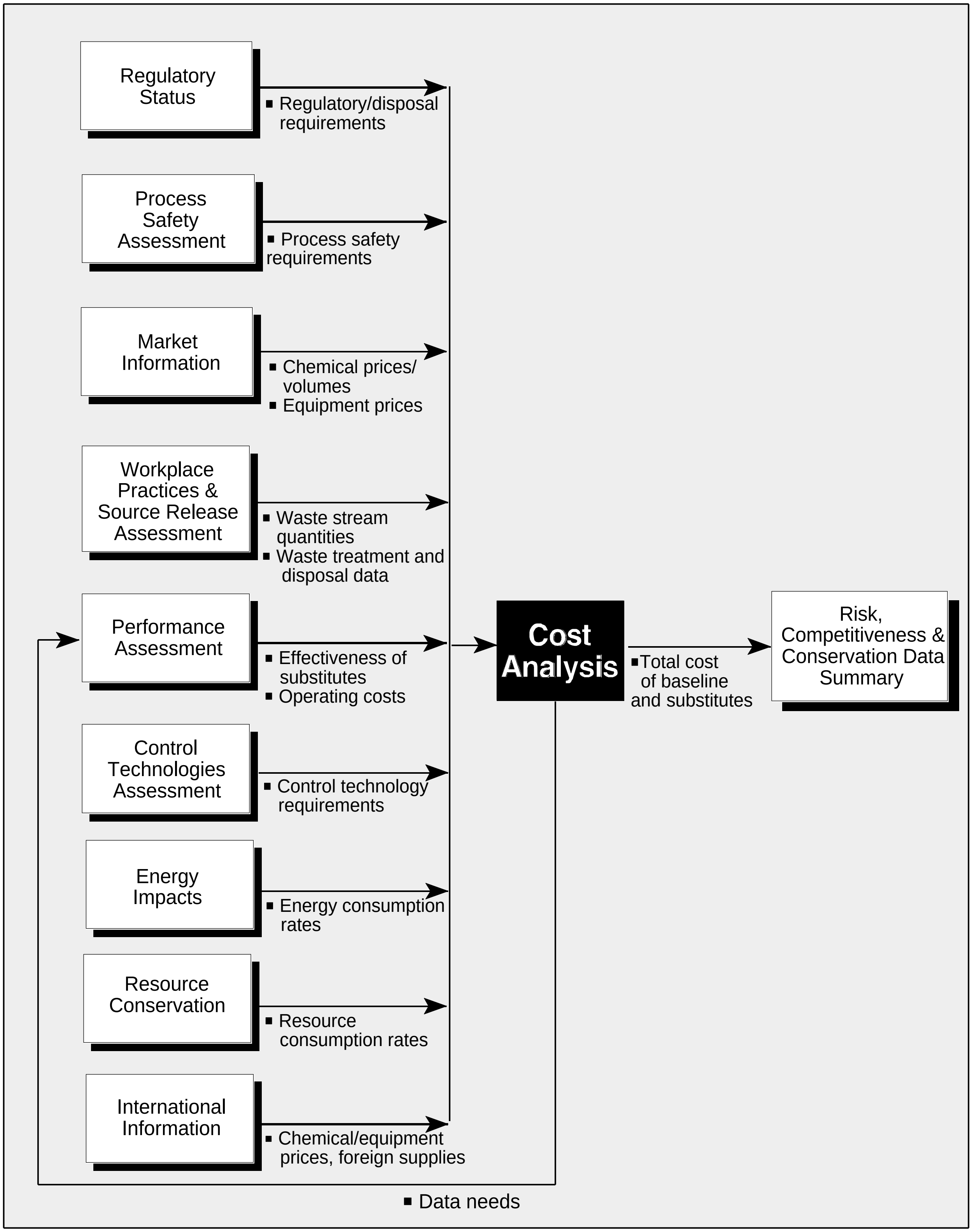
<u>Traditional Costing Method</u>: This method of cost analysis typically ignores future liability costs and considers all indirect costs as overhead or omits them altogether. These overhead costs, if considered, are randomly allocated to a process or product based on some measurable, yet arbitrary parameter (e.g., labor hours, capital equipment costs). This method is the most common accounting method used throughout industry.

<u>Total Cost Assessment (TCA)</u>: This accounting method attempts to analyze all of the costs and liabilities, along with the potential benefits, over an expanded time horizon to gain a more comprehensive profile and comparison of alternatives.

<u>Traditional Costing Methods vs. TCA</u>: Traditional cost accounting is the easiest and least complicated of the cost analysis methods. The need to quantify or estimate difficult-to-determine indirect costs and future liabilities is minimized or eliminated. The potential impacts the substitutes have on indirect costs are considered qualitatively. In contrast, TCA is an important improvement over traditional costing methods. By using an expanded time horizon, including indirect costs, and quantifying less-tangible costs, TCA is a more representative cost accounting method. One limitation of the TCA method is that there are no commonly accepted methods of quantifying some future liability costs, and little or no agreement on how less-tangible benefits should be valued. Both methods require little or no changes to the current financial/managerial accounting methods typically used in industry.

FLOW OF INFORMATION: This module provides data needs to the Performance Assessment module, receives information from the Regulatory Status, Process Safety Assessment, Market Information, Workplace Practices & Source Release Assessment, Performance Assessment, Control Technologies Assessment, Energy Impacts, Resource Conservation, and International Information modules, and transfers information to the Risk, Competitiveness & Conservation Data Summary module. Example information flows are shown in Figure 7-3.

FIGURE 7-3: COST ANALYSIS MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 7-3 lists references for computer models to assist with a cost analysis. Tellus Institute, with funding from the EPA DfE Program and the National Institute for Standards and Technology, is developing environmental cost accounting and capital budgeting software designed to help small and medium-sized businesses cost pollution prevention projects. Currently, software is available for screen printers; software packages for lithographers, flexographers, the metal fabrication and finishing industries, and printed wiring board manufacturers are under development.

TABLE 7-3: ANALYTICAL MODELS FOR COST ANALYSIS

Reference	Type of Model
Tellus Institute. 1993. *P2/Finance: Version 2.0.*	Financial analysis and cost evaluation software for the personal computer.
Tellus Institute. 1995. *P2/Finance for Screen Printers: Version 1.0.*	Financial analysis and cost evaluation software for the personal computer.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 7-4 presents references for published guidance on cost analysis.

TABLE 7-4: PUBLISHED GUIDANCE ON COST ANALYSIS

Reference	Type of Guidance
Brimson, James A. 1991. *Activity Accounting - An Activity-Based Costing Approach.*	Describes activity based costing method.
Brown, Lisa, Ed. 1992. *Facility Pollution Prevention Guide.*	Provides overview of total cost assessment issues and method.
Collins, Frank, Ed. 1991. *Implementing Activity Based Costing.*	Describes activity based costing method.
Northeast Waste Management Officials Association. UNDATED. *Costing and Financial Analysis of Pollution Prevention Investments.*	Provides methods of financial analysis.
Tellus Institute. 1991a. *Alternative Approaches to the Financial Evaluation of Pollution Prevention Investments.*	Describes and compares various costing methods.
Tellus Institute. 1991b. *Total Cost Assessment: Accelerating Industrial Pollution Prevention Through Innovative Project Financial Analysis, with Applications to the Pulp and Paper Industry.*	Describes total cost assessment methods.

TABLE 7-4: PUBLISHED GUIDANCE ON COST ANALYSIS

Reference	Type of Guidance
U.S. Environmental Protection Agency. 1989c. *Pollution Prevention Benefits Manual: Phase II.*	Formulas for incorporating future liabilities into a cost analysis.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

Chapter 8

CONSERVATION

This chapter presents module descriptions for the conservation component of a CTSA, including the following modules:

- Energy Impacts.

- Resource Conservation.

Businesses are finding that by conserving energy and resources they can cut costs, improve the environment, and improve their competitiveness. Energy use and resource consumption may be significant factors in evaluating alternatives. Data from both of these modules are considered in the Social Benefits/Costs Assessment and Decision Information Summary modules along with risk data, traditional competitiveness information (e.g., regulatory status, performance, and cost), and other information.

The Energy Impacts module may involve assessing energy consumption both during chemical manufacturing and during process operation. This is used to compare energy uses of the baseline and substitutes. The Resource Conservation module includes evaluating the amount of materials currently used in the process (renewable and nonrenewable resources) and the effects substitutes would have on resource use. Both of these modules use the Performance Assessment module as a key data source.

ENERGY IMPACTS

OVERVIEW: Energy consumption, either during the manufacture of a chemical or the use of a product, process, or technology can vary with a selected chemical or process change. The Energy Impacts module describes methods for evaluating the energy impacts of the baseline and substitutes within a use cluster. In a CTSA, data on the energy impacts of the baseline and substitutes are usually collected in the Performance Assessment module.

GOALS:

- Determine the energy requirements of the baseline and of the substitutes.
- Evaluate the relative energy impacts of the baseline as compared to the substitutes.
- Provide data on energy requirements and relative energy impacts to the Cost Analysis and Risk, Competitiveness & Conservation Data Summary modules.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Familiarity with sources and rates of energy consumption (e.g., equipment) in the use cluster.
- Ability to perform simple energy calculations involving power ratings (kW or BTU/hr), duty (hr/day), and equipment load (percent of rated power used during equipment operation).

Within a business or DfE project team, the people who might supply these skills include a plant engineer, environmental engineer, line supervisor, line operator, or equipment vendors.

DEFINITION OF TERMS:

British Thermal Unit (BTU): The quantity of heat required to raise the temperature of one pound of water from 60 to 61 ^{o}F at a constant pressure of one atmosphere.

Duty: Period of time equipment is operated under powered conditions (e.g., lights may be utilized for 16 hrs/day).

Horsepower (hp): The predominant English unit of power used to describe motor ratings in the U.S. In the metric system the usual measure of power is Joules/hr. One hp = 42.43 BTU/min = 2.7×10^6 Joules/hr = 0.7457 kilowatts (kW).

Kilowatt Hour (kWh): One kWh is the quantity of energy converted or consumed in 1 hour at the constant power rate of 1 kW. One kWh is equivalent to 3413 BTU.

Load: A factor reflecting the actual power used by a piece of equipment relative to the design power rating. For example, an electric motor may be oversized and draw only 80 percent of its nominal power rating when operating a specific piece of equipment.

Nominal Power Rating: The nominal energy use rate of energy consuming equipment operating under design conditions (e.g., an electric motor may have a power rating of 1 hp).

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for evaluating the energy impacts of substitutes. Methodology details for Steps 3, 4, and 6 follow this section.

Step 1: Review the Chemistry of Use & Process Description module to identify pieces of equipment that consume energy in the baseline or the substitutes. Note equipment that would be added or deleted, depending on the substitute. Examples of specific pieces of equipment which consume energy include drive motors, air fans, direct resistance heating elements, refrigeration system compressors, and natural gas-fired ovens.

Step 2: Review the Control Technologies Assessment module to identify the control technologies that are recommended or required for the baseline or the substitutes. This can include air pollution control technologies, chemical destruction technologies (e.g., incineration, etc.) as well as in-plant waste water treatment technologies. The energy consumption of control technologies should also be evaluated, particularly if a control technology is required to meet environmental regulations.

Step 3: Based on the equipment identified in Steps 1 and 2, determine the data required to evaluate the rates of energy consumption of the baseline and of the substitutes. Provide data requirements to the Performance Assessment module so that energy consumption data can be collected during the performance demonstration project. For each piece of energy using equipment, typical data requirements include:

- The nominal power rating.
- The average duty.
- The average load.
- Production capacity/through-put (e.g., parts/hr, ft^2 processed/day).

Data should be collected on a per unit production basis, or some other basis that allows a comparative evaluation of the energy trade-off issues.

Step 4: Obtain data from the Performance Assessment module and calculate the energy requirements of the baseline and of the substitutes. Again, energy requirements should be calculated on a common basis to allow for a comparative evaluation of the substitutes.

Step 5: Provide the energy requirements for the baseline and the substitutes to the Cost Analysis module. The cost of energy usages can be obtained from supplier (e.g., electric utility, natural gas utility) rate schedules.

Step 6: If up-stream energy impacts are being evaluated in the CTSA, review the Chemical Manufacturing & Product Formulation module to evaluate energy requirements during the manufacturing of chemical ingredients or the formulation of chemical products. CTSA pilot projects have qualitatively evaluated up-stream energy impacts.

Step 7: Tabulate energy requirements calculated in Step 4 together with data on up-stream energy impacts from Step 6 to evaluate the relative energy impacts of the baseline as compared to the substitutes.

Step 8: Report the relative energy impacts of the substitutes to the Cost Analysis and Risk, Competitiveness & Conservation Data Summary modules.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 3, 4, and 6. If necessary, additional information on this and other steps can be found in previously published guidance.

Details: Step 3, Collecting Data on Energy Consumption

Data for each substitute should be collected for a consistent unit process, such as the time to complete the function defined by the use cluster one time. This facilitates a comparative evaluation of the substitutes. The following summarizes sources of nominal power rating, duty, and load data:

- The nominal power rating is usually displayed on an identification plate on the equipment (e.g., a pump motor nameplate may read 1.0 hp). In some cases where nameplate data are unavailable, power ratings may be obtained from the manufacturer's literature or from equipment vendors.
- Duty can be measured using a simple timer or estimated by the equipment operator. Again, duty should be measured for a consistent process (e.g., the time a pump is required to dispense a solvent when cleaning ten 3,200 in^2 printing screens).
- Electric load can be calculated from the average current amperage and the supply voltage (e.g., average current amperage multiplied by supply voltage yields average electric power in kW). The average current amperage can be measured with an electric current (amp) meter. Gas use can be measured with gas metering equipment or it can be estimated by knowledgeable plant personnel.

If performance data are being collected from existing sources instead of tests performed as part of the CTSA, estimates of energy usage data can be obtained from equipment vendors or other sources.

Details: Step 4, Calculating Energy Requirements

Depending upon the particular circumstances, the method for calculating energy use will vary. For example, if each piece of energy consuming equipment in a process is unique and the required data can be readily collected (for example, with a dedicated power meter), the electrical energy consumption rate can be estimated using the following formula:

Net Energy Consumption (energy use/time)
= (No. pieces of equipment) x (power rating/unit) x (average duty) x (load)

Example: A coolant system for a machining operation requires 2 pumps to supply the operation with coolant liquid. The characteristics and operating parameters of each pump are as follows:

pump power rating = 10 hp
average duty = 8 hours/day
estimated operating load = 80 percent

Thus, the estimated net energy consumption for the coolant pumping operation is calculated as:

Net Energy Consumption (kWh/day)
= (2 pumps) x (10 hp/pump) x (1 kW/0.746 hp) x (8 hours/day) x (0.80)
= 172 kWh/day

For equipment using natural gas, the net energy consumption may be given by:

Net Energy Consumption (BTU/day)
= (rating in BTU/hr) x (hours/day duty) x (load)

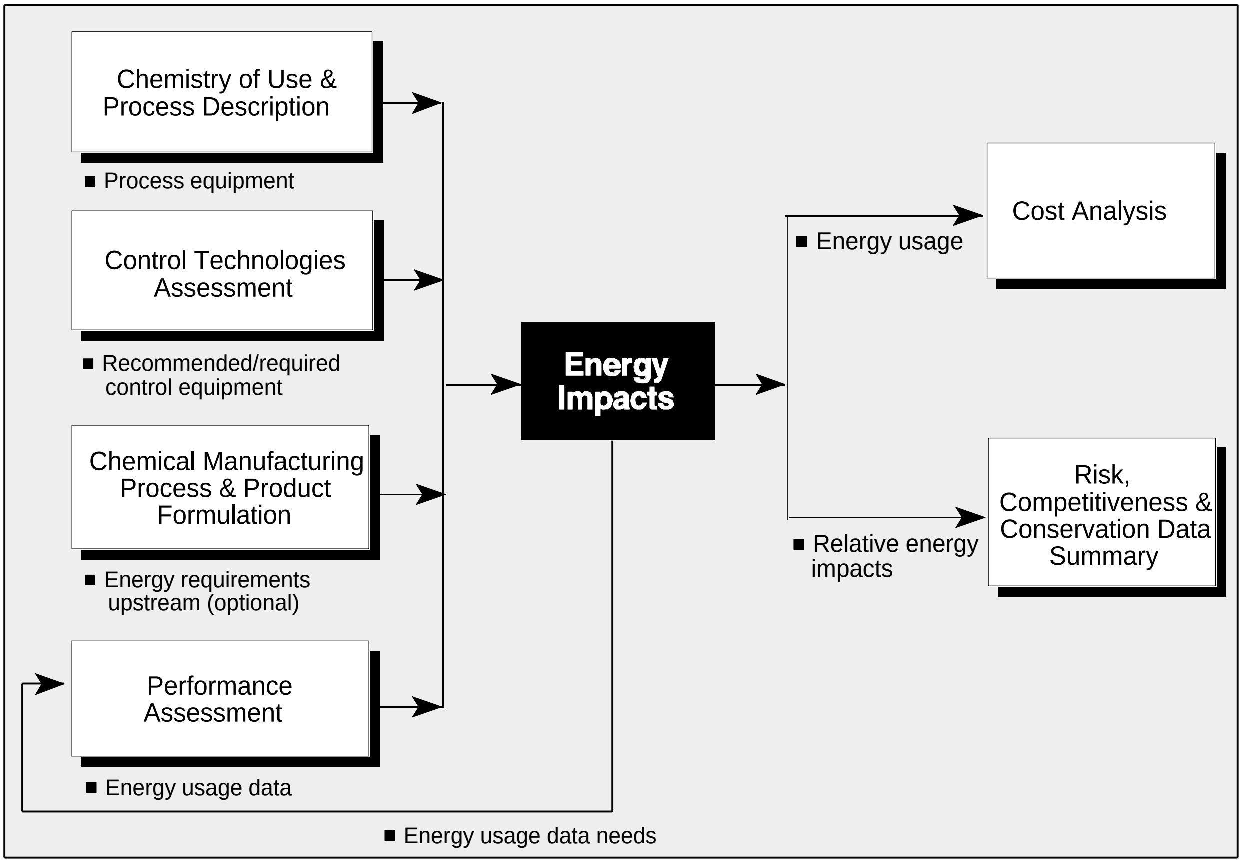
Details: Step 6, Evaluating Up-stream Energy Impacts

The following are examples of the types of questions a DfE project team might consider when qualitatively evaluating up-stream energy impacts:

- Are chemical ingredients made from raw materials that have an energy equivalence (e.g., petroleum-based chemicals versus vegetable-based)?
- Under what types of reactor conditions are chemical ingredients manufactured (e.g., what is the reactor temperature, pressure, and retention time)?
- Is the chemical formulation a simple mixing process? Does it involve chemical reactions between the formulation ingredients? Are heat or pressure required to get chemical ingredients into solution?

FLOW OF INFORMATION: Data requirements for the Energy Impacts module are identified based on information from the Chemistry of Use & Process Description, Control Technologies Assessment, and Chemical Manufacturing Process & Product Formulation modules and collected in the Performance Assessment module. (The energy impacts of up-stream processes, such as chemical manufacturing or product formulation, could be collected from suppliers during a performance demonstration project. Up-stream energy impacts have not been quantitatively evaluated in DfE pilot projects, however.) The Energy Impacts module transfers data to the Cost Analysis and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 8-1.

FIGURE 8-1: ENERGY IMPACTS MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 8-1 presents references for published guidance on estimating energy consumption for process equipment and performing energy audits.

TABLE 8-1: PUBLISHED GUIDANCE ON ENERGY ASSESSMENTS

Reference	Type of Guidance
Smith, Craig B. 1981. *Energy Management Principles, Applications, Benefits, and Savings.*	Methods for performing energy audits and calculating energy consumption for process equipment.
Thumann, Albert. 1979. *Handbook of Energy Audits.*	Methods for performing energy audits and calculating energy consumption for process equipment.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 8-2 lists sources of energy consuming equipment data.

TABLE 8-2: SOURCES OF ENERGY CONSUMPTION DATA

Reference	Type of Data
American Council for an Energy-Efficient Economy. 1991. *Energy-Efficient Motor Systems.*	Methods for determining energy consumption and efficiency for various types of electric motors.
Garay, Paul N. 1989. *Pump Application Desk Book.*	Methods for determining energy consumption and efficiency for various liquid pumping systems.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

RESOURCE CONSERVATION

OVERVIEW: Resource conservation is the process of selecting and using products, processes, or technologies that minimize the overall use or consumption of resources while effectively achieving a desired function. The Resource Conservation module describes methods for identifying the relative amounts of resources or materials used or consumed by a business as a consequence of changing from a chemical, process, or technology to a substitute. In a CTSA, resource consumption data are usually collected in the Performance Assessment module.

The methods described here focus on direct resource use rates (e.g., the amount of materials consumed to manufacture a product), *not* indirect resource use rates (e.g., the amount of land that is consumed by landfilling waste). Indirect resource consumption is qualitatively evaluated in the Social Benefits/Costs Assessment module.

GOALS:

- Determine the relative amounts of resources consumed by the baseline and the substitutes.

- Evaluate the relative effects on resource conservation of the baseline as compared to the substitutes.

- Provide data on resource consumption rates and relative impacts to the Cost Analysis and Risk, Competitiveness & Conservation Data Summary modules.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Familiarity with the types, sources, and supply of resources consumed by the baseline and substitutes.

- Familiarity with the common operating practices employed by the industry that might affect the rate of resources consumption.

Within a business or a DfE project team, the people who might supply these skills include a plant engineer, material scientist, environmental engineer, line operator, or suppliers of the substitutes.

DEFINITION OF TERMS:

Natural Resources: Material or substance which in its basic form is found in nature. For example, water, petroleum, and wood are natural resources in the sense that they do not have to be made in an industrial process.

Renewable Resource: As defined in Society of Environmental Toxicology and Chemistry publications, a renewable resource is one that is being replenished at a rate greater than or equal to its rate of depletion.   For example, wood used to make paper can be replaced with wood supplied by the growth of new trees as long as the rate of paper production combined with the rate of wood consumption does not exceed the rate of replenishment.

Resource: Material or substance used as a process raw material or required for process operation (e.g., oil for machine lubrication or a chemical feedstock for a chemical reactor).

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for evaluating the potential impacts of substitutes on resource conservation. Further methodology details for Steps 1, 3, 6, and 7 follow this section.

Step 1: Review the Chemistry of Use & Process Description module to identify the types of resources consumed and the specific process steps where resources are consumed by the baseline and by the substitutes. It may be useful to categorize resources (e.g., chemical products, water, renewable vs. nonrenewable, etc.) to facilitate the evaluation of the relative impacts of alternatives in Step 7. *(Although energy may be derived from renewable and nonrenewable resources, this module does not focus on energy consumption, which is addressed in the Energy Impacts module.)*

Step 2: Review the Control Technologies Assessment module to identify the control technologies that are recommended or required for the baseline or the substitutes. This can include air pollution control technologies, chemical destruction technologies, and in-plant waste water treatment technologies. Evaluate the control technologies to identify the types of resources they consume (e.g., chemical flocculants used in waste water treatment).

Step 3: Determine the data required to evaluate the rates of consumption of the resources identified in Steps 1 and 2. Provide the data requirements to the Performance Assessment module so that resource consumption data can be collected during the performance demonstration project. Data should be collected on a per unit production basis, or some other basis that allows a comparative evaluation of the resource impacts. If performance data are being collected from existing sources instead of tests performed as part of the CTSA, estimates of resource consumption can be obtained from equipment vendors, industry representatives, or other sources.

Step 4: Obtain data from the Performance Assessment module and calculate the resource requirements of the baseline and of the substitutes. Resource requirements should be calculated using a common basis, such as a per unit production basis or the amount of solvent required to perform a cleaning function one time. This facilitates a comparative evaluation of the substitutes.

Step 5: Provide the resource requirements calculated in Step 4 to the Cost Analysis module, where consumption rates will be converted into monetary values.

Step 6: If up-stream resource conservation impacts are being evaluated in the CTSA, review the Chemical Manufacturing Process & Product Formulation module to evaluate resource requirements during the manufacturing of chemical ingredients or the formulation of chemical products. CTSA pilot projects have qualitatively evaluated up-stream resource conservation impacts.

Step 7: Tabulate resource requirements in Step 4 together with data on up-stream resource consumption from Step 6. Evaluate the relative impacts on resource conservation of the baseline as compared to the substitutes.

Step 8: Report the results of the evaluation to the Cost Analysis and Risk, Competitiveness & Conservation Data Summary modules.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 1, 3, 6, and 7. If necessary, additional information on this and other steps can be found in the published guidance.

Details: Step 1, Categorizing Resources

To simplify the process for evaluating the relative impact of substitutes on resource conservation, it is useful to develop a means of categorizing similar resources. For example, different chemical products used in one or more process steps could be categorized together, as could water resources, or process materials such as lubricating oils. Table 8-3 gives an example of categorizing the resources consumed during a three-step process to clean manufacturing equipment.

In this example, the equipment is cleaned with a chemical cleaning product; the resources consumed are water, chemicals, and the machine oil necessary to lubricate the cleaning equipment. After cleaning, the cleaned equipment is rinsed with water; process materials are also consumed in this step as the manufacturing equipment degrades incrementally with each cleaning, until it must be replaced. In the final step, some amount of trial processing is required after the cleaning, which results in finished products that do not meet specifications and must be discarded. The two resources consumed in this step are the waste product from the run and the machine oil that is used to lubricate the equipment.

TABLE 8-3: EXAMPLE OF CATEGORIZING SIMILAR RESOURCES

Process Step	Resources			
	Water	**Chemical Products**	**Final Product Materials**	**Process Materials**
Step 1 - Cleaning	Dilute chemical product with water	Chemical cleaning product	None	Machine oil to lubricate cleaning equipment
Step 2 - Rinsing	Water rinse	None	None	Manufacturing equipment depleted after x cleanings
Step 3 - Waste Run	None	None	Trial processing after cleaning to achieve acceptable quality	Machine oil to lubricate manufacturing equipment

Details: Step 3, Collecting Data on Resource Consumption Rates

Data on resource consumption rates can be estimated based on purchase (inventory) records, process operator judgement, vendor data, or measured directly. Whichever technique is used, resource consumption data should be collected or converted into consistent units for the baseline and the substitutes, usually in unit mass (pounds or kilograms) per unit time or unit production. The following are examples of different types of data that can be used to estimate resource consumption rates.

Example, Using Existing Records

For the example of using purchase records to estimate the amount of plastic used in a plastic extrusion operation:

- Records show that 2,500 lbs of plastic pellets are purchased each year.
- It is estimated by the process specialist that 40 percent of this amount is used in the specific process under review.
- (0.40) (2,500 lbs/year) = 1,000 lbs used per year in process.

For the example of using purchasing records to estimate the amount of paint used in a parts painting operation:

- A potential substitute is a technology change where an improved paint spray system with a higher application efficiency will be utilized.
- It is estimated from case study data that a 35 percent reduction in paint use will be achieved since overspray losses will be substantially reduced with the use of the new system.
- From purchasing records it is calculated that 20,000 lbs of paint are currently purchased annually.

- The reduction in raw material (resource) use is estimated as:
  (20,000 lbs per year) - ([1-0.35] x [20,000 lbs per year]) = 7,000 lbs per year.

Example, Using Direct Measurement

For the example of using direct measurement to determine the amount of water utilized per year in a continuous flow rinse tank operation:

- Divert water flow from tank inlet into a container of known volume.
- Collect liquid until 1.5 gallon container is full (determine time interval using a stopwatch).
- Determine amount of time rinse tank is utilized per year.
- If it takes 5 minutes to collect 1.5 gallons, and the tank is used 8 hours/day, 5 days/week, 52 weeks/year:

  Water Consumption Rate = (1.5 gal/5 min) (60 min/hr) (8 hr/day) (5 day/wk) (52 wks/yr) = 37,440 gallons/yr

  Converting to lbs/yr:

  Water Consumption Rate = (37,440 gal/yr) x (8.34 lbs/gal) = 312,249 lbs/yr

Details: Step 6, Evaluating Up-stream Resource Conservation Impacts

The following are examples of the types of questions a DfE project team might consider when qualitatively evaluating up-stream resource conservation impacts:

- Are chemical products made from renewable or nonrenewable resources?
- Are scarce resources consumed to manufacture the chemicals or technologies in the use cluster?
- Are the raw materials used to manufacture the substitutes only found in low concentrations in their natural state (e.g., metals only in low concentrations in their ores)?

Details: Step 7, Evaluating the Impacts on Resource Conservation

Tabulate the types and quantities of resources consumed by each substitute and baseline technology. Use the tabulation to determine if use of a substitute would result in a relative increase or decrease in overall resource consumption for similar categories of resources. The table may also be used to determine if renewable resources are being substituted for nonrenewable ones or if scarce resources are being substituted for resources in abundant supply. For the example above (see Table 8-3), Table 8-4 gives an example format for tabulating consumption rates.

TABLE 8-4: EXAMPLE OF TABULATED RESOURCE CONSUMPTION DATA FOR ONE SUBSTITUTE

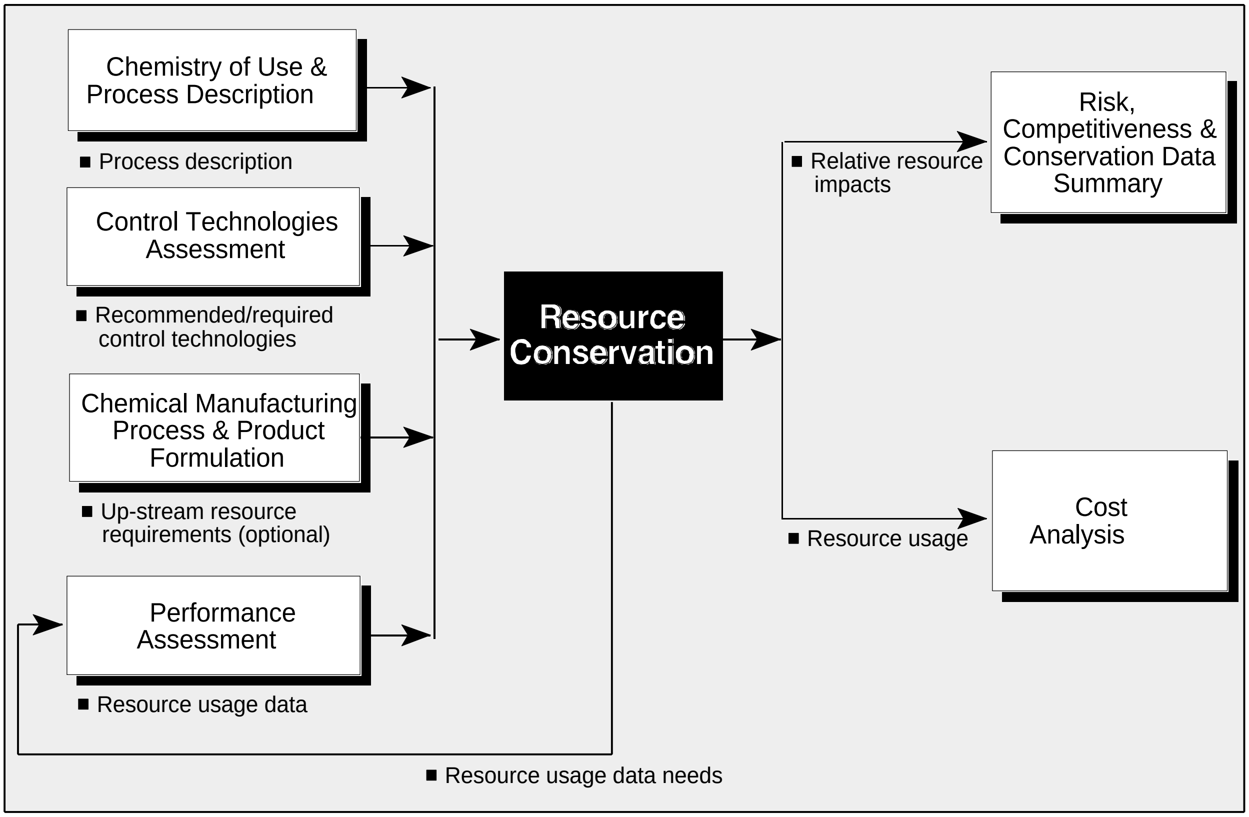
Process Step	Resource						
	Water	Chemical Product		Waste Product		Process Materials	
	Rate (gallons/hr)	Rate (lb/hr)	Renewable	Rate (lb/hr)	Renewable	Rate (amt/time)	Renewable
Step 1 - Cleaning	1	10	yes[a]	N/A	N/A	1 lb/shift	no
Step 2 - Rinsing	100	0	N/A	N/A	N/A	2 sets/yr	no
Step 3 - Waste Run	0	0	N/A	5	no	1 lb/shift	no
TOTAL	101	10	----	5	----	2 lb/shift of oil 2 sets equipment/yr	

N/A: Not applicable.

a) A citrus oil-based cleaner might be an example of a cleaner made from renewable ingredients. (However, petrochemicals are frequently used in the manufacture of chemicals made from vegetable products.)

FLOW OF INFORMATION: Data requirements for the Resource Conservation module are identified based on information from the Chemistry of Use & Process Description, Control Technologies Assessment, and Chemical Manufacturing Process & Product Formulation modules and collected in the Performance Assessment module. (The resource impacts of up-stream processes, such as chemical manufacturing and product formulation, could be collected from suppliers during a performance demonstration project. Up-stream resource conservation impacts have not been quantitatively evaluated in DfE pilot projects, however.) The Resource Conservation module transfers data to the Risk, Competitiveness & Conservation Data Summary and Cost Analysis modules. Example information flows are shown in Figure 8-2.

FIGURE 8-2: RESOURCE CONSERVATION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 8-5 presents published guidance on estimating the rates of resource consumption.

TABLE 8-5: PUBLISHED GUIDANCE ON ESTIMATING RESOURCE CONSUMPTION

Reference	Type of Guidance
Brown, Lisa, Ed. 1992. *Facility Pollution Prevention Guide.*	General methods for identifying and quantifying process materials consumption.
Dally, James W., et. al. 1984. *Instrumentation for Engineering Measurements.*	Methods for analyzing waste stream and raw material input quantities are discussed in cases where physical measurements are required.
Theodore, Louis and Young C. McGuinn. 1992. *Pollution Prevention.*	General description of process analysis.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 8-6 lists sources of data which may be useful in calculating resource consumption rates.

TABLE 8-6: SOURCES OF DATA ON RESOURCE CONSUMPTION RATES

Reference	Type of Data
Bolz, Ray E. and G.L. Tuve. 1970. *Handbook of Tables for Applied Engineering Science.*	Contains data which may be useful in analysis, such as material densities.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

Chapter 9

ADDITIONAL ENVIRONMENTAL IMPROVEMENT OPPORTUNITIES

This chapter presents module descriptions for identifying additional environmental improvement opportunities, including the following modules:

- Pollution Prevention Opportunities Assessment.
- Control Technologies Assessment.

Pollution prevention involves changes in production, operating processes, or raw materials used to prevent or reduce pollution at the source. Although the entire CTSA process can be thought of as a means of evaluating pollution prevention opportunities, the Pollution Prevention Opportunities Assessment module involves assessing workplace practices and process conditions for pollution prevention opportunities above and beyond the use of a substitute. This assessment results in a specific list of suggested actions that could be taken to reduce or eliminate pollution for each of the alternatives.

The Control Technologies Assessment module involves an assessment of end-of-the-pipe treatment and disposal technologies for pollution generated for the alternatives. Control technologies are used to reduce the toxicity and/or volume of pollutants released. The information from this module can be used to identify available options that may be used for the evaluated process and substitutes.

Data from the Pollution Prevention Opportunities Assessment module do not necessarily flow into other modules in a CTSA. This module is intended to give individual businesses ideas for preventing pollution, regardless of which alternative they use. Recommended control technologies from the Control Technologies Assessment module may flow into the Cost Analysis module for costing, particularly if the controls are required by environmental regulation.

POLLUTION PREVENTION OPPORTUNITIES ASSESSMENT

OVERVIEW: Pollution prevention is the process of reducing or preventing pollution at the source through changes in production, operation, and materials use. Pollution prevention can result in reduced materials usage, pollution control, and liability costs. It can also help protect the environment and may reduce risks to worker health and safety.

The improved Pollution Prevention Opportunities Assessment module focusses on workplace practices and equipment (other than the substitutes being evaluated in a CTSA) that can be used to reduce pollution at the source. It also describes methods individual businesses can use to identify pollution prevention opportunities, which often apply to many or all of the substitutes being evaluated.

GOALS:

- Perform a pollution prevention opportunities assessment for the specific process under consideration.

- Arrive at a specific list of actions which can be implemented to prevent pollution.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of the process under review, including the types and amounts of chemicals used in the process; the sources, nature and quantity of waste streams; and process optimization techniques.

- Knowledge of waste tracking for the process under review, including access to records of rates of materials purchases and associated costs.

- Knowledge of federal, state, and local waste stream release reporting and historical waste disposal practices.

Within a business or DfE project team, the people who might supply these skills include a plant engineer, environmental engineer, line supervisor, line operator, or suppliers of chemicals or equipment.

DEFINITION OF TERMS:

Pollution Prevention: As defined in the Pollution Prevention Act of 1990, pollution prevention is the reduction in the amount or hazards of pollution at the source (see Source Reduction).

Recycling: In-process recovery of process material effluent, either on-site or off-site, which would otherwise become a solid waste, air emission, or a waste water stream.

Reuse: On-site recovery and subsequent introduction of a waste stream back into the process.

Source Reduction: As defined in the Pollution Prevention Act of 1990, any practice which: (1) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and (2) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants. Source reduction includes equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control.

Waste Management Hierarchy: National policy declared in the Pollution Prevention Act of 1990 which gives the following hierarchy to waste management, ordered from highest to lowest level of desirability:

- Pollution prevention at the source.
- Recycling in an environmentally safe manner.
- Treatment in an environmentally safe manner.
- Disposal or other release into the environment only as a last resort and in an environmentally safe manner.

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for conducting a pollution prevention opportunities assessment. Steps 6 and 7 of the methodology concern implementing pollution prevention opportunities which would normally be done by individual businesses outside of the CTSA process. These steps are presented here to emphasize the importance of following through on a pollution prevention program.

Since the overall CTSA mainly focuses on pollution prevention through process modifications, reformulation or redesign of products, and chemical substitution, the methodology presented here focuses on identifying equipment modifications and improved workplace practices to prevent pollution. Further methodology details for Steps 3 and 4 follow this section.

Step 1: Obtain the process flow diagram from the Chemistry of Use & Process Description Module. The process flow diagram from this module provides the framework to identify process input and output streams, including waste point sources.

Step 2: Review the Workplace Practices & Source Release Assessment module to identify the types and quantities of hazardous and non-hazardous releases to air, land, or water, and the workplace practices associated with these releases.

Step 3: Evaluate each of the sources of releases and the associated workplace practices identified in Step 2 for pollution prevention opportunities. The best results occur when all plant personnel are involved in discussions to identify pollution prevention opportunities. In addition, EPA and many state agencies have prepared industry-specific guides to pollution prevention. Many states also provide pollution prevention technical assistance to small- and medium-sized businesses.

Step 4: Evaluate each of the pollution prevention opportunities identified in Step 3 to set priorities for implementing a pollution prevention activity. Factors that could be considered include:

- Company priorities (e.g., for the elimination of a "problem" chemical such as an EPA-regulated solvent).
- Relative amounts of waste streams.
- Relative toxicity of waste streams.
- Percentage of an existing waste stream that would be prevented.
- Regulatory status of waste streams, both before and after a pollution prevention opportunity is implemented.
- Employee health (e.g., cancer risk) and safety (e.g., fire risk).
- Cost of waste steam management (e.g., treatment and disposal costs).
- Ease of implementation.
- Cost of implementation and payback period.
- Potential for waste stream recyclability or reuse.
- Potential for regulations that may phase out certain chemicals or processes.

Step 5: Prior to implementing pollution prevention opportunities, review federal, state, and local regulations relating to the waste stream(s) under consideration. The Regulatory Status module should have relevant information pertaining to existing wastes streams, but may not cover new waste streams or changes in waste stream characteristics that would result from implementing a pollution prevention measure. This step is needed to assure that pollution prevention measures do not result in a violation of existing regulations. For example, if a pollution prevention measure would result in a waste water discharge of a regulated substance beyond acceptable limits, the measure would have to be eliminated from further consideration. Measures that shift pollution from one media to another or create new waste streams are not typically considered to be pollution prevention, however.

Step 6: Develop a schedule for implementing technically and economically feasible pollution prevention opportunities. (Pollution prevention projects are usually more cost-effective than indicated by traditional costing methods that lump environmental compliance costs into an overhead cost factor and do not consider potential liability costs and less tangible benefits. See the Cost Analysis module for more details.)

Step 7: Conduct periodic, in-house audits to assess the effectiveness of the pollution prevention program and to identify new pollution prevention opportunities on a regular basis.

METHODOLOGY DETAILS: This section presents the methodology details for completing Steps 3 and 4. If necessary, additional information on conducting a pollution prevention opportunities assessment can be found in the published guidance.

Details: Step 3, Identifying Pollution Prevention Opportunities

Pollution Prevention through Improved Workplace Practices

Improved workplace practices that prevent pollution are often inexpensive and easy to implement, while offering almost immediate reduction of waste. The basic framework for pollution prevention through improved workplace practices involves:

- Raising employee awareness of pollution prevention benefits.
- Materials management and inventory control.
- Process improvement.
- Periodic in-house audits.

Raising employee awareness is the best way to get employees to actively participate in a pollution prevention program. Materials management and inventory control includes understanding how chemicals and materials flow through a facility to identify the best opportunities for pollution prevention. Process improvement through improved workplace practices includes reevaluating the day-to-day operations in a facility to identify good operator practices that prevent pollution. Finally, in-house audits are used to collect real-time data on the effectiveness of a pollution prevention program. This step gives both operators and managers the incentive to strive for continuous improvement.

Examples of process improvements through improved workplace practices include:

- Training operators in techniques to optimize the process (e.g., manual adjustment of pH levels to extend the life of a plating bath).
- Training of employees to not "overuse" materials (e.g., only using the amount needed to perform a particular task).
- Covering containers to reduce evaporative losses (e.g., covering solvent containers while not in use).
- Covering containers of chemicals between process steps to minimize contamination.
- Improved inventory control (e.g., using chemicals before the listed expiration date).
- Improved handling of materials (e.g., training of personnel to reduce spills and wastage of liquids and solids).
- Segregation of raw materials and waste streams.

Pollution Prevention through Equipment Modifications

Modifying equipment to prevent pollution is usually more complicated and costly than changes in workplace practices. However, substantial improvements in process operation can be achieved through equipment modifications that are not equipment, process or technology substitutions. For example, pollution prevention through equipment modification for a chemical reactor/chemical delivery system could include:

- Increasing reactor volume and monitoring residence time to obtain an increased product yield.
- Installing sample loops on product sampling purge line to return unused sample to the process.
- Using an adjustable applicator system to control the quantity and direction of a chemical product (e.g., cleaning agent, paint or coating, etc.) applied to a substrate.
- Installing a recirculation system to recirculate chemicals that are being discarded before they are completely spent.

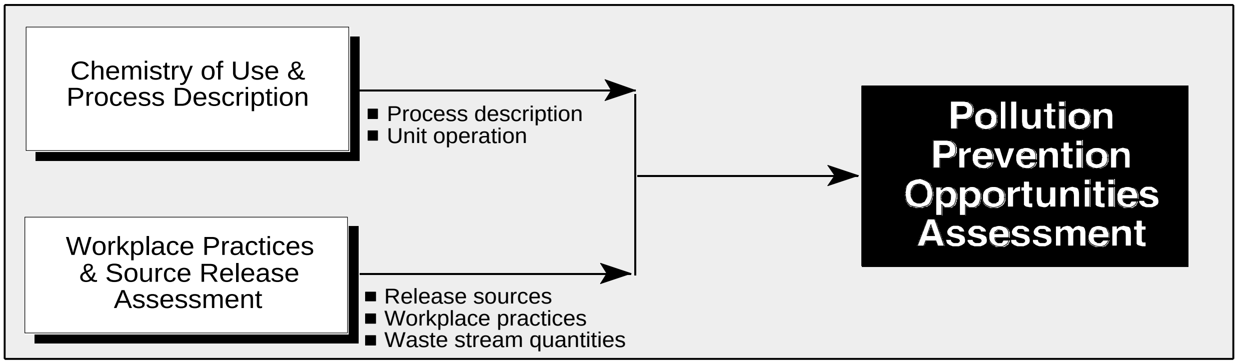
Details: Step 4, Setting Priorities

The percentage of a waste stream that would be prevented by a pollution prevention activity can be estimated based on:

- Knowledge of chemical reactions and mass and energy balance calculations.
- Professional judgement and process experience of the process specialist, waste manager, process operator and others familiar with the process.
- Data provided by vendors (e.g., chemical vendors).
- Data from published case studies of similar waste streams or facilities (see reference section).

FLOW OF INFORMATION: This module can be used alone to help identify pollution prevention opportunities in a commercial business or manufacturing facility. In a CTSA, this module receives data from the Chemistry of Use & Process Description and Workplace Practices & Source Release Assessment modules. Example information flows are shown in Figure 9-1.

FIGURE 9-1: POLLUTION PREVENTION OPPORTUNITIES ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 9-1 presents examples of published guidance on performing a pollution prevention opportunities assessment. Additional guidance can be obtained by contacting the U.S. Environmental Protection Agency's Pollution Prevention Information Clearinghouse at (202) 260-1023.

TABLE 9-1: PUBLISHED GUIDANCE ON PERFORMING POLLUTION PREVENTION OPPORTUNITIES ASSESSMENT

Reference	Type of Guidance
Brown, Lisa, Ed. 1992. *Facility Pollution Prevention Guide.*	Methods for performing assessments, ranking of pollution prevention options, and assessment of waste reduction benefits.
Freeman, Harry M. 1994. *Industrial Pollution Prevention Handbook.*	Technical reference on pollution prevention strategies and technologies.
Higgins, Thomas E. 1989. *Hazardous Waste Minimization Handbook.*	Outlines specific approaches to industrial pollution prevention.
Metcalf, Cam, Ed. 1991. *Waste Reduction Assessment and Technology Transfer Training Manual.*	Example of pollution prevention assistance provided by many states. Check with local state agencies for a state specific guide.
Theodore, Lewis and Young C. McGuinn. 1992. *Pollution Prevention*.	Outlines assessment procedures.
U.S. Environmental Protection Agency. 1992h. *Pollution Prevention Information Exchange System: User Guide Version 2.1*	Users guide on accessing online database and performing information searches.
U.S. Environmental Protection Agency. 1992i. *Pollution Prevention Case Studies Compendium.*	Case studies of pollution prevention assessments.
U.S. Environmental Protection Agency. 1992j. *Guide to Pollution Prevention: The Metal Finishing Industry*.	Provides pollution prevention guidelines for specific industries. Call EPA at (513) 569-7562 to obtain guides for other industries or processes.
U.S. Environmental Protection Agency. 1992k. *PIES. Pollution Prevention Information Exchange System*.	On-line data base containing a compilation of different types of pollution prevention data.
U.S. Environmental Protection Agency. 1994m. *Pollution Prevention Directory*.	Directory of U.S. pollution prevention sources.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

CONTROL TECHNOLOGIES ASSESSMENT

OVERVIEW: Control technologies can be used to minimize the toxicity and volume of released pollutants. Most control technologies involve altering either the physical or chemical characteristics of a waste stream to isolate, alter the concentration of, or destroy target chemicals. This module describes methods for identifying control technologies that may be suitable for on-site treatment and disposal of product or process waste streams.

GOALS:

- Identify treatment and disposal options for residual waste(s) remaining after the implementation of pollution prevention or waste minimization (including recycling) opportunities.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of materials, chemical properties, and available processes to ameliorate hazardous properties, including ability to guide the selection of control technologies based on specific waste stream chemical characteristics.

- Familiarity with the details of how chemicals are used in the process under consideration, including an understanding of the nature and amounts of waste streams requiring control technology application.

- Knowledge of environmental statutes, and regulatory requirements pertaining to environmental releases (e.g., water and air emissions), waste disposal requirements (e.g., landfilling), and the applicable control technologies.

Within a business or DfE project team, the people who might supply these skills include a plant engineer, environmental engineer, line supervisor, regulatory specialist, or suppliers of control technology equipment.

DEFINITION OF TERMS: The following definitions are compiled from EPA regulatory documents and the references listed in Table 9-3.

<u>Absorption:</u> A unit operation involving the removal of a substance from a gas by contacting the substance with a liquid into which the desired component dissolves. The rate of transfer of the desired material from the gas to the liquid is dependent on its concentration in the gas and the liquid, the mass transfer coefficients in each phase, the solubility of the material in the liquid, and the amount of gas-liquid interfacial area available. Typical examples of importance in pollution abatement are the removal of sulfur dioxide from stack gases by absorption with alkaline

solutions and the absorption of carbon dioxide from combustion products into aqueous amine solutions.

Best Available Control Technology (BACT): A term applied to control technologies required under the Clean Air Act and its amendments for certain air releases from major new sources depending upon the class of attainment area. EPA determines BACT requirements by: (1) identifying all control technologies; (2) eliminating technically infeasible options; (3) ranking remaining control options by effectiveness; (4) evaluating the most effective controls and documenting results; and (5) selecting BACT.

Best Available Control Technology Economically Practical (BAT): A term applied to technology-based effluent limitations required under the Clean Water Act for certain water releases from existing sources. More recently-issued permits are likely to require compliance with BAT standards, which are usually more stringent than BPT standards.

Best Conventional Pollution Control Technology (BCT): A term applied to technology-based effluent limitations required under the Clean Water Act for water releases of conventional pollutants (e.g., oil and grease, fecal coliform, biochemical oxygen demand, total suspended solids, pH) from certain existing sources.

Best Practicable Control Technology Currently Available (BPT): A term applied to technology-based effluent limitations required under the Clean Water Act for certain water releases from existing sources.

Carbon Adsorption: Adsorption is the accumulation of a substance at the interface between two phases. In carbon adsorption, gases, liquids or solutes sorb onto the surface of activated carbon. Carbon adsorption is most frequently used for VOC abatement.

Chemical Oxidation/Reduction Reactions: Those reactions in which electrons are transferred from one chemical species to another, resulting in the oxidation state of one reactant being raised, while the oxidation state of the other reactant is lowered. When electrons are removed from an ion, atom, or molecule, the substance is oxidized; when electrons are added to a substance, it is reduced.

Chemical Precipitation: A process by which a soluble substance is converted to an insoluble form either by a chemical reaction or by changes in the composition of the solvent to diminish the solubility of the substance in it. The precipitated solids can then be removed by settling and/or filtration.

Disposal: Defined by the Resource Conservation and Recovery Act (RCRA) as the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwater.

Electrodialysis: Process to remove ions from water by forcing their migration through a membrane with an electric field.

Electrolytic Recovery: The use of ion-selective membranes and an electric field to separate anions and cations in solution, used primarily for the recovery of metals from process streams or waste waters.

Evaporation: The conversion of a liquid into vapor. In waste treatment, evaporation involves the vaporization of a liquid from a solution or a slurry. Evaporation is commonly used for the removal of water from sludges.

Filtration: A method for separating solid particles from a fluid of liquid or gas, through the use of a porous medium, that retains the particles as a separate phase or cake and allows the filtrate to pass through. The driving force in filtration is a pressure gradient, caused by gravity, centrifugal force, vacuum, or higher than atmospheric pressure.

Fluidized Bed Incineration: Process using a single refractory-lined combustion vessel and high-velocity air to either fluidize the bed (bubbling bed) or entrain the bed (circulation bed); primarily used for processing sludges or shredded solid materials.

Hazardous Air Pollutants (HAPs): A statutory list of designated chemicals deemed hazardous as defined by the Clean Air Act and its amendments.

Hyperfiltration: A method to separate ionic or organic components from water by limiting the size of membrane pores through which a contaminant can pass.

Incineration: The destruction of wastes by high temperature oxidation (e.g., burning). Liquid injection incineration is used for gases, liquids, and slurries, while rotary kilns are used for all types of wastes including solids.

Ion Exchange: A process where undesirable ions are removed from an aqueous waste stream via exchange with counterions associated with an interactive polymer resin matrix, well-suited to the detoxification of large flows of waste water containing relatively low levels of heavy-metal contaminants, such as those emanating from electroplating facilities.

Liquid Injection Incineration: A process where a pumpable liquid waste is burned directly in a burner (combustor) or injected into the flame zone or combustion zone of the incinerator chamber (furnace) via nozzles.

Lowest Achievable Emission Rate (LAER) Technology: A term applied to control technologies required under the Clean Air Act and its amendments for air releases from certain new sources in nonattainment areas. LAER is the most stringent emission limitation derived from either of the following: (1) the most stringent emission limitation contained in the implementation plan of any state for such class or category of source; or (2) the most stringent emission limitation achieved in practice by such class or category of source.

Maximum Achievable Control Technology (MACT): A term applied to control technologies required under the Clean Air Act and its amendments to achieve acceptable emission limits for HAPs (see above listing).

Membrane Separation: A process which separates a contaminant (solute) from a liquid phase (solvent, typically water) by the application of a semi-permeable membrane and includes reverse osmosis, ultrafiltration, hyperfiltration, and electrodialysis.

Molten Glass: A process which destroys and/or immobilizes hazardous wastes into a stable glass form. The final product is reduced in volume and mass by driving moisture from the waste permanently, destroying portions of the waste thermally, and consolidating the residuals into a dense glass and crystalline product.

Ozonation: The treatment of industrial waste or waste water using ozone (O_3) as an oxidizing agent.

Pyrolysis: The chemical decomposition or change brought about by heating in the absence of oxygen.

Reasonably Available Control Technology (RACT): The lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility. Applied to control technologies required under the Clean Air Act and its amendments for certain air releases from major existing sources in ozone non-attainment areas

Reverse Osmosis: A membrane-separation technique in which a semipermeable membrane allows water permeation while acting as a selective barrier to the passage of dissolved, colloidal, and particulate matter used to separate water from a feed stream containing inorganic ions.

Rotary Kiln: Equipment which provides a number of functions necessary for incineration. A rotary kiln provides for the conveyance and mixing of solids, provides a mechanism for heat exchange, serves as host vessel for chemical reactions, and provides a means of ducting the gases for further processing.

Sedimentation: The process by which particles are separated from a fluid of liquid or gas by gravitational forces acting on the particles. Sedimentation is often used in removal of solids from liquid sewage wastes.

Solidification: A treatment process in which materials are added to the waste to produce a solid. It may or may not involve a chemical bonding between the toxic contaminant and the additive.

Stabilization: A process (such as solidification or a chemical reaction to transform the toxic component to a new, nontoxic compound or substance) by which a waste is converted to a more chemically stable form.

Stripping: A physical unit operation in which dissolved molecules are transferred from a liquid into a flowing gas or vapor stream. The driving force for mass transfer is provided by the concentration gradient between the liquid and gas phases, with solute molecules moving from the liquid to the gas until equilibrium is reached. In *air stripping* processes, the moving gas is air, usually at ambient temperature and pressure, and the governing equilibrium relationship is Henry's Law Constant. In *steam stripping* processes, the moving gas is live steam, and the vapor-liquid equilibrium between water and the organic compound(s) is the key equilibrium relationship. Steam stripping is more widely applicable than air stripping because it can effectively remove less volatile or more soluble compounds.

Treatment: Defined by RCRA as any method, technique or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize it, or render it nonhazardous or less hazardous or to recover it, make it safer to transport, store, or dispose of, or amenable for recovery, storage, or volume reduction.

Ultrafiltration: The application of membranes to separate moderately high molecular weight solutes from aqueous solutions, primarily used to separate organic components from water according to the size (molecular weight) of the organic molecules.

APPROACH/METHODOLOGY: The following presents a summary of the technical approach or methodology for identifying potentially applicable control technologies for treating or controlling a waste stream. Methodology details for Steps 7 and 8 follow this section.

Step 1: Obtain a description of the unit operations and the process flow diagram for the baseline and substitutes from the Chemistry of Use & Process Description module.

Step 2: Review the Workplace Practices & Source Release Assessment module to identify the sources, nature and quantity of releases from the baseline and alternatives.

Step 3: Review the Regulatory Status module to identify any control technology requirements for the baseline and the substitutes. For example, air releases may be subject to the required use of MACT or BACT. Water releases may be subject to BAT or BPT control technology requirements.

Step 4: Use the results of Steps 1 through 3 to identify the waste streams, if any, that will be the subject of the control technologies assessment. If a regulatory requirement exists for certain waste streams generated by the baseline or the alternatives, it must be included as part of the process in the CTSA, with some exceptions. For example, if the CTSA is focussing on small businesses that are exempt from regulatory requirements due to the quantity of wastes or emissions they generate, it may not be necessary to include control technologies required for major sources.

Step 5: Obtain physical/chemical properties of the chemicals of concern in the waste streams identified in Step 4 from the Chemical Properties module.

Step 6: Obtain chemical fate properties (e.g., biodegradation data, biochemical oxygen demand, chemical oxygen demand, etc.) and treatability summaries for the chemicals of concern from the Environmental Fate Summary module.

Step 7: Characterize the waste streams identified in Step 4 to determine the concentrations of hazardous constituents and properties needing modification (e.g., acid neutralization) for treatment/disposal.

Step 8: Prepare a list of potential treatment processes or control technologies that provide the desired function (e.g., acid neutralization, removal of cyanides, etc.) while meeting regulatory requirements.

Step 9: Provide a list of candidate control technologies to the Cost Analysis module so that the cost of the controls can be estimated. It may also be necessary to provide this information to the Energy Impacts and Resource Conservation modules, particularly if the potential control technologies are energy-intensive or require treatment chemicals and/or water. Also provide the type of control and its removal efficiency (e.g., the amount of pollutants that it typically removes from a similar waste stream) to the Exposure Assessment module.

METHODOLOGY DETAILS: This section provides methodology details for completing Steps 7 and 8. If necessary, additional details on this and other steps can be found in the published guidance.

Details: Step 7, Characterizing Waste Streams

Table 9-2 gives examples of waste characteristics and the objectives of treating the waste.

TABLE 9-2: WASTE CHARACTERISTICS AND TREATMENT OBJECTIVES

Waste Characteristic	Treatment Objective
Corrosive	pH neutralization.
Flammable	Destroy active component.
Reactive	Consume active component in a controlled reaction.
Toxic	Destroy toxic constituents.
Bio-hazardous	Destroy biological hazard.

Details: Step 8, Identifying Potential Treatment Technologies

Figure 9-2 illustrates the applicability of broad classes of treatment technologies to certain types of waste streams.

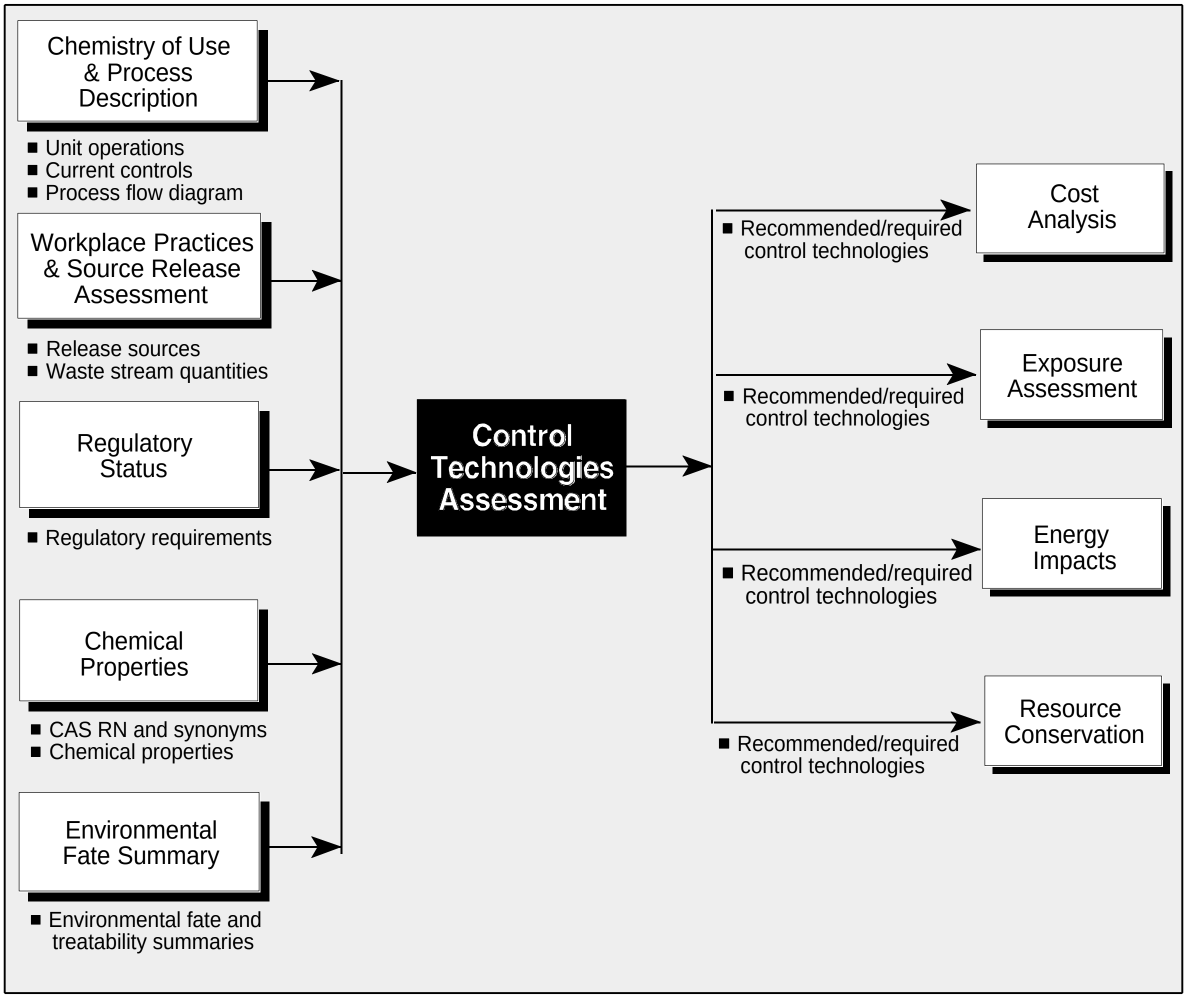
FIGURE 9-2: POTENTIAL TREATMENT TECHNOLOGIES BY TYPE OF WASTE STREAM

	Type of Waste Streams												Form of Waste		
Treatment Technology	Corrosives	Cyanides	Halogenated solvents	Nonhalogenated solvents	Chlorinated organics	Other organics	Oily wastes	PCBs	Aqueous with metals	Aqueous with organics	Reactives	Contaminated soils	Liquids	Solids/sludges	Gases
Separation/filtration		X	X	X	X	X			X	X			X		
Carbon adsorption									X	X	X		X		X
Air and stream stripping			X	X	X	X				X			X		
Electrolytic recovery									X				X		
Ion exchange	X								X	X			X		
Membranes									X	X			X		
Chemical precipitation	X												X		
Chemical oxidation/reduction		X								X			X		
Ozonation		X		X		X					X		X		X
Evaporation			X	X	X	X	X						X	X	
Solidification	X	X										X	X	X	
Liquid injection incineration			X	X	X	X	X						X		X
Rotary Kilns			X	X	X	X	X	X				X	X	X	X
Fluidized bed incineration			X	X	X	X	X	X				X	X	X	X
Pyrolysis			X	X	X	X						X	X	X	
Molten glass			X	X	X	X	X			X			X	X	X

Source: Freeman (1989).

FLOW OF INFORMATION: This module can be used alone to guide the selection of control technologies for treating or controlling waste streams in a facility. In a CTSA, this module receives data from the Chemistry of Use & Process Description, Workplace Practices & Source Release Assessment, Regulatory Status, Chemical Properties, and Environmental Fate Summary modules and transfers data to the Cost Analysis, Exposure Assessment, Energy Impacts, and Resource Conservation modules. Example information flows are shown in Figure 9-3.

FIGURE 9-3: CONTROL TECHNOLOGIES ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODULES: Various computer programs are available for either monitoring, controlling, or managing air emissions, water discharges, and hazardous wastes. Check with EPA Headquarters (Washington, D.C., 202-382-2080) or consult trade magazines for information on the software packages currently available.

PUBLISHED GUIDANCE: Table 9-3 presents references for published guidance on the selection of control technologies to mitigate waste releases.

TABLE 9-3: PUBLISHED GUIDANCE ON CONTROL TECHNOLOGIES ASSESSMENT

Reference	Type of Guidance
Freeman, Harry M. 1989. *Standard Handbook of Hazardous Waste Treatment and Disposal*.	Information on various treatment technologies for hazardous waste.
Masters, Gilbert M. 1991. *Introduction to Environmental Engineering and Science.*	Provides overview of treatment technologies for hazardous waste.
Reynolds, Tom D. 1996. *Unit Operations and Processes in Environmental Engineering.*	Information on the design of processes to treat industrial waste.
U.S. Environmental Protection Agency. 1987c. *A Compendium of Technologies Used in the Treatment of Hazardous Wastes.*	Describes the various treatment technologies available for air, water, and land releases.
U.S. Environmental Protection Agency. 1990b. *Treatment Technologies.*	General information on treatment technologies for waste streams.
Walk, Kenneth and Cecil F. Warner. 1981. *Air Pollution, Its Origin and Control.*	Information on the regulatory aspects of air pollution and treatment methods to mitigate its impact.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

Chapter 10

CHOOSING AMONG ALTERNATIVES

This chapter presents the module descriptions for the final trade-off evaluations of a CTSA, including the following modules:

- Risk, Competitiveness & Conservation Data Summary.
- Social Benefits/Costs Assessment.
- Decision Information Summary.

First, data summaries are prepared in the Risk, Competitiveness & Conservation Data Summary module, including a discussion of the uncertainties in the data and, in some cases, the significance of results (e.g., whether the risk characterization indicates a "clear," "possible," or "negligible" level of concern for a substitute). These data summaries provide the basic information needed for an individual decision-maker to consider the private (internal) benefits and costs of implementing a substitute.

Next, the data summaries are transferred to the Social Benefits/Costs Assessment module to evaluate the net benefits or costs to society of implementing a substitute as compared to the baseline. This involves a qualitative assessment of health, recreation, productivity, and other social welfare issues including benefits or costs that cannot be quantified in monetary terms. Thus, the Social Benefits/Costs Assessment module provides information needed to assess the external benefits and costs of implementing a substitute.

The results of the Risk, Competitiveness & Conservation Data Summary and the Social Benefits/Costs Assessment modules are combined in the Decision Information Summary module to identify the overall advantages an disadvantages of the baseline and the substitutes from both an individual business perspective and a societal perspective. The Decision Information Summary mmodule does not make value judgements or recommendations. The actual decision of whether or not to implement a substitute is made outside of the CTSA process.

RISK, COMPETITIVENESS & CONSERVATION DATA SUMMARY

OVERVIEW: The Risk, Competitiveness & Conservation Data Summary module organizes data from the risk, competitiveness, and conservation components of a CTSA together with data from the Process Safety Assessment, Market Information, and International Information modules. Data organized in this module are transferred to the Social Benefits/Costs Assessment module for analysis of: (1) the benefits and costs to the individual of alternative choices (referred to as private benefits and costs); and (2) the benefits and costs to others who are affected by the choices (referred to as external benefits and costs). Data are also transferred to the Decision Information Summary module where they are combined with the results of the Social Benefits/Costs Assessment to identify the overall advantages and disadvantages of the baseline and the substitutes.

GOALS:

- Compile data on the baseline to serve as a basis of comparison when evaluating the trade-offs among risk, competitiveness, and conservation.
- Compile data on each of the substitutes to identify the trade-offs among risk, competitiveness, and conservation issues associated with a substitute.
- Compile information on the uncertainties in the data that should be considered in the decision-making process.
- Develop simplified, interpretive summaries of the data that note clear distinctions in trade-off issues of the substitutes as compared to the baseline.
- Transfer data to the Social Benefits/Costs Assessment and Decision Information Summary modules.

PEOPLE SKILLS: The Risk, Competitiveness & Conservation Data Summary module requires the people skills outlined in the previous module descriptions for the analytical components of a CTSA, as well as the people skills required for the Social Benefits/Costs Assessment module. Completing this module should be a joint effort by all members of a DfE project team. Knowledgeable personnel and technical experts who completed the analytical modules are needed to evaluate results and identify uncertainties in the information.

DEFINITION OF TERMS: None cited.

APPROACH/METHODOLOGY: The following presents a summary of a general approach for organizing the data compiled in a CTSA. Methodology details for Steps 10 and 12 follow this section.

Risk

Step 1: Obtain data on environmental releases and transfers of pollutants from the Survey of Workplace Practices & Source Release Assessment module. Note any assumptions, scientific judgements, and uncertainties in the data. The Exposure Assessment module analyzes modeled or measured environmental concentrations of pollutants to determine exposure levels, but other effects of emissions (e.g., a smokestack that deposits soot on someone's laundry) may be considered in the Social Benefits/Costs Assessment.

Step 2: Review the Exposure Assessment module to determine the potential for chemical exposure via the evaluated pathways (e.g., dermal, inhalation, ingestion). In past CTSAs, exposure potential has been used as an indicator of risk potential when toxicity data were not available. Note any assumptions, scientific judgements, and uncertainties included in the assessment.

Step 3: Obtain data on the human health and environmental risks of alternatives from the Risk Characterization module. Note any assumptions, scientific judgements, and uncertainties included in the assessment.

Step 4: Review the Process Safety Assessment module to determine if the baseline or alternatives pose particular process safety hazards. List special precautions or actions that may be required to mitigate safety hazards.

Competitiveness

Step 5: Review the Regulatory Status module to determine which alternatives are regulated by environmental statutes, including any bans or restrictions that may affect availability. Alternatives being banned or phased-out should have been eliminated from consideration when the Regulatory Status module was completed. However, other alternatives may be under consideration for a ban or phase-out.

Step 6: Obtain data on the relative performance of the substitutes as compared to existing performance standards or as compared to the baseline from the Performance Assessment module. Note any assumptions, judgements, or uncertainties that should be reported with the performance data.

Step 7: Obtain the costs of alternatives from the Cost Analysis module. Note the assumptions and types of costs (e.g., operating, capital, indirect, etc.) that are included in the cost figures.

Step 8: Review the Market Information and International Information modules to identify any current or anticipated problems with the supply of or demand for the substitutes. This can include supply shortfalls or international trade issues (e.g., taxes, tariffs, or prohibitions) that might limit the availability of a substitute.

Conservation

Step 9: Review the Energy Impacts and Resource Conservation modules for conservation data. Note alternatives that consume scarce resources or that are derived from nonrenewable resources.

Data Summaries and Data Transfer

Step 10: Construct data summary tables of the data obtained in Steps 1 through 9.

Step 11: Review the data for each alternative to determine the trade-off issues associated with any one substitute. Note changes in trends from the baseline to the substitutes (e.g., the baseline performs well, is cost-effective, but consumes large amounts of water and has a high potential for worker exposure; an alternative performs well, is expected to be cost-effective if supply/demand relationships stabilize; has reduced water consumption and potential for exposure as compared to the baseline).

Step 12: Using data from the baseline, trends among trade-offs identified in Step 11, and existing published guidance or data from modules describing the levels of concern for different parameters (e.g., risk assessment guidance on concerns for risk), develop simplified, interpretive summaries of the data that note clear distinctions in trade-off issues of a substitute as compared to the baseline.

Step 13: Transfer the risk, competitiveness, and conservation data summary information and any assumptions, judgements, or uncertainties that should be reported with the data to the Social Benefits/Costs Assessment and Decision Information Summary modules.

METHODOLOGY DETAILS: This section provides methodology details for completing Steps 10 and 12. In some cases, information on interpreting the significance of results can be found in the published guidance listed previously in other module descriptions.

Details: Steps 10 and 12, Constructing Data Summary Tables and Interpretive Summaries

In Step 10, relevant information from the CTSA can be structured in table, or matrix, format for ease of understanding. Data summaries that compare the substitutes to the baseline should be presented using some consistent unit of measure for each category. Table 10-1 is an example of a matrix that can be used to compare the impacts of alternatives on health and the environment. Data for the baseline and the alternatives should be included in the matrix. A DfE project team may show quantitative data in the matrices, or use symbols (e.g., "+" or "-") or text to illustrate the impacts of the alternatives as compared to the baseline. Note that impacts which are stronger than others can also be recognized (e.g., high, medium, or low positives or negatives).

TABLE 10-1: EXAMPLE MATRIX OF ENVIRONMENTAL RELEASE AND RISK-RELATED DATA

Alternative	On-site Releases[a]			Off-site Transfers[a]			Risk[b,d]			
	Air	Water	Land	POTW[c]	Hazardous Waste Disposal	Recycling	Worker		General	
							Exposed Population	Risk Characterization	Exposed Population	Risk Characterization
Baseline										
Alternative 1										

a) Data on environmental releases and transfers are obtained from the Survey of Workplace Practices & Source Release Assessment and the Exposure Assessment modules (environmental releases and transfers that must be modeled).

b) Risk data are obtained from the Risk Characterization module. Quantitative data included here could include individual or population cancer and non-cancer risk to workers and other exposed human populations, and risk to aquatic organisms. Qualitative data might include an assessment of the potential for exposure to the health and environmental hazards identified in the Human Health Hazards and Environmental Hazards Summary modules.

c) Publicly Owned Treatment Works.

d) Data on population sizes are obtained or can be developed from the Survey of Workplace Practices & Source Release Assessment and Exposure Assessment modules.

Table 10-2 is an example matrix for compiling conservation information. The cost of energy and other resources should have already been incorporated in the Cost Analysis module. However, it is important to note the rate of resource consumption, or choices that consume scarce resources or that are derived from nonrenewable resources.

TABLE 10-2: EXAMPLE MATRIX OF CONSERVATION INFORMATION[a]

Alternative	Energy Consumption[b]		Other Resources Consumption[c]		
	Natural gas (BTU/hr)	Electricity (kWh/day)	Water (gallons/day)	Chemical Product (gallons/yr)	Machine Oil (gallons/mo)
Baseline					
Alternative 1					
Alternative 2					

a) Resource data are usually collected in units of mass or volume per unit time (m/t or L^3/t). To convert to mass or volume per unit production, multiply by the reciprocal of the production rate (e.g., 10 Btu/hr x 1 hr/50 widgets = 0.2 Btu/widget).

b) Energy data are obtained from the Energy Impacts module.

c) Other resource data are obtained from the Resource Conservation module.

To the extent possible, data should be normalized to some consistent basis, preferably per unit production ($/widget, Btu/widget, No. of product rejects/widgets produced, etc.). Normalization allows the baseline and substitutes to be compared directly. The following discusses the data summaries in more detail.

Exposure Potential and Health or Ecological Risk. The exposure potential and risk associated with using the baseline or a substitute can be presented together, particularly since risk is a function of exposure potential. For each system, qualitative descriptors could be used to list the potential for dermal (skin), inhalation, and ingestion exposure as high (+++), moderate (++), or low (+). Below each exposure scenario would be listed the corresponding risk level. Concerns for risk could be categorized as "clear," "possible," negligible," or "not quantified."

"Clear" concern indicates an inadequate margin-of-safety according to generally accepted risk assessment standards for exposure to the chemicals in question (see the list of published guidance in the Risk Characterization module). "Possible" concerns indicate that the margin-of-safety is slightly less than desirable and may not afford adequate protection in some circumstances. "Negligible" concerns indicate that an adequate margin-of-safety exists for exposure to the chemicals in question under the expected conditions of use.

For some chemicals evaluated in a CTSA, there may be insufficient data to quantify the risk, and although the exposure potential may be well-characterized, the precise risk cannot be quantified; these risks should be listed as "not quantified." Categorizing of risk into concern levels should only be undertaken by someone with expertise in accepted risk assessment standards.

Regulatory Status. Highlight alternatives that have a clearly different regulatory status as compared to the baseline or other alternatives. These might include alternatives being banned or phased-out, alternatives with no VOC content, or alternatives that do not use or contain regulated toxic chemicals.

Process Safety. Briefly summarize the safety hazards associated with the baseline in general. Use qualitative descriptors to indicate if an alternative improves working conditions by reducing safety hazards or may negatively influence working conditions by introducing a new safety hazard (e.g., "+" for improved safety; "-" for reduced safety). Special precautions or actions required to mitigate additional safety hazards of alternatives should be listed.

Performance. If performance data were collected on more than one measure of performance, the data can be combined into one overall assessment of the relative performance of a substitute or listed separately. If a substitute performs well, but fails to meet some traditional performance measure (e.g., the brightness requirement of virgin paper), it may be necessary to assess the performance measure to determine if industry standards are changing in response to environmental or other concerns.

Cost. Cost data should be provided in terms of dollars per unit production or some other consistent unit. The categories of costs (e.g., capital, operating, maintenance, indirect, etc.) and any assumptions that are included in the cost data should be clearly documented.

Energy and Resource Consumption. The types of energy or other resources evaluated and any assumptions should be clearly documented. If the project team focusses on a particular category of resources (e.g., water usage), information should be provided on the reasons for concern about the resource (e.g., continuing usage of large amounts of water could limit the industry's potential for growth; reliance on a scarce resource creates societal burdens and limits growth potential; mandated restrictions on use are anticipated, etc.).

Market and International Information. Businesses need to be aware of any expected supply shortfalls or international conditions that could limit the availability of a substitute. This information should also be briefly summarized.

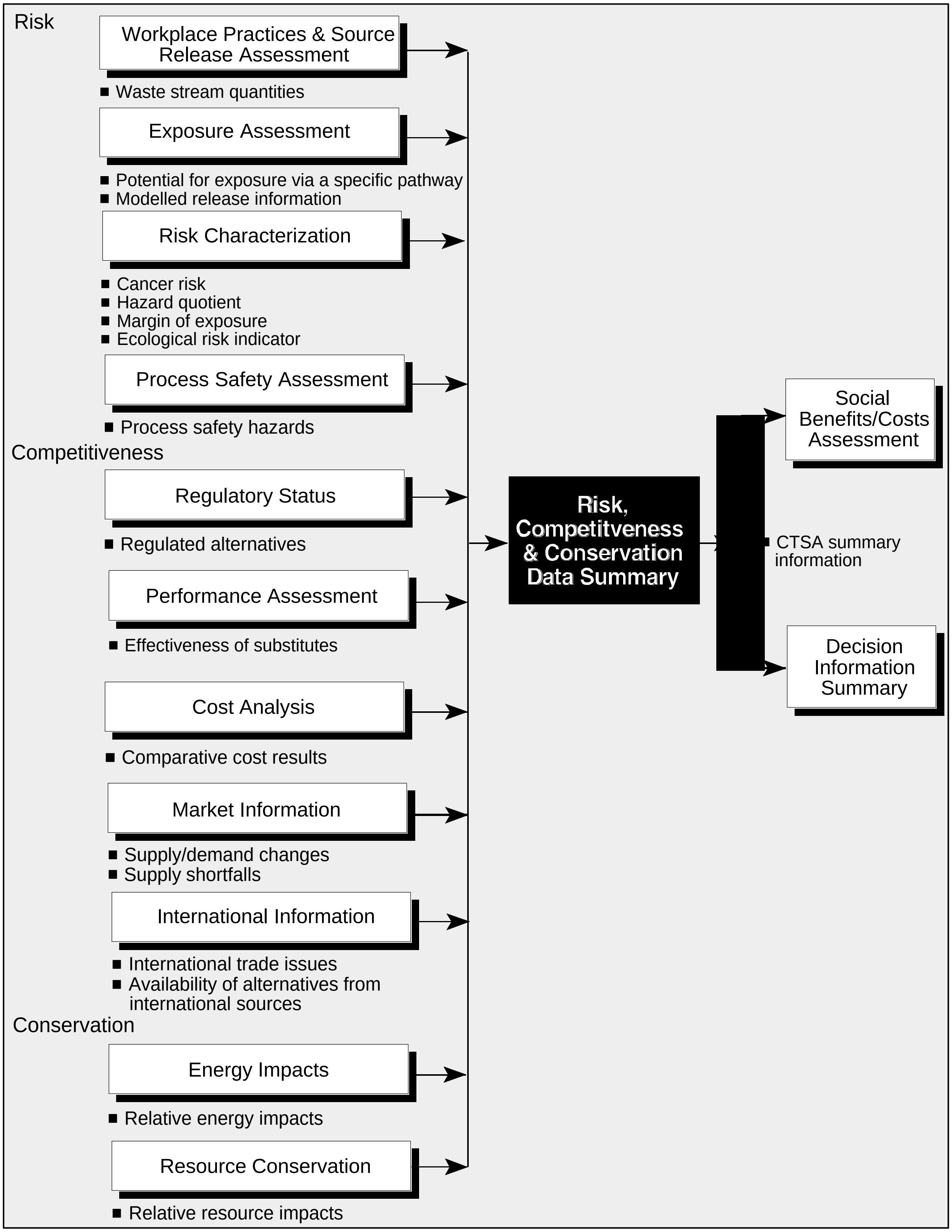
FLOW OF INFORMATION: This module summarizes the data on risk, competitiveness, and conservation compiled throughout a CTSA. The data summaries should report the technical data compiled in a CTSA in an understandable manner that will assist individual decision-makers in the decision-making process. The Risk, Competitiveness & Conservation Data Summary module receives data from the Workplace Practices & Source Release Assessment, Exposure Assessment, Risk Characterization, Process Safety Assessment, Regulatory Status, Performance Assessment, Cost Analysis, Market Information, International Information, Energy Impacts, and Resource Conservation modules. It transfers data to the Social Benefits/Costs Assessment and Decision Information Summary modules. Example information flows are shown in Figure 10-1.

ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: None cited.

DATA SOURCES: None cited.

FIGURE 10-1: RISK, COMPETITIVENESS & CONSERVATION DATA SUMMARY MODULE: EXAMPLE INFORMATION FLOWS



SOCIAL BENEFITS/COSTS ASSESSMENT

OVERVIEW: Policy makers decide on policies for society in part by utilizing social benefits/costs assessment to evaluate the impact of those decisions on others. Social benefits/costs assessment is the process of systematically evaluating the impacts made on all of society by individual decisions. It includes the benefits and costs to the individual of alternative choices (referred to as private benefits and costs) and the benefits and costs to others who are affected by the choices (referred to as external benefits and costs). Public decision-makers utilize social benefits/costs assessment to choose the best alternative among several options. Benefits are determined by the differences in risks between the baseline system or product and the alternative; costs are determined by the differences in the costs of using the alternative system versus the baseline. The criterion is to choose the alternative with the largest net benefits, i.e., the alternative with the largest positive difference between benefits and costs. Social benefits/costs assessment is important because it provides a complete view of the effects of alternative choices regarding pollution, allowing the policy maker to make choices based upon both private and external benefits and costs.

In a free market economy, firms typically make decisions based upon the knowledge at hand in order to maximize profits. However, this is often without full knowledge of the effects of those decisions on others. Private effects could include changes in worker productivity, worker compensation claims, liability claims, hazardous waste disposal costs, costs of meeting regulatory requirements, and sales due to negative or positive publicity. External effects include the effects of pollution on health, recreation, and productivity, which ultimately can impact publicity (related to sales and good will) and liability. By considering these effects, social benefits/costs assessment can be used by industry to improve the outcome of decision-making for a business and for society as a whole. Further information on the relevance of social benefits/costs assessment can be found in the Methodology Details section of this module.

GOALS:

- Describe expected private and external benefits of the alternatives relative to the baseline, including any beneficial effects that cannot be quantified in monetary terms and the identify of those likely to receive the benefit.

- Describe expected private and external costs of the alternatives relative to the baseline, including any adverse effects that cannot be quantified in monetary terms and the identify of those likely to bear the costs.

- Determine the potential net benefits (benefits minus costs) of the alternatives as compared to the baseline, including an evaluation of effects that cannot be quantified in monetary terms.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of social benefits/costs assessment of human health and environmental risk management options.

Within a business or DfE project team, the people who might supply these skills include an economist or a policy analyst.

DEFINITION OF TERMS:

<u>Benefit</u>: A benefit is the value to society of a good or service. From a firm's perspective, the benefit of a good or service can be measured by the revenue the firm receives from its sales as compared to the costs incurred when producing its products. From the consumer's perspective, the benefit can be measured by what the consumer would be willing to pay for the good or service. Some goods and services, such as environmental amenities and health risk reductions, are not generally for sale in a market economy. However, these goods and services do provide benefits to society which should be recognized. Economists attempt to estimate the value of these goods and services through various nonmarket valuation methods, which are briefly described in the Methodology Details section below.

<u>Direct Medical Costs</u>: Costs associated specifically with the identification and treatment of a disease or illness (e.g., costs of visits to the doctor, hospital costs, costs of drugs).

<u>Discounting</u>: Economic analysis procedure by which monetary valuations of benefits and/or costs occurring at different times are converted into <u>present values</u> which can be directly compared to one another.

<u>Exposed Population</u>: The estimated number of people from the general public or a specific population group who are exposed to a chemical, process, and/or technology. The general public could be exposed to a chemical through wide dispersion of a chemical in the environment (e.g., DDT). A specific population group could be exposed to a chemical due to its physical proximity to a manufacturing facility (e.g., residents who live near a facility using a chemical), through the use of the chemical or a product containing a chemical, or through other means.

<u>Exposed Worker Population</u>: The estimated number of employees in an industry exposed to the chemical, process, and/or technology under consideration. This number may be based on market share data as well as estimations of the number of facilities and the number of employees in each facility associated with the chemical, process, and/or technology under consideration.

<u>Externality</u>: A cost or benefit that involves a third party who is not a part of a market transaction; "a direct effect on another's profit or welfare arising as an incidental by-product of some other person's or firm's legitimate activity" (Mishan, 1976). The term "externality" is a general term which can refer to either <u>external benefits</u> or <u>external costs</u>.

External Benefits: A positive effect on a third party who is not part of a market transaction. For example, if an educational program (i.e., a smoking-cessation class) results in behavioral changes which reduce the exposure of a population group to a disease (i.e., lung cancer), then an external benefit is experienced by those members of the group who did not participate in the educational program (i.e., those inhaling second-hand smoke). External benefits also occur when environmental improvements enhance enjoyment of recreational activities (e.g., swimming, hiking, etc.).

External Costs: A negative effect on a third party who is not part of a market transaction. For example, if a steel mill emits waste into a river which poisons the fish in a nearby fishery, the fishery experiences an external cost to restock as a consequence of the steel production. Other examples of external costs are the effects of second-hand smoke on nonsmokers, increasing the incidence of respiratory distress, and a smokestack which deposits soot on someone's laundry, thereby incurring costs of relaundering.

Human Health Benefits: Reduced health risks to workers in an industry or business as well as to the general public as a result of switching to less toxic or less hazardous chemicals, processes, and/or technologies. An example would be switching to a less volatile chemical or a new method of storing or using a volatile, hazardous chemical, to reduce the amount of volatilization, thereby lessening worker inhalation exposures as well as decreasing the formation of photochemical smog in the ambient air.

Human Health Costs: The cost of adverse human health effects associated with production, consumption and disposal of a firm's product. An example is the cost to individuals and society of the respiratory effects caused by stack emissions, which can be quantified by analyzing the resulting costs of health care and the reduction in life expectancy, as well as the lost wages as a result of being unable to work.

Illness Costs: A financial term referring to the liability and health care insurance costs a company must pay to protect itself against injury or disability to its workers or other affected individuals. These costs are known as illness benefits to the affected individual. Appendix J summarizes several cost of illness valuation methods.

Indirect Medical Costs: Indirect medical costs associated with a disease or medical condition resulting from exposure to a chemical, product or technology. Examples would be the costs of decreased productivity of patients suffering a disability or death and the value of pain and suffering borne by the afflicted individual and/or family and friends.

Individual Risk: An estimate of the probability of an exposed individual experiencing an adverse effect, such as "1 in 1,000" (or 10^{-3}) risk of cancer.

Net Benefit: The difference between the benefits and the costs. For a company this could be interpreted as revenue - costs, assuming that the revenue and the costs are fully determined.

Opportunity Cost: A hidden or implied cost incurred due to the use of limited resources such that they are not available for an alternative use. For example, the use of specific laborers in the production of one product precludes their use in the production of another product. The opportunity cost to the firm of producing the first product is the lost profit from not producing the second. Another example would be a case where in hiring legal representation to respond to a lawsuit, and due to limited financial resources, a firm must cancel a planned expansion. The opportunity cost of responding to the lawsuit is the lost gain from not expanding.

Population Risk: An aggregate measure of the projected frequency of effects among all exposed people, such as "four cancer cases per year."

Present Value: The value in today's terms of a sum of money received in the future. Present Value is a concept which specifically recognizes the time value of money, i.e., the fact that $1 received today is not the same as $1 received in ten years time. Even if there is no inflation, $1 received today can be invested at a positive interest rate (say 5 percent), and can yield $1.63 in ten years; $1 received today is the same as $1.63 received ten years in the future. Alternately, the present value of $1 received in ten years is $0.61. The rate at which future receipts are converted into present value terms is called the discount rate (analogous to the interest rate given above). The formula for calculating present value is given in the Cost Analysis module.

Private (Internalized) Benefits: The direct gain received by industry or consumers from their actions in the marketplace. One example includes the revenue a firm obtains in the sale of a good or service. Another example is the satisfaction a consumer receives from consuming a good or service.

Private (Internalized) Costs: The direct negative effects incurred by industry or consumers from their actions in the marketplace. Examples include a firm's cost of raw materials and labor, a firm's costs of complying with environmental regulations, or the cost to a consumer of purchasing a product.

Social Benefit: The total benefit of an activity that society receives, i.e., the sum of the private benefits and the external benefits. For example, if a new product prevents pollution (e.g., reduced waste in production or consumption of the product), then the total benefit to society of the new product is the sum of the private benefit (value of the product that is reflected in the marketplace) and the external benefit (benefit society receives from reduced waste).

Social Cost: The total cost of an activity that is imposed on society. Social costs are the sum of the private costs and the external costs. Therefore, in the example of the steel mill, social costs of steel production are the sum of all private costs (e.g., raw material and labor costs) and the sum of all external costs (e.g., the costs associated with replacing the poisoned fish).

Willingness-to-Pay: Estimates used in benefits valuation intended to encompass the full value of avoiding a health or environmental effect, which are often not observable in the marketplace. For human health effects, the components of willingness-to-pay include the value of avoided pain and suffering, impacts on the quality of life, costs of medical treatment, loss of income, and, in the case of mortality, the value of a statistical life.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for conducting a social benefits/costs assessment. This should be used as a general guideline. After completing this procedure, it will be possible to compare the baseline with the alternatives for both private and external benefits and costs. It should be recognized that not all benefits may be quantifiable, but they should still be considered in a qualitative manner. Further information on the relevance of and framework for quantitative social benefits/costs analysis and methodology details for Steps 7 through 11 follow this section. Appendix I presents the social benefits/costs assessment from the Lithography CTSA.

Step 1: Obtain risk, competitiveness, and conservation data summary information, including interpretive data summaries, from the Risk, Competitiveness & Conservation Data Summary module. The risk summary information may include data on environmental releases and transfers of pollutants, chemical exposure levels, health and environmental risks from toxic chemical exposure, and process safety information. The competitiveness summary information may include information on the regulatory status of chemicals, performance data, cost data, as well as market information and international information related to the availability of a substitute. The conservation data summary typically describes energy impacts and effects on resource conservation.

Step 2: From the competitiveness summary, eliminate any alternatives that exhibited clearly unacceptable performance or that are banned or being phased-out. Keep in mind that there may be a variety of reasons that an alternative did not work (e.g., standards that are more stringent than necessary, worker apprehension, or misuse of the alternative due to lack of familiarity), and that some of these conditions may change over time. For instance, recycled paper has become acceptable in many circumstances even though it doesn't have the brightness attainable with virgin feedstock.

Step 3: Review data in the risk summary on the relative risk of alternatives, as compared to the baseline. This provides information necessary to determine both private and external effects. For instance, improving a worker's health may lead to fewer sick days and possibly a more productive employee and therefore provides private benefits. External benefits include the reduction in health care cost, which may lead to lower overall premiums. It may be necessary to review exposed population and release and transfer information included in the risk summary, particularly if chemical toxicity data were not available.

Step 4: Review data on the process safety hazards posed by the baseline and alternatives. This provides information about the relative safety of the various alternatives. Replacing a carcinogen with a fire hazard may or may not be appropriate.

Step 5: Review the rates of energy and natural resource consumption of the baseline and alternatives from the conservation summary. Differences in operating costs, which should incorporate the cost of energy and other resources, should have already been incorporated in the Cost Analysis module. However, it is important to note choices that consume scarce resources or that are derived from nonrenewable resources, as conservation of those resources could play an important role. In addition, as scare resources are used, there is a potential for them to become more costly.

Step 6: Using quantitative risk characterization data from the risk summary, if available, quantify changes in individual or population risks as a result of implementing an alternative as compared to the baseline. Options that reduce risk provide the social benefit of reduced mortality and morbidity.

Step 7: For all of the data in the risk, competitiveness and conservation data summaries, identify other potential external effects (in addition to quantitative individual or population risk) of implementing an alternative as compared to the baseline. For examples of potential effects see the Methodology Details section, below.

Step 8: For each effect identified in Steps 3 through 7, identify which relate to private or external effects and the affected populations (e.g., workers at a facility, consumers using the finished product, persons fishing in the stream that receives pollutants, etc.). Some of this information will be summarized in the risk summary from the Risk, Competitiveness & Conservation Data Summary module.

Step 9: Evaluate the effects of each alternative compared to the baseline to determine if the effects are beneficial to society or create additional societal burdens. These effects would not necessarily be considered by firms in typical business planning. However, consideration of the effects of each alternative could eventually affect a firm's profitability in the long run by increasing employee productivity, lowering the potential for lawsuits, reducing the likelihood of regulation, or through other means. Keep in mind that the larger the societal effect, the greater the potential for future regulation.

Step 10: Compare the results of Step 9 to the results of the cost analysis, performance assessment, and other competitiveness data (regulatory status, market availability of a substitute, etc.) found in the competitiveness summary. For example, does the alternative increase or decrease private costs (e.g., capital costs, operating and maintenance costs)? Does the alternative perform as well as or better than the baseline, resulting in a product with increased societal value? Keep in mind that performance may be acceptable even if different from the baseline. (Recall the example about the acceptability of recycled paper given in Step 2.) Are there environmental regulations affecting the alternative? Is the supply of a substitute stable?

Step 11: Use the results of Steps 9 and 10 to qualitatively evaluate the net benefits or costs of the alternatives. For example, the value of reduced human health risks would most likely greatly exceed the value of slightly higher operating costs. To develop a quantitative estimate of net benefits or costs economists monetize benefits using the concepts of willingness-to-pay and discounting. There are many texts which describe various monetization techniques (see sections on analytical models and published guidance for references on quantitative social benefits/costs analysis). The Cost Analysis module gives the formula for calculating present value.

Step 12: Transfer the results of the Social Benefits/Costs Assessment to the Decision Information Summary module.

METHODOLOGY DETAILS: This section presents further information on the relevance of and framework for social benefits/costs analysis and provides methodology details for completing Steps 7 through 11. If necessary, additional information on this and other steps can be found in previously published guidance (see section on published guidance).

Relevance of Social Benefits/Costs Analysis

Imagine a pasture which is open for common use by cattle producers in a community. Every cow that grazes on the pasture represents additional revenue a producer can receive, with no additional cost to the producer for grazing. Therefore, with other costs held constant, each producer has an incentive to graze as many cows as possible on the pasture. Since every producer has the same incentive, the pasture can easily become overgrazed, resulting in the eventual destruction of the pasture and the elimination of the food supply for the cattle. There was no incentive for a single producer to constrain use of the common resource in order to preserve it, thereby resulting in the ruin of free pasturage for all.

A similar problem occurs with pollution. Each generator of waste may find it cheaper to emit wastes into the environment than to treat the wastes, or to use an alternative process which does not cause the wastes. However, with many generators of wastes, the ability of the environment to assimilate wastes becomes overwhelmed, and pollution results. Increases in pollution lead directly to reductions in the quality of life in the affected area.

The fundamental similarity in each case is that a resource is being used, but no recognition of the costs of its use is being acknowledged. If the resource were privately held, the owner would have the right to demand payment for the use of the resource and has an incentive to prevent use of the resource to the point of destruction. However, in many instances, private ownership is not feasible - for example, ownership rights of the air for assimilating emissions have not generally been established in market economies. Therefore, failure to recognize the costs of utilizing a resource will eventually lead to its overuse, and in some cases, its destruction.

The approach to solving this problem that has generally been used in the U.S. is for the government to assume responsibility for commonly held resources such as the air, and to impose limits on their use through the implementation of standards, technology requirements, and other policies. Social benefits/costs analysis is the means by which the services of these resource are valued in developing these policies. Social benefits/costs analysis also provides information to decision-makers about what levels of standards and what types of technology requirements would allow the most efficient use of commonly held resources. Companies can be proactive in their use of common resources and employ social benefits/costs analysis in making decisions about technology choices.

Framework for Social Benefits/Costs Analysis

Social benefits/costs analysis is widely used in government. Its function is to help decision-makers choose the policy option which is best from society's perspective among a choice of several alternative options. The criterion used is to choose the option which yields the greatest net benefit, i.e., the option for which the difference between social benefits and costs is the largest. Since benefits and costs are measured from a societal perspective, all the private and external effects are considered. Oftentimes it is easier to estimate the costs of policy alternatives than the benefits of those alternatives; information on such factors as the costs to business of new technology, the costs to consumers of higher prices, etc., is more readily available than information on the value of reduced health risks or the value of an endangered species.

Economists attempt to place a monetary value on benefits such as reduced health risks and environmental improvements for policy decision-making because monetizing benefits makes them easier to compare to costs, and therefore makes them less likely to be ignored. While monetization of benefits may likely be difficult for a DfE or other CTSA development team given resource limitations, a very brief overview of benefits estimation is given here to help convey the concept of social benefits/costs analysis. It is also given to assist those firms or industry groups that do have the resources to do quantitative social benefits/costs analysis, rather than the qualitative assessment that is the focus of this module.

The main methods economists use in valuing social benefits include travel cost techniques, hedonic pricing, and contingent valuation. These willingness-to-pay estimates are then used to estimate a total benefit to society of the potential improvement. Travel cost methods use an estimate of how much people actually spend on trips to environmental sites as the basis for calculating the value of benefits at those sites. Hedonic pricing methods use wage or price differentials to estimate market valuations of health risks on the job or environmental problems such as air pollution. Contingent valuation is a survey method in which individuals are asked what they would be willing to pay for health or environmental benefits, such as reduced health risk, improved air or water quality, or preservation of an endangered species.

The benefits estimation techniques described here are highly resource-intensive, and are not generally conducted in the EPA Office of Pollution Prevention and Toxics. Instead, economic literature reviews can provide information on existing studies, from which social benefits estimates can be drawn. However, if resources and information are too limited to conduct a quantitative analysis, then a qualitative analysis will provide useful information.

Cost analysis is conducted by identifying all the relevant inputs (e.g., labor, equipment, energy) to a production process, and placing a monetary value on the use of these inputs for a given production level or time period. The monetary value of the inputs is their price times the amount used in the process. In this way, performance is incorporated into the analysis. Price and use information can be obtained from supplier, industry associations, etc. The cost analysis is repeated for each alternative under consideration. All direct and indirect costs, including less tangible costs such as liability costs, should be included in the analysis.

Again, the importance of the social benefit/cost analysis is not to develop a precise numerical estimate of social benefits and costs, but to use a systematic form of analysis in order to identify the best alternative among a choice of several possible options. The quantitative following approach discussed in this module can be used when a project team has limited resources and/or limited information.

Details: Steps 7 through 11, Identifying and Evaluating Social Benefits and Costs

<u>External Effects of Pollution</u>

Recall that externalities are effects on third parties who are not part of a market transaction. Market economies do not implicitly have mechanisms which consider these effects. Failure to recognize external costs means that costs are being imposed on someone else. Legislative, administrative, or judicial remedies can often be imposed on perpetrators, therefore recognition of the external effects on others can be a proactive business decision. Freeman (1982) lists the following external effects of pollution:

Effects on Living Systems (Involving Biological Mechanisms)

1. Human health
    a. mortality
    b. morbidity
2. Economic productivity of ecological systems
    a. agriculture
    b. commercial fisheries
    c. forestry
3. Other ecological system effects impinging directly on human activities
    a. sports fishing
    b. hunting
    c. wildlife observation
    d. water-based recreation
    e. home gardening and landscaping
    f. commercial, institutional, public landscaping
4. Ecological system effects not directly impinging on humans
    a. species diversity
    b. ecosystem stability

Effects on Nonliving Systems

1. Producers
    - a. damages to materials, for example, corrosion
    - b. soiling
    - c. reduction in product quality
2. Households
    - a. damages to materials
    - b. soiling
3. Changes in weather and climate
4. Other
    - a. visibility
    - b. tranquility

In addition to the external effects of pollution from operating plants, externalities also occur from consumption of energy or nonrenewable resources. For example, economists say that energy is not priced optimally because the price does not reflect the value of the externalities that occur from energy production and use. A decrease in energy consumption will reduce these externalities, resulting in social benefits.

Evaluating the Effects of Alternatives on Society

Examples of the types of questions that could be asked in evaluating these effects are: Would the alternative avoid or mitigate illness or disease when compared to the baseline? Would the alternative reduce employee absence or turnover through the provision of a better workplace? Would the alternative improve air quality by decreasing the cumulative air emissions from the industry as a whole? Would the recreational value of streams and rivers be improved due to decreases in the environmental loading of pollutants from all businesses in the industry? Would the alternative decrease the cumulative hazardous waste from the industry, thus requiring less land for hazardous waste disposal? Note that some effects may have substantially stronger positives and negatives than others. This should be taken into consideration.

Developing Social Benefits and Costs Information

For the baseline and each alternative, the social (private and external) benefit and cost information should now be developed. This type of information can be identified from data reviewed in Steps 3 through 6 (obtained from the Risk, Competitiveness & Conservation Data Summary module), and from additional information obtained in Steps 7 through 10.

For an example of how to develop this information, suppose we are currently using a chemical in a production process (the baseline) which has the following concerns:

(1) It can cause both acute (for nausea) and chronic (for lung disease) worker health risks.

(2) It has a noxious odor both in the plant and in the surrounding area.

(3) It is a hazardous substance, and must be disposed of in a hazardous waste facility. This poses a threat of groundwater contamination by the landfill, and subsequent liability problems.
(4) Some of the chemical is released into waste water, and could be contributing to the reduced stock of gamefish in a nearby reservoir.

Alternative 1 is being considered which would avoid use of this chemical entirely, but it has the following problems:

(1) It would require investment in new equipment.
(2) It would utilize more energy, resulting in higher energy costs and an increase in emissions from energy production or consumption to the air.
(3) It is more labor intensive, leading to higher labor costs.
(4) It results in a slightly inferior final product.

From information contained in the risk, competitiveness and conservation data summaries, it is possible to say something, even if qualitative, about the impact on social benefits and costs from changing from the Baseline to Alternative 1. For example, the risk characterization summary should show that there are health concerns for acute and chronic conditions associated with the Baseline that do not exist with Alternative 1. The risk summary will also show that releases to waste water and transfers to landfills decline to zero with Alternative 1, but that releases to the air will increase. On and off-site odor information will also be contained in this table. From the conservation summary, data will show that Alternative 1 will utilize more energy than the Baseline. The Cost Analysis reviewed in Step 10 will show that Alternative 1 has higher equipment, labor, and energy costs, but lower hazardous waste costs than the Baseline. The Performance Assessment results reviewed in Step 2 will indicate that Alterative 1 yields a slightly inferior final product.

However, assessment of the social benefits and costs will demonstrate that this is just part of the story. Reductions in health risks in moving from the Baseline to Alternative 1 may reduce employee absence from illness, and therefore contribute to increased productivity, a private benefit to the firm. Another private benefit is the ability of the firm to market to environmentally concerned consumers. These consumers might try to avoid products made with the Baseline, or might be willing to pay a premium for products they consider to be "green." External benefits include reduced odor in the nearby vicinity of the plant, improved water quality in the reservoir, and reduced health risks to workers. Private costs associated with Alternative 1 are those costs which were identified in the Cost Analysis module, while external costs are associated with increased air emissions.

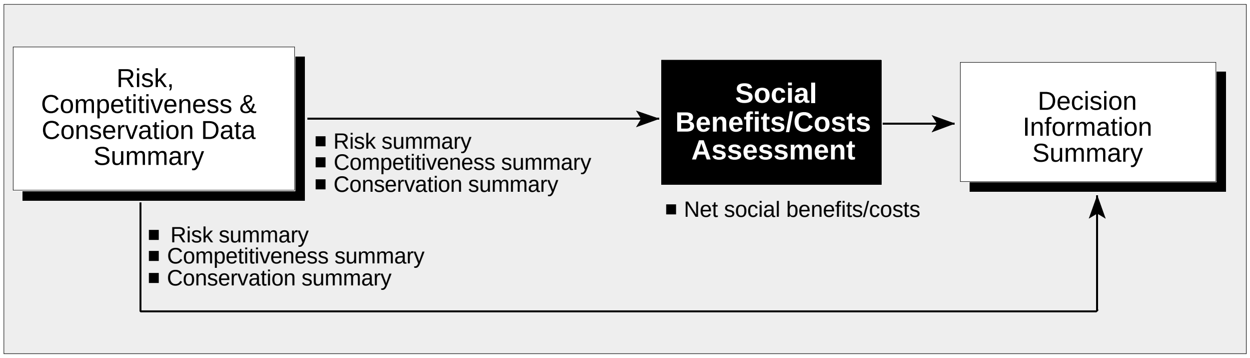
A table which illustrates the range of social benefits and costs can be constructed. Table 10-3 is a depiction of such a table. This table shows the social benefits and costs of Alternative 1 relative to the Baseline. Note that it may not be possible to identify either quantity or unit values for all of the items listed under type. As stated above, a review of economic literature might provide information, but generally resources may be too limited to provide monetary valuation of external benefits. A qualitative description should be included in that case. A problem with qualitative descriptions is the difficulty in weighing the benefits and costs - there is a tendency to ignore those benefits which are not quantified. It may be possible to get an idea of the magnitude of the qualitative description through the use of quantified aspects such as affected population size. For instance, it appears that the choice is clear in looking at benefits of $1,000 versus $50 per individual; however, if in the first case 5 individuals are affected and in the second 100 individuals are affected, the choices appear equal.

After compiling social benefits and costs information, the DfE team calculates the net benefits for each alternative. The net benefit is simply the difference between social benefits and costs. This information is then transferred to the Decision Information Summary module.

TABLE 10-3: BASELINE AND ALTERNATIVE 1: SOCIAL BENEFITS AND COSTS				
Type	**Unit**	**Quantity**	**Total Value (+, -, $)**	
			Baseline	**Alternative 1**
Benefits				
Private				
Employee productivity	$		Negative - Employees may be absent or ill on job	Positive - Fewer absences and more productive on job
Product quality	$	(Obtain from Performance Assessment)	Positive - Results in superior quality product	Negative - Inferior quality could lead to reduced sales
Odor within plant	Level (H, M, L)	(Obtain from Risk Characterization)	Negative - May cause absences, high turnover, poor morale	Positive - Reduced potential for sick days or employee turnover
Revenue from "green" consumers	$	(Obtain from Market Information)	None	Positive - May be able to sell to new consumers, or charge a higher price
External				
Health risk to workers	Worker lives saved	(Obtain from Risk Characterization)	Negative - Potential for employees to acquire lung disease	Positive - Workers less likely to suffer from lung disease
Odor outside plant	Level (H, M, L)	(Obtain from Risk Characterization)	Negative - Complaints from community	Positive - "goodwill" of community
Ambient water quality	ppm of chemical	(Obtain from Risk Characterization)	Negative - Potential source of reduced fish stocks	Positive - Possible increase in fish populations and more fishing
Potential for contamination in landfill	Level (H, M, L)	(Obtain from Risk Characterization)	Negative - Leaks could contaminate groundwater	None
Total Benefits				
Costs				
Private				
New equipment costs	$	(Obtain from Cost Analysis)	None	Positive - Must purchase new machinery
Hazardous waste disposal costs	$	(Obtain from Cost Analysis)	Positive - Must pay to dispose of chemical	None
Labor costs	$	(Obtain from Cost Analysis)	Positive	Positive - Higher than for Alpha
Energy costs	$	(Obtain from Cost Analysis)	Positive	Positive - Higher than for Alpha
Potential for liability claims	Expected value of damages	(Obtain from Cost Analysis)	Positive - High legal fees and damages if contamination event occurs	None
External				
Air emissions	Amount of particulate	(Obtain from Risk Characterization)	None	Positive - New technology causes air emissions
Total Costs				
Net Benefits				

FLOW OF INFORMATION: This module can be used to guide the selection and use of alternatives that produce societal benefits while optimizing performance and cost requirements. In a CTSA this module receives data from the Risk, Competitiveness & Conservation Data Summary module and transfers data to the Decision Information Summary module. Example information flows are shown in Figure 10-2.

FIGURE 10-2: SOCIAL BENEFITS/COSTS ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 10-4 lists references for applications of social benefits/costs assessment and Regulatory Impact Analyses prepared by EPA that can be used as analytical frameworks for performing social benefits/costs assessments of voluntary pollution prevention opportunities.

TABLE 10-4: ANALYTICAL MODELS

Reference	Type of Model
Arnold, Frank S. 1995. *Economic Analysis of Environmental Policy and Regulation.*	Presents a wide variety of practical applications of economics to environmental policies.
Augustyniak, Christine. 1989. *Regulatory Impact Analysis of Controls on Asbestos and Asbestos Products.*	Example of an application of benefit/cost analysis for regulatory decision-making.
Clark, L.H. 1987. *EPA's Use of Benefit-Cost Analysis 1981 - 1986.*	Discusses the contributions that benefit/cost analysis has made to EPA's regulatory process and examines the limitations of benefit/cost analysis.
U.S. Environmental Protection Agency. 1993c. *Review and Update of Burden and Cost Estimates for EPA's Toxic Release Inventory Program.*	Analysis to review and update estimates of the incremental burden and costs to industry and EPA developed for the 1990 Section 313 Information Collection Request established under the Emergency Planning and Community Right-to-know Act.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 10-5 lists sources of published guidance on social benefits/costs assessment.

TABLE 10-5: SOURCES OF SOCIAL BENEFITS/COSTS ASSESSMENT PUBLISHED GUIDANCE

Reference	Type of Guidance
Estes, Ralph W. 1976. *Corporate Social Accounting.*	Case study textbook. Provides an overview of social accounting as it has been and may be applied in corporations, government institutions, and non-corporate organizations.
Freeman, A. Myrick, III. 1979. *The Benefits of Environmental Improvement: Theory and Practice.*	Basic textbook. Technical review of application of economic tools and theory to social benefits/costs analysis.
Freeman, A. Myrick, III. 1982. *Air and Water Pollution Control: A Benefit-Cost Assessment*.	Case study textbook. Describes in layman's terms the term benefits and economist's methods for measuring benefits. Discusses tools available for social benefits/costs analysis and how they are being applied in practice.
Kneese, Allen V. 1984. *Measuring the Benefits of Clean Air and Water*.	Case study textbook of social benefits/costs analyses as applied to urban air pollution and rural and regional air and water pollution.
Mishan, E.J. 1976. *Cost-Benefit Analysis.*	Basic textbook. Theoretical discussion of environmental economics and the theory of social benefits/costs analysis.
Seneca, Joseph and M.K. Taussig. 1984. *Environmental Economics.*	Basic textbook. Introduction to environmental economics and the theory of social benefits/costs analysis.
Tietenberg, Tom. 1994. *Environmental Economics and Policy*.	Introduction to environmental economics and the theory of social benefits/costs analysis.
U.S. Environmental Protection Agency. 1983. *Guidelines for Performing Regulatory Impact Analysis*.	EPA guidelines for assessing benefits, analyzing costs, and evaluating benefits and costs.
U.S. Environmental Protection Agency. 1993d. *Guidance on the Preparation of Economic Analyses and Regulatory Impact Analysis in OPPT*.	EPA guidance for preparing economic analyses and Regulatory Impact Analyses in support of rulemakings under the Toxic Substances Control Act, the Emergency Planning and Community Right-to-Know Act, the Asbestos Hazard Emergency Response Act, and the Residential Lead-Based Paint Hazard Reduction Act.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

DECISION INFORMATION SUMMARY

OVERVIEW: The Decision Information Summary is the final module of a CTSA. It combines the results of the Risk, Competitiveness & Conservation Data Summary module with the Social Benefits/Costs Assessment module to identify the advantages and disadvantages of the baseline and the substitutes from both an individual business and a societal perspective. The Decision Information Summary module does not include value judgements or recommendations. Instead, the trade-off issues and uncertainty in the data are summarized to enable decision-makers to make decisions that incorporate their own circumstances, while considering the results of a CTSA. A key point is that decisions about whether or not to use an alternative are made outside of the CTSA process.

GOALS:

- Compile the results of the Risk, Competitiveness & Conservation Data Summary and the Social Benefits/Costs Assessment modules for the baseline and the substitutes.
- Compile information on the uncertainties in the data that should be considered in the decision-making process.
- Identify the trade-offs among risk, competitiveness, conservation, and social benefits/costs associated with the baseline and substitutes.

PEOPLE SKILLS: The Decision Information Summary module requires the skills outlined in the previous module descriptions for the analytical components of a CTSA. Knowledgeable personnel and technical experts who completed the analytical modules are needed to evaluate results and identify uncertainties in the information. Completing this module should be a joint effort by all members of a DfE project team.

DEFINITION OF TERMS: Several terms from the Exposure Assessment and Risk Characterization modules are used in the Decision Information Summary module. Refer to these modules for definitions.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for preparing a decision information summary. Methodology details for Steps 1, 2, and 3 follow this section.

Step 1: Obtain data summaries from the Risk, Competitiveness & Conservation Data Summary module. The data summaries should describe any assumptions, scientific judgements, and uncertainties in the data.

Step 2: Obtain information regarding the net social benefits/costs of the baseline and alternatives from the Social Benefits/Costs Assessment module. Note any assumptions, scientific judgements, and uncertainties included in the assessment.

Step 3: Identify other factors that an individual business might consider when choosing among alternatives. Consider these additional factors when listing uncertainties in the data that should be considered in the individual decision-making process. For example, workplace practices data from large facilities may not be representative of the types of workplace practices at smaller facilities.

Step 4: Review the data and uncertainties for each alternative to determine the trade-off issues associated with any one substitute from both an individual business and a societal perspective. Note changes in trends from the baseline to the substitutes (e.g., the baseline performs well, is cost-effective, but consumes large amounts of water and has a high potential for worker exposure; an alternative performs well, is expected to be cost-effective if supply/demand relationships stabilize; and has greater net social benefits due to reduced water consumption and potential for exposure as compared to the baseline).

Step 5: In addition to publishing the Decision Information Summary in a CTSA, provide results to the communications and implementation work groups of a DfE project team. These workgroups typically prepare CTSA summary brochures that present the CTSA results in a user-friendly format. (For more information on the roles of these work groups, see the companion publication, *Design for the Environment: Building Partnerships for Environmental Improvement* [EPA, 1995a].)

METHODOLOGY DETAILS: This section provides methodology details for completing Steps 1, 2, and 3. In some cases, information on interpreting the significance of results can be found in the published guidance listed previously in other module descriptions.

Details: Steps 1, 2, and 3, Identifying Uncertainties and Other Factors Important to Decision-Making

Identifying Uncertainties in the Risk Characterization

Because information for risk characterization comes from the Environmental Hazards Summary, Human Health Hazards Summary, and Exposure Assessment modules, an assessment of uncertainty should include the uncertainties in the hazard and exposure data. There is also the issue of compounded uncertainty; as uncertain data are combined in the assessment, uncertainties may be magnified in the process. EPA guidance documents (e.g., *Risk Assessment Guidance for Superfund* [EPA, 1989a]; "Guidelines for Exposure Assessment" [EPA, 1992a]) contain detailed descriptions of uncertainty assessment, and the reader is referred to these for further information.

Uncertainties in the hazard data could include:

- Uncertainties from use of quantitative structure-activity relationships (QSARs) for aquatic toxicity.
- Using dose-response data from high dose studies to predict effects that may occur at low levels.
- Using data from short-term studies to predict the effects of long-term exposures.
- Using dose-response data from laboratory animals to predict effects in humans.
- Using data from homogeneous populations of laboratory animals or healthy human populations to predict the effects on the general human population, with a wide range of sensitivities.
- Assuming 100 percent absorption of a dose when the actual absorption rate may be significantly lower.
- Using toxicological potency factors from studies with a different route of exposure than the one under evaluation.
- Effects of chemical mixtures (effects may be independent, additive, synergistic or antagonistic).
- Possible effects of substances not included because of a lack of toxicity data.
- Carcinogen weight-of-evidence classifications; for any chemicals assessed as carcinogens (described in the Human Health Hazards Summary module), the weight-of-evidence classification should be presented with any cancer risk results.

Uncertainties in the exposure data could include:

- Description of exposure setting - how well the typical facility used in the exposure assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been included because they are minor or proprietary ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgment.
- Uncertainty in combining pathways for an individual.

In the CTSA, uncertainty is typically addressed qualitatively. Variability in the exposure assessment is typically addressed through the use of exposure descriptors, which are discussed in the Exposure Assessment module.

Identifying Uncertainties in Performance and Cost Data

The Performance Assessment module is typically designed to evaluate characteristics of a technology's performance, not to define parameters of performance or to substitute for thorough on-site testing. Thus, performance demonstration projects conducted during CTSA pilot projects are intended to be a "snapshot" of a substitutes performance at actual operating facilities.

Similarly, the Cost Analysis module evaluates the average cost of a substitute at a "typical" or "model" facility using data collected from performance demonstration sites, the Workplace Practices & Source Release Assessment module, and other sources. Neither the Cost Analysis nor the Performance Demonstration are intended to yield absolute cost or performance information, but they do result in comparative information on the relative cost or performance of the baseline and substitutes.

Uncertainties in the Social Benefits/Costs Assessment

Due to time and resource constraints, the CTSA process utilizes a qualitative assessment of social benefits and costs that does not provide monetary valuation of external benefits. A problem with qualitative descriptions is the difficulty in weighing the benefits and costs - there is a tendency to ignore those benefits or costs that are not monetized. The project team members who perform the social benefits/costs assessment may illustrate the magnitude of a qualitative description through the use of quantified aspects such as affected population size. The Decision Information Summary module should contain both the qualitative and quantitative results of the Social Benefits/Costs Assessment. The importance of social benefits/costs assessment is not to develop a precise numerical estimate of social benefits and costs, but to recognize that these benefits and costs exist and use a systematic form of analysis to identify the best alternative(s) among a choice of several possible options.

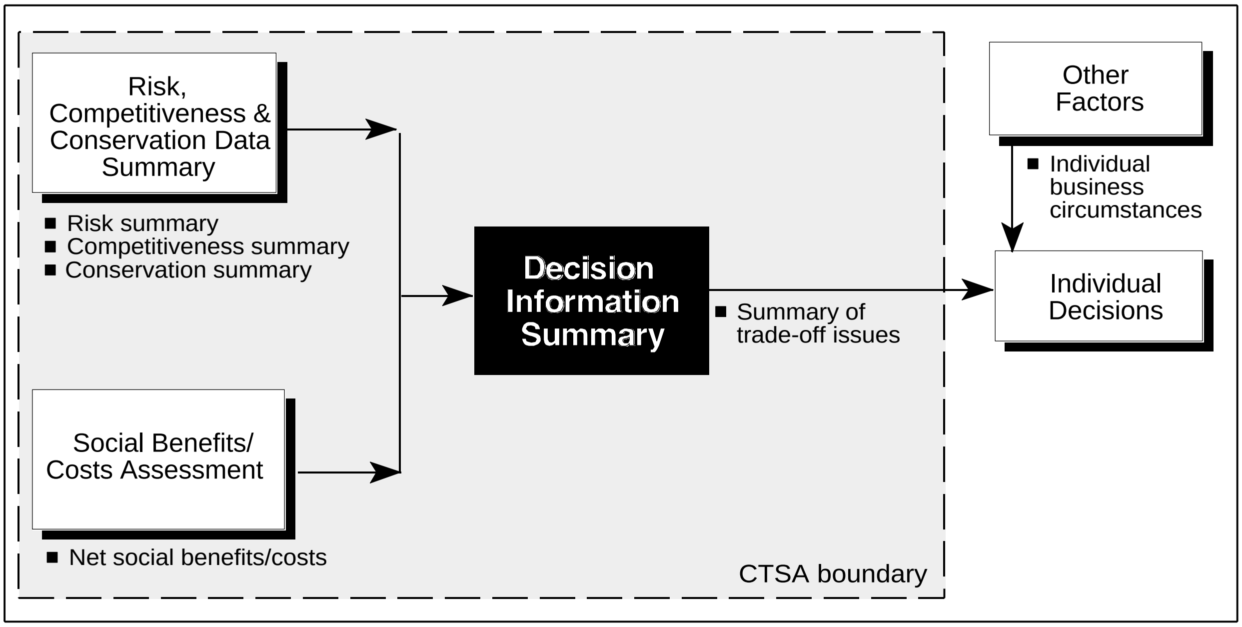
Other Factors Important to Decision-Making

A CTSA provides comparative information on the relative risk, performance, costs and resource conservation of alternatives to individual decision-makers, but actual decisions about whether or not to implement an alternative are made outside of the CTSA process. Individual decision-makers typically consider a number of other factors before deciding upon an alternative. A few examples of these other factors include the following:

- The individual business circumstances, including cultural and political circumstances.
- The position of the business within the overall market it serves (e.g., steady, growing, shrinking).
- The status of the overall market for the product being delivered, including the outlook for long-term growth.
- The availability of funds for capital investments, if required.

FLOW OF INFORMATION: The Decision Information Summary is the final module of a CTSA. It combines the results of the Risk, Competitiveness & Conservation Data Summary with the Social Benefits/Costs Assessment modules to identify the overall advantages and disadvantages of the baseline and the substitutes from both an individual decision-maker's perspective and a societal perspective. The actual decision of whether or not to implement an alternative is made by individual decision-makers outside of the CTSA process, who typically consider a number of other factors, such as their individual business circumstances, together with the information presented in a CTSA. The relationship of the CTSA process to the actual decision-making process and example information flows among the final modules of a CTSA are shown in Figure 10-3.p

FIGURE 10-3: DECISION INFORMATION SUMMARY MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: None cited.

DATA SOURCES: None cited.

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APPENDIX A

EXAMPLES OF WORKPLACE PRACTICES QUESTIONNAIRES

WORKPLACE PRACTICES QUESTIONNAIRE
FOR
SCREEN PRINTERS

Prepared by
Screen Printing Association International
in cooperation with
University of Tennessee
Center for Clean Products and Clean Technologies,
and EPA Design for the Environment Staff

This questionnaire is designed to characterize typical screen printing facilities and workplace practices associated with the screen printing/reclamation process. The results of the questionnaire will be used to estimate exposure and characterize risk from this process and to help identify pollution prevention opportunities. Pollution Prevention is the use of materials, processes, practices or products that avoid, reduce or eliminate wastes or toxic releases, through activities such as material substitution, source reduction and closed loop recycling. *This information is being developed for industry use to help printers make informed choices about the environmental attributes of alternative cleaning and reclamation products and technologies.*

Please mail completed questionnaires to:
Marcia Y. Kinter
Director of Government Affairs
Screen Printing Association International
10015 Main Street
Fairfax, VA 22031-3489

If you have questions about the questionnaire or would like a copy of the summary of results, please contact Lori Kincaid from the Center for Clean Products and Clean Technologies, University of Tennessee at 615/974-4251 (fax 615/974-1838).

Respondents to this questionnaire are guaranteed anonymity. Responses will not be attributed to any individual or company in reports or other written documentation of the results of this research. Company name and other information requested below are optional.

Company Name ____________________
Address ____________________
____
Questionnaire Completed by ____________________
Title ____________________
Telephone Number ____________________

The purpose of this questionnaire is to characterize typical screen printing facilities and workplace practices associated with the screen printing/reclamation process. The business profile and general facility information requested below allows us to understand your workplace practices within the context of your overall printing business.

1) **Business Profile**

Approximately what percentage of your products are printed on the following substrates? (Please check the boxes that apply.)

	<50%	50-95%	95-100%
Plastics (rigid/flexible)	☐	☐	☐
Paper (coated or uncoated)	☐	☐	☐
Metal	☐	☐	☐
Ceramic	☐	☐	☐
Glass	☐	☐	☐
Other (specify below)	☐	☐	☐
______________________________			

2) **Please list the major products produced at your facility.**

____

____

____

3) **General Facility Information**

How many staff do you employ? How many hours per day does your staff spend removing ink and cleaning/reclaiming screens? Ink removal is the removal of the bulk of the ink from the screens prior to further cleaning/reclamation. Screen cleaning/reclamation activities include residual ink removal, emulsion removal, and haze removal. Questions about ink removal do not pertain to press-side operations, unless this is the only site used for ink removal. Please assume a 5-day work week with one 8-hour shift each day. (Please check the boxes that apply.)

Number of Employees at this Location	Number of Employees Involved in Ink Removal	Number of Employees Involved in Screen Cleaning/Reclamation	Average time (hr/day) a single individual is involved w/ ink removal	Average time (hr/day) a single individual is involved w/ cleaning/reclaiming screens
0-5 ☐	1-3 ☐	1-3 ☐	<1 ☐	<1 ☐
6-10 ☐	4-6 ☐	4-6 ☐	1-2 ☐	1-2 ☐
11-15 ☐	7-10 ☐	7-10 ☐	2-4 ☐	2-4 ☐
16-30 ☐	>11 ☐	>11 ☐	4-6 ☐	4-6 ☐
31-50 ☐	specify ____	specify ____	6-8 ☐	6-8 ☐
>50 ☐			other ☐	other ☐

4) **Equipment and Materials Use**

A) _What types of and how much ink do you use in your printing processes? What do you use as a reducer/retarder? What is the primary substrate you use with each ink type? (Please check or list all that apply)

Type of Ink	Volume of Ink Used/Year[b] (gallons)	Type of Reducer/Retarder	Primary Substrate
Traditional solvent-based			Plastic ☐ Paper ☐ Metal ☐ Glass ☐ Ceramic ☐ Other (specify) ☐
UV Curable			Plastic ☐ Paper ☐ Metal ☐ Glass ☐ Ceramic ☐ Other (specify) ☐
Water-based		Water ☐ Solvent ☐ Water/Solvent Mixture ☐ (specify trade name)	Plastic ☐ Paper ☐ Metal ☐ Glass ☐ Ceramic ☐ Other (specify) ☐
Other (specify)[a]			Plastic ☐ Paper ☐ Metal ☐ Glass ☐ Ceramic ☐ Other (specify) ☐

[a] Other types of ink include metallic inks, etc.

[b] If you do not use a type of ink, enter "0"

The remaining questions are only in reference to solvent- or UV-based inks printed on plastic/vinyl substrates. If your facility does not primarily use these types of substrates or inks, please do not complete the rest of the questionnaire.

B) - What is the average number of screens cleaned/reclaimed each day for future use? (Please check the appropriate box)

☐ 0 - 5
☐ 5 -10
☐ 10 -15
☐ > -15
Specify ______

C) Please specify the average size of frame used at your facility? __________
(Please specify units; e.g. ft x ft or in x in, ect.)

D) Do you have separate areas for ink removal and screen reclamation activities? ☐ yes ☐ no
If yes, please check all that apply in the following table.

Separate areas for ink removal and screen cleaning/reclamation activities*			
Size of Ink Removal Area (ft^2)	Type of Ventilation	Size of Screen Reclamation Area (ft^2)	Type of Ventilation
<20 ☐	local (mechanical) ☐	<20 ☐	local (mechanical) ☐
20-50 ☐	plant (facility-wide) ☐	20-50 ☐	plant (facility-wide) ☐
50-100 ☐	natural ☐	50-100 ☐	natural ☐
100-200 ☐	other (specify below) ☐	100-200 ☐	other (specify) ☐
>200 ☐		>200 ☐	
Specify size _____		Specify size _____	

* Screen cleaning/reclamation activities include residual ink removal, emulsion removal, and haze removal.

E) Do you have a combined area for ink removal and screen reclamation? ☐ yes ☐ no
If yes, please check all that apply in the following table.

Combined area for ink removal and screen reclamation activities	
Size of Combined Area (ft2)	Type of Ventilation
<20 ☐	local (mechanical) ☐
20-50 ☐	plant (facility-wide) ☐
50-100 ☐	natural ☐
100-200 ☐	other (specify) ☐
>200 ☐	
Specify Size _____	

5) Ink Removal Procedures (NOT press-side/process cleaning)

A) If you recycle ink removal products in-house, how much material was recycled in 1992? ____________gal.

B) What ink removal products do you purchase? What type of personal protective equipment do you typically use when you remove ink? What are typical ink removal procedures at your facility? These questions do not apply to process cleaning (e.g., press-side operations such as ink removal before going to lunch.) (Please check all that apply.)

Ink Removal Product (Trade Name)	Annual Volume of Ink Removal Product Purchased (gallons)	Cost of Ink Removal Product ($/gallon)	Type of Ink with which Product Works Best	Personal Protective Equipment Used	Method of Applying Ink Removal Product	Equipment or Materials Used to Loosen Ink	Ave. No. of Rags Used Per Screen to Remove Ink
			Solvent-based ☐	Gloves ☐	Pour from container onto screen surface ☐	Brush ☐	0-2 ☐
			UV Curable ☐	Eye protection ☐	Dip rag or brush into container and wipe screen ☐	Squeegee ☐	2-4 ☐
			Either[a] ☐	Aprons ☐	Spray on with nozzle from tank ☐	Disposable Rag ☐	4-6 ☐
			Solvent-based ☐	Respiratory protection ☐	Spray on with spray bottle ☐	Reusable Rag ☐	6-8 ☐
			UV Curable ☐	Barrier Cream ☐	Use specialized spraying equipment (specify) ☐	Other (specify) ☐	8-10 ☐
			Either[a] ☐	None Used ☐	Other (specify) ☐		Other ☐
			Solvent-based ☐	Other (specify) ☐			(specify number____)
			UV Curable ☐				
			Either[a] ☐				

[a] e.g., ink removal product works equally well with either type of ink.

6) **Emulsion Removal Procedures**

A) What percent of the time do you use the following types of stencils?

	<50%	50-95%	95-100%	Are these dual cured?	
Direct photo stencils	☐	☐	☐	yes ☐	no ☐
Indirect photo stencils	☐	☐	☐	yes ☐	no ☐
Capillary film	☐	☐	☐	yes ☐	no ☐

B) What emulsion removal products do you use? What type of personal protective equipment do you typically use when you remove emulsion? What are typical emulsion removal procedures at your facility? (Please check all that apply.)

Emulsion Removal Product (Trade Name)	Annual Volume of Emulsion Removal Product Used (gallons)	Cost of Emulsion Removal Product ($/gallon)	Personal Protective Equipment Used	Method of Applying Emulsion Removal Product	Equipment or Materials Used to Remove Emulsion	Ave. No. of Rags Used Per Screen to Remove Emulsion
			Gloves ☐	Pour from container onto screen surface ☐	Brush ☐	0-2 ☐
			Eye protection ☐	Dip rag or brush into container and wipe screen ☐	Low-pressure Water-spray ☐	2-4 ☐
			Aprons ☐	Spray on with nozzle from tank ☐	High-pressure Water-spray ☐	4-6 ☐
			Respiratory protection ☐	Spray on with spray bottle ☐	Water-blaster ☐	6-8 ☐
			None Used ☐	Use specialized spraying equipment (specify) ☐	Automatic Screen Cleaning System ☐	8-10 ☐
			Other (specify) ☐	Other (specify) ☐	Disposable Rag ☐	Other ☐
					Reusable Rag ☐	(Specify number ______)
					Other (specify) ☐	

7) **Haze Removal Procedures**

A) Please complete the following chart if you use haze remover to remove ghost images.

Haze Removal Product (Trade Name)	Annual Volume of Haze Removal Product Used (gallons)	Cost of Haze Removal Product ($/gallon)	Percent of Time Haze Remover Used	Personal Protective Equipment Used	Method of Applying Haze Removal Product	Equipment or Materials Used to Remove Haze	Ave. No. of Rags Used Per Screen to Remove Haze
			0-5 ☐	Gloves ☐	Pour from container onto screen surface ☐	Brush ☐	0-2 ☐
			5-25 ☐	Eye protection ☐	Dip rag or brush into container and wipe screen ☐	Low-pressure Water-spray ☐	2-4 ☐
			25-50 ☐	Aprons ☐	Spray on with nozzle from tank ☐	High-pressure Water-spray ☐	4-6 ☐
			>50 ☐	Respiratory protection ☐	Spray on with spray bottle ☐	Water-blaster ☐	6-8 ☐
			(specify _____)	Barrier Cream ☐	Use specialized spraying equipment (specify) ☐	Squeegee ☐	8-10 ☐
				None Used ☐	Other (specify) ☐	Disposable Rag ☐	Other (specify) ☐
				Other (specify) ☐		Reusable Rag ☐	
						Other (specify) ☐	

8) Screen Cleaning/Reclamation Alternatives

A) Do you use a screen degreaser? ☐ yes ☐ no
Trade Name of Product ____________________

B) Do you use a separate ink degradant before applying emulsion remover? (Answer yes only if the ink degradant is different than the primary ink removal product)? ☐ yes ☐ no
Trade Name of Product ____________________

9) Materials Storage

A) Where do you store ink removal and screen reclamation products and in what quantity? (Please check all that apply.)

Ink Removal and Screen Cleaning Area(s)		Ink/Chemical Storage Room	
30- or 55-gallon drum with bung hole kept open	☐	30- or 55-gallon drum with bung hole kept open	☐
30- or 55-gallon drum with bung hole kept closed	☐	30- or 55-gallon drum with bung hole kept closed	☐
30- or 55-gallon drum with top removed	☐	30- or 55-gallon drum with top removed	☐
Open pail	☐	Open pail	☐
Closed pail	☐	Closed pail	☐
Quart or smaller squirt bottle	☐	Quart or smaller squirt bottle	☐
Safety can	☐	Safety can	☐
Safety cabinet	☐	Safety cabinet	☐
Not kept in the press room	☐	No separate storage area	☐
Other (specify below)	☐	Other (specify below)	☐
		Size of storage room	____ ft x ____

B) How do you retrieve ink removal and screen reclamation products from ink/chemical storage? If you keep both large and small containers in the ink removal and screen cleaning/reclamation areas, how do you transfer the products from large containe to small containers for use?

Retrieval from Storage Room		Transfer from Large to Small Container for Use	
Entire container moved to press room	☐	Pumped into small container used at work station	☐
Pumped into smaller container	☐	Poured into smaller container	☐
Poured into smaller container	☐	Ladled into smaller container	☐
Ladled into smaller container	☐	Other (specify below)	☐
Other (specify below)	☐		

10) Waste Disposal

A) Please indicate the quantity of waste you dispose of annually as <u>hazardous</u> waste for:

spent solvent waste __________ (Number of 55 gal. drums) OR __________ (gal. in bulk)

ink waste __________ (Number of 55 gal. drums) OR __________ (gal. in bulk)

used shop rag waste __________ (Number of 55 gal. drums) OR __________ (gal. in bulk)

B) What quantity of wastes from ink removal and screen cleaning/reclamation operations do you generate annually? How are these waste materials treated or disposed of? (<u>Please check all that apply</u>.)

Ink Removal Wastes			Screen Cleaning/Reclamation Wastes		
Quantity Generated Annually (gallons)	Method of Storage Prior to Treatment and/or Disposal	Method of Treatment or Disposal	Quantity Generated Annually	Method of Storage Prior to Treatment or Disposal	Method of Treatmen and/or Disposal
	In closed containers ☐	Filter or treat prior to disposal or recycle ☐		In open containers ☐	Filter or treat prior to disposal or recycle ☐
	In open containers ☐	Send to recycler ☐		In closed containers ☐	Discharge to sewer ☐
	No specified container ☐	Recycle on site ☐		No specified containers ☐	Discharge to septic tank ☐
	Other (specify) ☐	Discharge to sewer ☐		Other (specify) ☐	Hazardous Waste ☐
		Dispose as hazardous waste ☐			Non-Hazardous waste ☐
		Dispose as non-hazardous waste ☐			
		Other (specify) ☐			

C) How are waste rags contaminated with ink removal and screen cleaning/reclamation products stored, treated or dispose of? (Please check all that apply.)

Method of Storage Prior to Pretreatment or Disposal	Method of Pretreatment	Method of Recycle or Disposal
In open containers ☐	Centrifuge ☐	On-site water laundry ☐
In closed containers ☐	Allow liquid to drain out ☐	On-site dry cleaner ☐
No specified containers ☐	Other (specify) ☐	Off-site water laundry ☐
	None ☐	Off-site dry cleaner ☐
		Hazardous waste ☐
		Non-hazardous waste ☐
		Do not use rags ☐
		Other (specify) ☐

11) Pollution Prevention Opportunities

Please use the following table to describe the experiences at your facility with pollution prevention techniques. Pollution prevention is the use of materials, processes, practices or products that avoid, reduce or eliminate wastes or toxic releases, through activities such as toxic use reduction, source reduction, and closed loop recycling.

Do you have a pollution prevention, waste minimization, or source reduction program?		yes ☐ no ☐	If you answered yes, would you be willing to share a description of your program with the DFE Printing Project?	yes ☐ no ☐
Have you tried any different chemical products for environmental or worker safety reasons to replace your current ink removal or screen cleaning/reclamation products?		yes ☐ no ☐	If you answered yes, please list the product name:	
If you have tried a different chemical product, please check the box that best describes your experience with the product:[a]	Cleaner worked well: Cleaner was OK but not as good as old cleaner: Cleaner was not satisfactory: Other (please explain below):	☐ ☐ ☐ ☐	If you have not tried a different chemical product, please check the box that best describes your reason for not trying alternatives: Lack adequate information to evaluate environmental performance of alternatives: Operators do not believe alternatives will work: Not impressed with product descriptions: Cost is prohibitive: Other (please explain below):	 ☐ ☐ ☐ ☐ ☐
Besides different chemical products, have you implemented any changes in equipment ☐, products ☐, processes ☐, or work practices ☐ that reduced your use of ink removal or screen cleaning/reclamation products? (If you have implemented changes, please check all boxes that apply.)		yes ☐ no ☐	If you answered yes, would you be willing to share the changes with the DFE Printing Project?	yes ☐ no ☐

		increased	decreased	no change
If you have implemented changes that reduced your use of ink removal or screen cleaning/reclamation products, how have these changes affected:	materials cost:	☐	☐	☐
	time required to clean the screen:	☐	☐	☐
	disposal costs:	☐	☐	☐

If you should decide or have decided to implement changes in your screen cleaning/reclamation process to incorporate pollution prevention opportunities, which of the following factors would have the greatest priority in this decision? Please rank these factors from 1 to 6, with 1 indicating the highest priority.

______ cost
______ regulations
______ environmental hazard
______ performance
______ health hazard
______ other (specify

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[a] If you have tried more than one different chemical product, please fill out a copy of this section for each product.

IPC

WORKPLACE PRACTICES QUESTIONNAIRE FOR THE MAKING HOLES CONDUCTIVE PROCESS

DESIGN FOR THE ENVIRONMENT (DfE) PRINTED WIRING BOARD PROJECT

This document is prepared by the University of Tennessee Center For Clean Products and Clean Technologies in Partnership with U.S. EPA Design for the Environment (DfE) Program, IPC, PWB manufacturers, and other DfE Partners

March 1995

**Note: This survey is not as long as it looks since you will only complete a part of it. This survey has 7 sections; however, we ask you to complete only sections 1,2,3 and the section that pertains to your making holes conductive (MHC) process.*

WORKPLACE PRACTICES QUESTIONNAIRE FOR THE MAKING HOLES CONDUCTIVE PROCESS

Design for the Environment Project

PLEASE RETURN BY FRIDAY, MARCH 31, 1995 TO: IPC — ATTN: STAR SUMMERFIELD, 7380 N. LINCOLN AVENUE, LINCOLNWOOD, IL 60646-1705

DO NOT COMPLETE ALL SECTIONS OF THE QUESTIONNAIRE. The following explains which sections you should complete based on the type of making holes conductive (MHC) process used at your facility, provides background information on the questionnaire, and describes how the data will be handled to ensure confidentiality.

1. This questionnaire was prepared by the University of Tennessee Center for Clean Products and Clean Products in partnership with the EPA DfE Program, IPC, PWB manufacturers, and other members of the DfE PWB Industry Project.

2. For the purposes of this survey and the DfE Project, the "Making Holes Conductive (MHC)" process is defined as beginning after the desmear and etchback steps and ending prior to the dry film resist outer layer step (if required) and copper electroplating step.

3. Shaded sections of the questionnaire denote areas where responses to questions should be entered. Unshaded sections are instructions or keys required to answer the question.

4. Throughout the questionnaire, many questions request specific data, such as chemical volumes, the amount of water consumed by the MHC line or the characteristics of wastewater from the MHC line. If specific data are not readily available, estimates based on your knowledge of the process and the facility, are adequate. In cases where no data are available and there is no basis for an accurate estimate, mark your response as "ND."

5. Please complete sections 1 through 3 of the questionnaire, regardless of which process is used at your facility to make drilled through-holes conductive prior to electroplating.

6. After completing Sections 1 through 3, please complete only the section(s) of the survey that corresponds to the MHC process(es) currently being operated at your facility, as listed below.

Electroless Copper	Section 4
Graphite-based	Section 5
Carbon-based	Section 6
Palladium-based	Section 7

If the MHC process used at your facility is not listed, you have completed the questionnaire.

7. If your responses do not fit in the spaces provided, please photocopy the section to provide more space or use ordinary paper and mark the response with the section number to which it applies.

8. Appendix A contains the definitions of certain terms and acronyms used in the survey form.

9. **Confidentiality**
All information and data entered into this survey form are confidential. The sources of responses will not be known by IPC, University of Tennessee, EPA, or other project participants. Any use or publication of the data will not identify the names or locations of the respondent companies or the individuals completing the forms.

   Please use the following procedures to ensure confidentiality:

   (1) Complete the survey form. Make a copy of the completed form and retain it for your records.
   (2) Separate the facility and contact information page of the survey form from the remainder of the form. Place the facility and contact information into Envelope #1 and seal the envelope.
   (3) Place the remainder of the survey form plus any additional sheets or exposure monitoring data into Envelope #2 and seal it.
   (4) Place sealed Envelopes #1 and #2 into the larger return envelope and mail it to IPC.
   (5) When the package is received by IPC, only Envelope #1 will be opened. IPC will place a code number on the outside of Envelope #2 and forward it to the Center for Clean Products and Clean Technologies at the University of Tennessee. Envelope #1 will not be sent to the University of Tennessee.
   (6) Questions, clarifications, or requests for further information from the University of Tennessee will be relayed by code number to IPC, who will be able to contact the respondent. When it is determined that no further communications with respondents are necessary, the matrix of code numbers and respondents will be destroyed by IPC.

10. If you have any questions regarding the survey form, please contact Jack Geibig of the University of Tennessee Center for Clean Products and Clean Technologies at 615-974-6513 (e-mail: JGEIBIG@UTKVX.UTK.EDU).

PLEASE RETURN BY FRIDAY, MARCH 31, 1995 TO: IPC — ATTN: STAR SUMMERFIELD, 7380 N. LINCOLN AVENUE, LINCOLNWOOD, IL 60646-1705 (PH. 708/677-2850 ext. 347; FAX 708/677-9570)

Section 1. Facility Characterization

Estimate manufacturing data for the previous 12 month period or other convenient time period of 12 consecutive months (e.g., FY94). Only consider the portion of the facility dedicated to PWB manufacturing when entering employee and facility size data.

1.1 General Information			
Size of portion of facility used for manufacturing PWB's :	sq.ft.	Number of days MHC line is in operation:	days/yr
Number of full-time equivalent employees (FTE's):		Total PWB panel sq. footage processed by the MHC process:	sq.ft./yr
Number of employee work days per year:	days/yr		

1.2 Facility Type

Type of PWB manufacturing facility (check one)	Independent		OEM	

1.3 Process Type

Estimate the percentage of PWBs manufactured at your facility using the following methods for making holes conductive (MHC). Specify "other" entry.

Standard electroless copper	%
Palladium-based system	%
Carbon-based system	%
Graphite-based system	%
Electroless nickel	%
Other:	%
TOTAL	100 %

Process Data	Shift			
	1	2	3	4
Number of hours per shift:				
Number of hours the MHC line is in operation per shift:				
Average square feet of PWB panel processed by the MHC line per shift:				

1.5 Process Area Employees

Complete the following table by indicating the number of employees of each type that perform work duties in the same process room as the MHC line for each shift and for what length of time. Report the number of hours per employee by either the month or the shift, whichever is appropriate for the worker category. Consider only workers who have regularly scheduled responsibilities physically within the process room. Specify "other" entry.

Type of Process Area Worker	Number of Employees per Shift				Hours per Shift per Employee	Hours per Month per Employee
	1	2	3	4	in Process Area (first shift)	in Process Area (first shift)
Line Operators					Hrs	Hrs
Lab Technicians					Hrs	Hrs
Maintenance Workers					Hrs	Hrs
Wastewater Treatment Operators					Hrs	Hrs
Supervisory Personnel					Hrs	Hrs
Contract Workers					Hrs	Hrs
Other:					Hrs	Hrs
Other:					Hrs	Hrs

Section 2. General Process Data

The information in this section will be used to identify the physical parameters of the process equipment as well as any operating conditions common to the entire process line.

2.1 Process Parameters

MHC process line dimensions Length:	ft.	
Width:	ft.	
Average time for panel to complete process:	min.	
Size of the room containing the process:	sq.ft.	
Temperature of the process room:	°F	
Is the process area ventilated (circle one)?	Yes No	
Air flow Rate:	cu.ft./min.	
Type of ventilation? (check one) general	☐	local ☐

2.2 General Water Usage

Amount of water used by the MHC process line when operating:	gal./day

2.3 Wastewater Characterization

Estimate the average and maximum values for the wastewater from the making holes conductive line.

	AVERAGE	MAXIMUM
Flow	gpm	gpm
TDS	mg/l	mg/l
pH		
Cu	mg/l	mg/l

	AVERAGE	MAXIMUM
Pd	mg/l	mg/l
Sn	mg/l	mg/l
TSS	mg/l	mg/l
TTO	mg/l	mg/l

2.4 Wastewater Discharge and Sludge Data

Wastewater discharge type (check one) Direct	☐	Indirect	☐	Zero	☐	
Annual quantity of sludge generated:						
Percent solids of sludge						
Percentage of total quantity generated by the MHC process:						
Method of sludge recycle/disposal (see key at right):						

Methods of Sludge Recycle/Disposal
[R]— Metals Reclaimed
[D]— Stabilized and Landfilled
[O]— Other

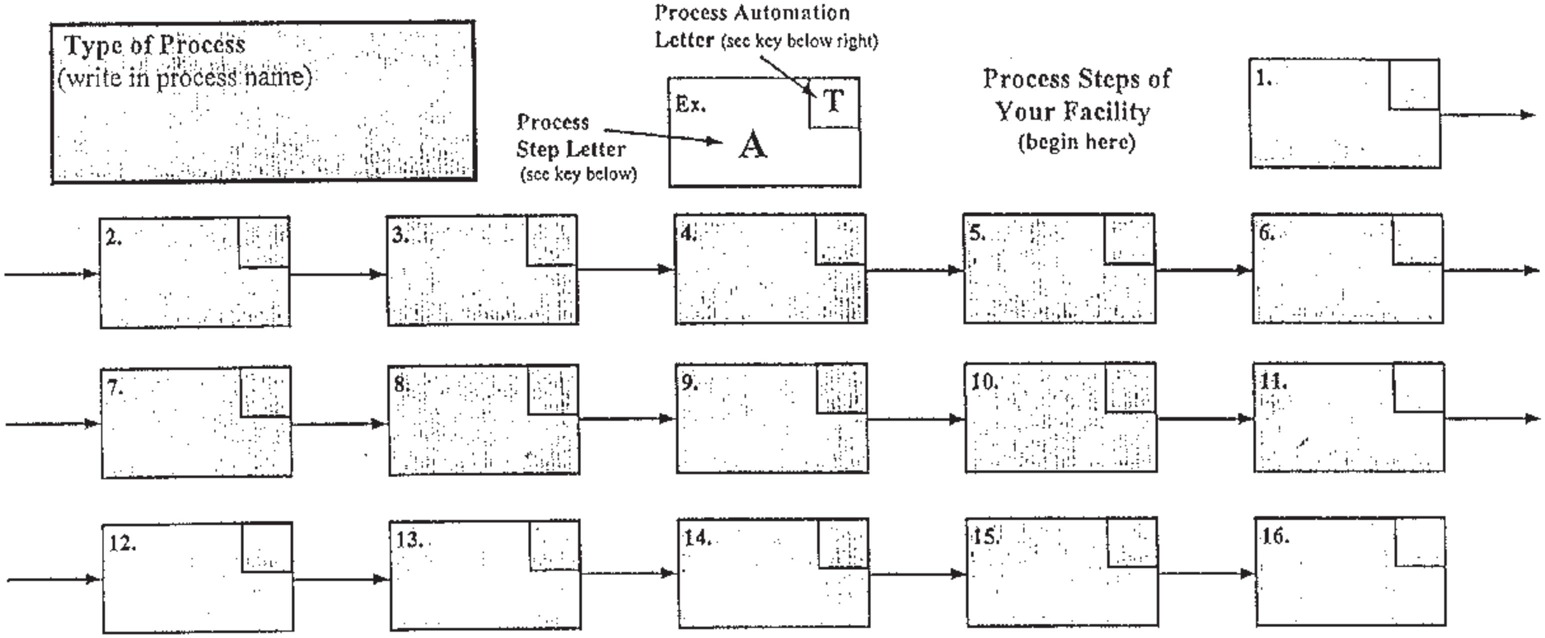
2.5 Panel Rack Specifications- (non-conveyorized MHC process only)

Average number of panels per rack:			
Average space between panels in rack:			in.
Average size of panel in rack: Length	in.	Width	in.

Section 3. Process Description

3.1 Process Schematic

Fill in the table below by identifying what type of making holes conductive process (e.g., electroless copper) your facility uses. Then, using the proper key at the bottom of the page, identify which letter corresponds with the first step in your process and write that letter in the first box (see example). Continue using the key to fill in boxes for each step in your process until your entire making holes conductive process is represented. If your process is not represented by a key below, complete the chart by writing in the name of each process step in your particular making holes conductive line. Finally, consult the process automation key at bottom right and enter the appropriate type of automation for the MHC process line. If the process is partially automated, enter the appropriate process automation letter for each step in the upper right-hand corner box (see example).



ELECTROLESS COPPER PROCESS STEPS

[A]— Conditioner/Cleaner
[B] — Micro Etch
[C] — Pre-dip
[D]— Activator/Catalyst
[E]— Accelerator
[F]— Electroless Copper
[G]— Reducer/Neutralizer
[H]— Anti-tarnish/Anti-oxidant
[W] — Water rinse
[O]— Other (specify step)

GRAPHITE-BASED PROCESS STEPS

[A]— Cleaner/Conditioner
[B]— Graphite
[C]— Fixer
[D]— Air knife/Oven
[E]— Post-clean Etch
[F]— Anti-tarnish/Anti-oxidant
[W]— Water rinse
[O]— Other (specify step)

CARBON-BASED PROCESS STEPS

[A]— Cleaner
[B]— Conditioner
[C]— Carbon
[D]— Air knife/Oven
[E]— Post-clean Etch
[F]— Anti-tarnish/Anti-oxidant
[W]— Water rinse
[O]— Other (specify step)

PALLADIUM-BASED PROCESS STEPS

[A]— Conditioner/Cleaner
[B] — Pre-dip
[C] — Palladium Catalyst
[D]— Accelerator
[E]— Enhancer
[F]— Electroless Copper
[G]— Post-Clean Etch
[H]— High pressure Water
[J]— Anti-tarnish/Anti-oxidant
[W] — Water rinse
[O]— Other (specify step)

PROCESS AUTOMATION

TYPE OF PROCESS AUTOMATION FOR ENTIRE MHC PROCESS ______
(Consult the key below)

* If the MHC process is partially automated (option R) enter 'R' on above line. Then, for each process step in chart above, consult the key below and enter the appropriate process automation letter in the box located in the upper right-hand corner of each process step (see example).

Process Automation Key

[P]— Automated non-conveyorized
[Q]— Automated conveyorized
[R]— Partially automated*
[S]— Manually controlled hoist
[T]— Manual (no automation)
[V]— Other (specify)

3.2 Rinse Bath Water Usage

Consult the process schematic in section 3.1 to obtain the process step numbers associated with each of the water rinse baths present. Enter, in the table below, the process step number along with the flow control and flow rate data requested for each water rinse bath. If the water rinse bath is part of a cascade, you need only report the daily water flow rate of one bath in the cascade.

Process Step Number [a]	Flow Control [b]	Daily Water Flow Rate [c]	Cascade Water Process Steps [d]
		gal./day	
		gal./day	
		gal./day	
		gal./day	
		gal./day	
		gal./day	
		gal./day	
		gal./day	

[a] **Process step number**- Consult the process schematic in question 4.1 and enter the process step number of the specific water rinse tank.

[b] **Flow control**- Consult key at right and enter the letter for the flow control method used for that specific rinse bath.

[c] **Daily water flow rate**- Enter the average daily flow rate for the specific water rinse tank.

[d] **Cascade Water Process Steps**- Enter the process step number for each water rinse tank in cascade with the present tank.

Flow Control Methods Key

[C]— Conductivity Meter
[P]— PH Meter
[V]— Operator control valve
[R]— Flow Restricter
[N]— None (continuous flow)
[O]— Other (explain)

3.3 Rack Cleaning- (non-conveyorized MHC process only)

Complete the following section by using the keys to the right of the table to identify the rack cleaning process used.

Frequency of cleaning:	
Number of personnel involved:	
Personal protective equipment (see key at right):	
Rack cleaning method used (see key at right): * If the above answer is [C], also enter the process step number from the process schematic (section 3.1) and do not complete section 3.4 below.	
Average time required to chemically clean rack (if applicable) :	min.
Cleaning schedule (see key at right):	
Is rack cleaning attended (circle one):	Yes No

Personal Protective Equipment Key

[E]— Eye protection
[L]— Labcoat/sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

Rack Cleaning Methods Key

[C]— Chemical bath on making holes conductive line
[D]— Chemical bath on another line
[T]— Temporary chemical bath
[S]— Manual scrubbing with chemical
[M]— Non-chemical cleaning
[N]— None

Rack Cleaning Schedule

[A]— After Hours
[L]— During operating hours- in MHC process room
[M]— During operating hours-outside MHC process room

3.4 Rack Cleaning Chemical Composition (non-conveyorized MHC process only)

Chemical Name	Conc.	Volume
		gal.
		gal.
		gal.

3.5 Conveyor Equipment Cleaning

Complete the following table on conveyorized equipment cleaning in the MHC process line by providing the information requested for each cleaning operation performed. If more space is needed or more than two cleaning operations occur, report them on a separate sheet of paper.

Equipment Cleaning Data	Cleaning Operation no.1	Cleaning Operation no.2
Description of cleaning operation: (briefly describe equip. cleaned)		
Process steps affected [a]		
Frequency of cleaning:		
Duration of cleaning:	min.	min.
Number of personnel involved:		
Personal protective equipment (see key at right):		
Cleaning method used (see key at right):		
Cleaning chemical used [b]		

Personal Protective Equipment Key
[E]— Eye protection
[G]— Gloves
[L]— Labcoat/sleeved garment
[A]— Apron
[R]— Respiratory protection
[B]— Boots
[Z]— All except Respiratory Protection
[N]— None

Conveyor Cleaning Methods Key
[C]— Chemical rinsing or soaking
[S]— Manual scrubbing with chemical
[M]— Non-chemical cleaning
[N]— None

[a] **Process Steps Affected**-Consult the process schematic from section 4.1 and enter the process step numbers of the specific steps affected by the cleaning operation.

[b] **Cleaning Chemical Used**- Enter the name of the chemical or chemical product (or bath type, if applicable) used in the specific cleaning operation.

3.6 Filter Replacement

Complete the following table on filter replacement in the MHC process line by providing the information requested for each set of filters replaced.

Replacement Information	Filter Assembly no.1	Filter Assembly no.2	Filter Assembly no.3
Bath filtered (enter process step from 3.1) :			
Frequency of replacement:			
Duration of replacement:	min.	min.	min.
Number of personnel involved:			
Personal protective equipment (see key below):			
Type of filter (see key below):			
Number of filters changed in assembly:			
Area of Filter:	sq. in.	sq. in.	sq. in.

Personal Protective Equipment Key
[E]— Eye Protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory Protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

Filter Type Key
[B]— Bag Filter
[C]— Cartridge Filter
[O]— Other (specify)

3.7 Process History

Complete the table below by indicating what making holes conductive process(es) your facility has employed in the past. Briefly explain the reasons for the process change and summarize how the change has had an affect upon production.

FORMER MAKING HOLES CONDUCTIVE PROCESS	DATE OF CHANGE TO CURRENT PROCESS
ELECTROLESS COPPER	
PALLADIUM-BASED	
GRAPHITE-BASED	
CARBON-BASED	
COPPER SEED	
ELECTROLESS NICKEL	
OTHER (specify)	

REASONS FOR CHANGE AND RESULTS		
Reason (see key)		Result (see key)
	Water Consumption	
	Process Cycle- time	
	Cost	
	Worker Exposure	
	Performance	
	Customer Acceptance	
	Product Quality	
	Process Maintenance	
	Other:	
	Other:	
	Other:	

Reasons

[X]— Mark all of the selections that apply

Results of change

[B]— Better
[W]— Worse
[N]— No Change

The remainder of the survey is dedicated to questions that are strictly specific to the type of making holes conductive process operated at your facility. **You should complete only the section(s) of the survey that corresponds to the MHC process(es) that is currently being operated.**

Select the making holes conductive process(es) that your facility currently operates and complete only the section(s) listed. If your process is not listed, then you have completed the questionairre.

Electroless Copper............... Section 4 (pgs. 9-17)
Graphite-Based.................... Section 5 (pgs. 19-26)
Carbon-Based...................... Section 6 (pgs. 27-34)
Palladium-Based .... Section 7 (pgs 35-43)

Section 4. Electroless Copper Process

The information requested below will allow us to generate an exposure assessment and risk characterization profile for each of the following baths and the associated activities involved in the operation and upkeep of the electroless copper process.

NOTE: You need to complete this section only if your facility uses an electroless copper process for making the holes conductive during the PWB manufacturing process.

4.1 Physical, Process, and Operating Conditions

Complete the table below by entering the data requested for each specific type of chemical bath listed. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH	PHYSICAL DATA			PROCESSING DATA		OPERATING CONDITIONS		
	LENGTH (inches)	WIDTH (inches)	NOMINAL VOLUME	IMMERSION [a] (seconds)	DRIP TIME [b] (seconds)	TEMP °F	AGITATION [c]	VAPOR CONTROL[d]
CLEANER/ CONDITIONER	in.	in.	gal.	sec.	sec.	°F		
MICRO ETCH	in.	in.	gal.	sec.	sec.	°F		
PRE-DIP	in.	in.	gal.	sec.	sec.	°F		
ACTIVATOR/ CATALYST	in.	in.	gal.	sec.	sec.	°F		
ACCELERATOR	in.	in.	gal.	sec.	sec.	°F		
ELECTROLESS COPPER	in.	in.	gal.	sec.	sec.	°F		
REDUCER/ NEUTRALIZER	in.	in.	gal.	sec.	sec.	°F		
ANTI-TARNISH/ ANTI-OXIDANT	in.	in.	gal.	sec.	sec.	°F		
OTHER(specify)	in.	in.	gal.	sec.	sec.	°F		

[a] Immersion Time- Enter the average elapsed time a rack of panels is immersed in the specific process bath.

[b] Drip Time- Enter the average elapsed time that a rack of panels is allowed to hang above the specific bath to allow chemical drainage from panels.

[c] Agitation - Consult the key at right and enter the letter for the agitation method used in the specific chemical bath.

[d] Vapor Control- Consult key at right and enter the letter of the vapor control method used for that specific chemical bath.

Agitation Methods Key
[P]— Panel Agitation
[F]— Fluid Circulation Pump
[A]— Air Sparge
[O]— Other (explain)

Vapor Control Methods Key
[P]— Push-Pull
[C]— Bath Cover (when not in use)
[B]— Plastic Balls (floating)
[E]— Fully Enclosed
[O]— Other (explain)

4.2 Initial Chemical Bath Make-Up Composition

Complete the chart below for each chemical component of the bath type listed. Provide the manufacturer name if the chemical used is known only by trade name. If more room is needed, please attach another sheet with the additional information. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH		CHEMICAL NAME	MANUFACTURER (if applicable)	WORKING VOLUME [a] (gallons)	CONCEN-TRATION [b]	ANNUAL QTY. USED[c] (gallons)
CLEANER/ CONDITIONER	1.					
	2.					
	3.					
	4.					
MICRO-ETCH	1.					
	2.					
	3.					
	4.					
PRE-DIP	1.					
	2.					
	3.					
	4.					
ACTIVATOR/ CATALYST	1.					
	2.					
	3.					
	4.					
ACCELERATOR	1.					
	2.					
	3.					
	4.					

[a] Working Volume- Enter the volume of the chemical used in the initial make-up of the bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration - Enter the concentration of the chemical in the working volume and specify units (e.g. molarity, grams/litre, etc.) of the chemical used.

[c] Annual Quantity Used- If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

4.2 Initial Chemical Bath Make-Up Composition- CONTINUED

BATH		CHEMICAL NAME	MANUFACTURER (if applicable)	WORKING VOLUME ^{a} (gallons)	CONCEN-TRATION ^{b}	ANNUAL QTY. USED^{c} (gallons)
ELECTROLESS COPPER	1.					
	2.					
	3.					
	4.					
REDUCER/ NEUTRALIZER	1.					
	2.					
	3.					
	4.					
ANTI-TARNISH/ ANTI-OXIDANT	1.					
	2.					
	3.					
	4.					
OTHER (specify)	1.					
	2.					
	3.					
	4.					

[a] Working Volume- Enter the volume of the chemical used in the initial make-up of the bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration - Enter the concentration of the chemical in the working volume and specify units (e.g. molarity, grams/litre, etc.) of the chemical used.

[c] Annual Quantity Used- If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

4.3 Chemical Bath Replacement

Complete the chart below by providing information on the process of replacing, treating, and disposing of a spent chemical bath.

Bath Type	Criteria for Replacement[a]	Frequency[b]	Duration of Replacment Procedure[c]	Number of People	Personal Protective Equipment[d]	On-Site Method of Treatment or Disposal[e]	Annual Volume Treated or Disposed[f]	Off-Site Method of Treatment or Disposal[e]
Cleaner/ Conditioner								
Micro Etch								
Pre-Dip								
Activator/ Catalyst								
Accelerator								
Electroless Copper								
Reducer/ Neutralizer								
Anti-Tarnish/ Anti-Oxidant								
Other (specify)								

[a] Criteria for Replacement- Consult the key at right and enter the letter for the criteria typically used to determine when bath replacement is necessary.

[b] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[c] Duration of Replacement- Enter the elapsed time from the beginning of bath removal until the replacement bath is finished.

[d] Personal Protective Equip.- Consult key at right and enter the letters of <u>all</u> the protective equipment worn by the workers physically replacing the spent bath.

[e] Methods of Treat. or Disp.- Consult keys at right and enter the letter of the method used.

[f] Annual Vol. Treat. or Disp.- Enter the yearly amount of the specific bath treated or disposed.

On-Site Method of Treatment or Disposal

[P]— Precipitation Pretreatment on-site
[N]— PH Neutralization Pretreatment on-site
[S]— Disposed directly to sewer with no treatment
[D]— Drummed for off-site treatment or disposal
[R]— Recycled on-site
[O]— Other (specify)

Off-Site Method of Treatment or Disposal

[R]— Sent to Recycle
[P]— Discharged to POTW
[O]— Other (specify)

Criteria for Bath Replacement

[S]— Statistical process control
[T]— Time
[P]— Panel Sq.Ft. processed
[O]— Other (specify)
[C]— Chemical testing

Personal Protective Equipment

[E]— Eye protection
[G]— Gloves
[L]— Labcoat/Sleeved garment
[A]— Apron
[R]— Respiratory protection
[B]— Boots
[Z]— All except Respiratory Protection
[N]— None

4.4 Chemical Handling Activities:Chemical Bath Replacement

Complete the table below by indicating the options your facility uses to replace each type of spent chemical bath. **If the same options are used to replace each of the various chemical baths, enter 'ALL' as the type of bath and fill out only one table.** Otherwise, please photocopy and attach additional charts, as necessary.

TYPES OF BATHS[a]:

REMOVAL OF SPENT BATH		
Method of Removing Spent Bath	Pump:	
	Siphon :	
	Drain/ Spigot:	
	Other (specify):	
Remove Spent Bath	Directly to Wastewater Treatment:	
	Directly to sewer:	
	To open-top container:	
	To closed-top container:	

CLEANING OF EQUIPMENT		
Tank Cleaning Method	Chemical Flush:	
	Hand Scrub:	
	Other (specify):	

CHEMICALS USED IN CHEMICAL FLUSH

Chemical	Gallons Per Year

NEW BATH MAKE-UP		
Chemical Retrieval from Stock into Container	Pump:	
	Pour:	
	Scoop (solid):	
	Other (specify):	
Container Type	Open-top container:	
	Closed-top container:	
	Safety container:	
	Other (specify):	

---

[a] Types of Baths- Enter the types of baths where the activities are used. If the chemical handling activities are the same for each bath type, enter 'ALL'.

4.5 Chemical Bath Sampling

Provide information on the chemical bath sampling procedures used in your facility. Duration of sampling and personnel involved should include only the portion of the testing procedure involving the manual sampling of the chemical baths, not automated sampling or the testing that may occur in another part of the facility, such as the lab.

BATH TYPE	TYPE OF SAMPLING [a]	FREQUENCY[b]	DURATION OF SAMPLING [c]	NUMBER OF PEOPLE [d]	PROTECTIVE EQUIPMENT [e]
CLEANER/ CONDITIONER			min.		
MICRO ETCH			min.		
PRE-DIP			min.		
ACTIVATOR/ CATALYST			min.		
ACCELERATOR			min.		
ELECTROLESS COPPER			min.		
REDUCER/ NEUTRALIZER			min.		
ANTI-TARNISH/ ANTI-OXIDANT			min.		
OTHER (specify)			min.		

[a] **Type of Sampling**- Consult the key at right and enter the letter for the type of sampling performed on the specific chemical bath.

[b] **Frequency**- Enter the average amount of time elapsed or number of panel sq. ft. processed between samples. Clearly specify units (e.g., hours, square feet, etc.)

[c] **Duration of Sampling**- Enter the average time for manually taking a sample from the specific chemical tank. Consider only time spent at the chemical bath.

[d] **Number of People**- Enter the number of people actually involved in manually taking the chemical samples. Exclude people doing the testing but not the sampling.

[e] **Personal Protect. Equip.**- Consult key at right and enter the letters for <u>all</u> protective equipment worn by the people performing the chemical sampling.

<u>Type of Sampling Key</u>

[A]— Automated Sampling	[B]— Both
[M]— Manual Sampling	[N]— None

<u>Personal Protective Equipment Key</u>

[E]— Eye Protection	[G]— Gloves
[L]— Labcoat/Sleeved garment	[A]— Apron
[R]— Respiratory Protection	[B]— Boots
[Z]— All except Respiratory Protection	[N]— None

4.6 Chemical Handling Activities:Chemical Sampling

Complete the table below by indicating what method your facility uses to manually collect bath samples and the type of container used.

Method of Obtaining Samples	Drain/Spigot:	
	Pipette:	
	Ladle:	
	Other (Specify):	
Chemical Sample Container	Open-top container:	
	Closed-top container:	

4.7 Chemical Bath Additions

Complete the following chart detailing the typical chemical additions that are made to maintain the chemical balance of each specific process baths. If more than four chemicals are added to a specific bath, attach another sheet with the additional information. If chemical additions to a bath are made <u>automatically</u>, do not complete the last three columns for that bath. If two tanks of the same type are used within the process, list the data for a single tank only.

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
CLEANER/ CONDITIONER	1.						min.		
	2.								
	3.								
	4.								
MICRO ETCH	1.						min.		
	2.								
	3.								
	4.								
PRE-DIP	1.						min.		
	2.								
	3.								
	4.								
ACTIVATOR/ CATALYST	1.						min.		
	2.								
	3.								
	4.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for <u>all</u> of the protective equipment worn by the people physically making the addition.

<u>Chemical Addition Method Key</u>

[A]— Automatic*

[M]— Manual

* If additions are automatic [A] then do not complete the last 3 columns.

<u>Personal Protective Equipment Key</u>

[E]— Eye protection

[L]— Labcoat/Sleeved garment

[R]— Respiratory protection

[Z]— All except Respiratory Protection

[G]— Gloves

[A]— Apron

[B]— Boots

[N]— None

4.7 Chemical Bath Additions- <u>CONTINUED</u>

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
ACCELERATOR	1.						min.		
	2.								
	3.								
	4.								
ELECTROLESS COPPER	1.						min.		
	2.								
	3.								
	4.								
REDUCER/ NEUTRALIZER	1.						min.		
	2.								
	3.								
	4.								
ANTI-TARNISH/ ANTI-OXIDANT	1.								
	2.								
	3.								
	4.								
OTHER (specify)	1.						min.		
	2.								
	3.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for <u>all</u> of the protective equipment worn by the people physically making the addition.

<u>Chemical Addition Method Key</u>

[A]— Automatic*
[M]— Manual

*** If additions are automatic [A] then do not complete the last 3 columns.**

<u>Personal Protective Equipment Key</u>

[E]— Eye protection	[G]— Gloves
[L]— Labcoat/Sleeved garment	[A]— Apron
[R]— Respiratory protection	[B]— Boots
[Z]— All except Respiratory Protection	[N]— None

4.8 Chemical Handling Activities: Chemical Additions

Complete the following table by indicating the methods your facility uses while performing chemical additions.

ACTIVITY	OPTIONS	
Chemical Retrieval from Stock into Container	Pump:	
	Pour:	
	Scoop (solid):	
	Other (specify):	
Container	Open-top container:	
	Closed-top container:	
	Safety container:	
	Other (specify):	
Method of Chemical Addition	Pour directly into tank:	
	Stir into tank:	
	Pour into automated chemical addition system:	
	Other (specify):	

4.9 Other Bath Related Activities

Complete the following table for any other bath related activities that your facility engages in.

BATH TYPE	TYPE OF ACTIVITY (describe)	FREQUENCY[a]	DURATION OF ACTIVITY[b]	NUMBER OF PEOPLE	PROTECTIVE EQUIPMENT[c]
CLEANER/ CONDITIONER					
MICRO ETCH					
PRE-DIP					
ACTIVATOR/ CATALYST					
ACCELERATOR					
ELECTROLESS COPPER					
REDUCER/ NEUTRALIZER					
ANTI-TARNISH/ ANTI-OXIDANT					
OTHER (specify)					

[a] Frequency- Enter the average amount of time elapsed or number of panel sq. ft. processed since the last time the activity was performed. Clearly specify units (e.g., hours, square feet, etc.)

[b] Duration of Activity- Enter the average time for performing the specified activity. Clearly specify units.

[c] Personal Protect. Equip.- Consult key on the previous page and enter the letters for all protective equipment worn by the people performing the activity.

Section 5. Graphite-Based Process

The information requested below will allow us to generate an exposure assessment and risk characterization profile for each of the following baths and the associated activities involved in the operation and upkeep of the graphite-based process.

NOTE: You need to complete this section only if your facility uses a graphite-based process for making the holes conductive during the PWB manufacturing process.

5.1 Physical, Process, and Operating Conditions

Complete the table below by entering the data requested for each specific type of chemical bath listed. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH	PHYSICAL DATA			PROCESSING DATA		OPERATING CONDITIONS		
	LENGTH (inches)	WIDTH (inches)	NOMINAL VOLUME	IMMERSION [a] (seconds)	DRIP TIME [b] (seconds)	TEMP °F	AGITATION [c]	VAPOR CONTROL[d]
CLEANER/ CONDITIONER	in.	in.	gal.	sec.	sec.	°F		
GRAPHITE	in.	in.	gal.	sec.	sec.	°F		
FIXER	in.	in.	gal.	sec.	sec.	°F		
POST-CLEAN ETCH	in.	in.	gal.	sec.	sec.	°F		
ANTI-TARNISH/ ANTI-OXIDANT	in.	in.	gal.	sec.	sec.	°F		
OTHER(specify)	in.	in.	gal.	sec.	sec.	°F		

[a] Immersion Time- Enter the average elapsed time a rack of panels is immersed in the specific process bath.

[b] Drip Time- Enter the average elapsed time that a rack of panels is allowed to hang above the specific bath to allow chemical drainage from panels.

[c] Agitation - Consult the key at right and enter the letter for the agitation method used in the specific chemical bath.

[d] Vapor Control- Consult key at right and enter the letter of the vapor control method used for that specific chemical bath.

Agitation Methods Key
[P]— Panel Agitation
[F]— Fluid Circulation Pump
[A]— Air Sparge
[O]— Other (explain)

Vapor Control Methods Key
[P]— Push-Pull
[C]— Bath Cover (when not in use)
[B]— Plastic Balls (floating)
[E]— Fully Enclosed
[O]— Other (explain)

AIR KNIFE/OVEN PROCESS STEP	
Air pressure:	psi.
Air temperature:	°F
Processing time per panel:	min.
Contained unit (circle one):	Yes No

5.2 Initial Chemical Bath Make-Up Composition

Complete the chart below for each chemical component of the bath type listed. Provide the manufacturer name if the chemical used is known only by trade name. If more room is needed, please attach another sheet with the additional information. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH		CHEMICAL NAME	MANUFACTURER (if applicable)	WORKING VOLUME [a] (gallons)	CONCEN-TRATION [b]	ANNUAL QTY. USED[c] (gallons)
CLEANER/ CONDITIONER	1.					
	2.					
	3.					
	4.					
GRAHITE	1.					
	2.					
	3.					
	4.					
FIXER	1.					
	2.					
	3.					
	4.					
POST-CLEAN ETCH	1.					
	2.					
	3.					
	4.					
ANTI-TARNISH/ ANTI-OXIDANT	1.					
	2.					
	3.					
	4.					
OTHER (specify)	1.					
	2.					
	3.					
	4.					

[a] Working Volume- Enter the volume of the chemical used in the initial make-up of the bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration - Enter the concentration of the chemical in the working volume and specify units (e.g. molarity, grams/litre, etc.) of the chemical used.

[c] Annual Quantity Used- If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

5.3 Chemical Bath Replacement

Complete the chart below by providing information on the process of replacing, treating, and disposing of a spent chemical bath.

Bath Type	Criteria for Replacement[a]	Frequency[b]	Duration of Replacement Procedure[c]	Number of People	Personal Protective Equipment[d]	On-Site Method of Treatment or Disposal[e]	Annual Volume Treated or Disposed[f]	Off-Site Method of Treatment or Disposal[e]
Cleaner/ Conditioner								
Graphite								
Fixer								
Post-Clean Etch								
Anti-Tarnish/ Anti-Oxidant								
Other (specify)								

[a] Criteria for Replacement- Consult the key at right and enter the letter for the criteria typically used to determine when bath replacement is necessary.

[b] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[c] Duration of Replacement- Enter the elapsed time from the beginning of bath removal until the replacement bath is finished.

[d] Personal Protective Equip.- Consult key at right and enter the letters of **all** the protective equipment worn by the workers physically replacing the spent bath.

[e] Methods of Treat. or Disp.- Consult keys at right and enter the letter of the method used.

[f] Annual Vol. Treat. or Disp.- Enter the yearly amount of the specific bath treated or disposed.

On-Site Method of Treatment or Disposal

[P]— Precipitation Pretreatment on-site
[N]— PH Neutralization Pretreatment on-site
[S]— Disposed directly to sewer with no treatment
[D]— Drummed for off-site treatment or disposal
[R]— Recycled on-site
[O]— Other (specify)

Off-Site Method of Treatment or Disposal

[R]— Sent to Recycle
[P]— Discharged to POTW
[O]— Other (specify)

Criteria for Bath Replacement

[S]— Statistical process control
[P]— Panel Sq.Ft. processed
[C]— Chemical testing
[T]— Time
[O]— Other (specify)

Personal Protective Equipment

[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

5.4 Chemical Handling Activities:Chemical Bath Replacement

Complete the table below by indicating the options your facility uses to replace each type of spent chemical bath. If the same options are used to replace each of the various chemical baths, enter 'ALL' as the type of bath and fill out only one table. Otherwise, please photocopy and attach additional charts, as necessary.

TYPES OF BATHS:*

REMOVAL OF SPENT BATH		
Method of Removing Spent Bath	Pump:	
	Siphon :	
	Drain/ Spigot:	
	Other (specify):	
Remove Spent Bath	Directly to Wastewater Treatment:	
	Directly to sewer:	
	To open-top container:	
	To closed-top container:	

CLEANING OF EQUIPMENT		
Tank Cleaning Method	Chemical Flush:	
	Hand Scrub:	
	Other (specify):	

CHEMICALS USED IN CHEMICAL FLUSH

Chemical	Gallons Per Year

NEW BATH MAKE-UP		
Chemical Retrieval from Stock into Container	Pump:	
	Pour:	
	Scoop (solid):	
	Other (specify):	
Container Type	Open-top container:	
	Closed-top container:	
	Safety container:	
	Other (specify):	

---

* Types of Baths- Enter the types of baths where the activities are used. If the chemical handling activities are the same for each bath type, enter 'ALL'.

5.5 Chemical Bath Sampling

Provide information on the chemical bath sampling procedures used in your facility. Duration of sampling and personnel involved should include only the portion of the testing procedure involving the manual sampling of the chemical baths, not automated sampling or the testing that may occur in another part of the facility, such as the lab.

BATH TYPE	TYPE OF SAMPLING [a]	FREQUENCY[b]	DURATION OF SAMPLING [c]	NUMBER OF PEOPLE [d]	PROTECTIVE EQUIPMENT [e]
CLEANER/ CONDITIONER			min.		
GRAPHITE			min.		
FIXER			min.		
POST-CLEAN ETCH			min.		
ANTI-TARNISH/ ANTI-OXIDANT			min.		
OTHER (specify)			min.		

[a] **Type of Sampling**- Consult the key at right and enter the letter for the type of sampling performed on the specific chemical bath.

[b] **Frequency**- Enter the average amount of time elapsed or number of panel sq. ft. processed between samples. Clearly specify units (e.g., hours, square feet, etc.)

[c] **Duration of Sampling**- Enter the average time for manually taking a sample from the specific chemical tank. Consider only time spent at the chemical bath.

[d] **Number of People**- Enter the number of people actually involved in manually taking the chemical samples. Exclude people doing the testing but not the sampling.

[e] **Personal Protect. Equip.**- Consult key at right and enter the letters for <u>all</u> protective equipment worn by the people performing the chemical sampling.

<u>Type of Sampling Key</u>

[A]— Automated Sampling
[M]— Manual Sampling
[B]— Both
[N]— None

<u>Personal Protective Equipment Key</u>

[E]— Eye Protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory Protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

5.6 Chemical Handling Activities:Chemical Sampling

Complete the table below by indicating what method your facility uses to manually collect bath samples and the type of container used.

Method of Obtaining Samples	Drain/Spigot:	
	Pipette:	
	Ladle:	
	Other (Specify):	
Chemical Sample Container	Open-top container:	
	Closed-top container:	

5.7 Chemical Bath Additions

Complete the following chart detailing the typical chemical additions that are made to maintain the chemical balance of each specific process baths. If more than four chemicals are added to a specific bath, attach another sheet with the additional information. If chemical additions to a bath are made <u>automatically</u>, do not complete the last three columns for that bath. If two tanks of the same type are used within the process, list the data for a single tank only.

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
CLEANER/	1.								
CONDITIONER	2.								
	3.								
	4.						min.		
GRAPHITE	1.								
	2.								
	3.								
	4.						min.		
FIXER	1.								
	2.								
	3.								
	4.						min.		
POST-CLEAN	1.								
ETCH	2.								
	3.								
	4.						min.		

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for <u>all</u> of the protective equipment worn by the people physically making the addition.

<u>Chemical Addition Method Key</u>

[A]— Automatic*
[M]— Manual

* If additions are automatic [A] then do not complete the last 3 columns.

<u>Personal Protective Equipment Key</u>

[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

5.7 Chemical Bath Additions- CONTINUED

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
ANTI-TARNISH/ ANTI-OXIDANT	1.						min.		
	2.								
	3.								
	4.								
OTHER (specify)	1.						min.		
	2.								
	3.								
	4.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for all of the protective equipment worn by the people physically making the addition.

Chemical Addition Method Key
[A]— Automatic*
[M]— Manual

* If additions are automatic [A] then do not complete the last 3 columns.

Personal Protective Equipment Key
[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

5.8 Chemical Handling Activities: Chemical Additions

Complete the following table by indicating the methods your facility uses while performing chemical additions.

ACTIVITY	OPTIONS	
Chemical Retrieval from Stock into Container	Pump:	
	Pour:	
	Scoop (solid):	
	Other (specify):	
Container	Open-top container:	
	Closed-top container:	
	Safety container:	
	Other (specify):	
Method of Chemical Addition	Pour directly into tank:	
	Stir into tank:	
	Pour into automated chemical addition system:	
	Other (specify):	

5.9 Other Bath Related Activities

Complete the following table for any other bath related activities that your facility engages in.

BATH TYPE	TYPE OF ACTIVITY (describe)	FREQUENCY[a]	DURATION OF ACTIVITY[b]	NUMBER OF PEOPLE	PROTECTIVE EQUIPMENT[c]
CLEANER/ CONDITIONER					
GRAPHITE					
FIXER					
POST-CLEAN ETCH					
ANTI-TARNISH/ ANTI-OXIDANT					
OTHER (specify)					

[a] Frequency- Enter the average amount of time elapsed or number of panel sq. ft. processed since the last time the activity was performed. Clearly specify units (e.g., hours, square feet, etc.)

[b] Duration of Activity- Enter the average time for performing the specified activity. Clearly specify units.

[c] Personal Protect. Equip.- Consult key on the previous page and enter the letters for all protective equipment worn by the people performing the activity.

Section 6. Carbon-Based Process

The information requested below will allow us to generate an exposure assessment and risk characterization profile for each of the following baths and the associated activities involved in the operation and upkeep of the carbon-based process.

<u>NOTE:</u> You need to complete this section only if your facility uses a <u>carbon-based</u> process for making the holes conductive during the PWB manufacturing process.

6.1 Physical, Process, and Operating Conditions

Complete the table below by entering the data requested for each specific type of chemical bath listed. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH	PHYSICAL DATA			PROCESSING DATA		OPERATING CONDITIONS		
	LENGTH (inches)	WIDTH (inches)	NOMINAL VOLUME	IMMERSION [a] (seconds)	DRIP TIME [b] (seconds)	TEMP °F	AGITATION [c]	VAPOR CONTROL[d]
CLEANER	in.	in.	gal.	sec.	sec.	oF		
CONDITIONER	in.	in.	gal.	sec.	sec.	oF		
CARBON	in.	in.	gal.	sec.	sec.	oF		
POST-CLEAN ETCH	in.	in.	gal.	sec.	sec.	oF		
ANTI-TARNISH/ ANTI-OXIDANT	in.	in.	gal.	sec.	sec.	oF		
OTHER(specify)	in.	in.	gal.	sec.	sec.	oF		

[a] Immersion Time- Enter the average elapsed time a rack of panels is immersed in the specific process bath.

[b] Drip Time- Enter the average elapsed time that a rack of panels is allowed to hang above the specific bath to allow chemical drainage from panels.

[c] Agitation - Consult the key at right and enter the letter for the agitation method used in the specific chemical bath.

[d] Vapor Control- Consult key at right and enter the letter of the vapor control method used for that specific chemical bath.

<u>Agitation Methods Key</u>
[P]— Panel Agitation
[F]— Fluid Circulation Pump
[A]— Air Sparge
[O]— Other (explain)

<u>Vapor Control Methods Key</u>
[P]— Push-Pull
[C]— Bath Cover (when not in use)
[B]— Plastic Balls (floating)
[E]— Fully Enclosed
[O]— Other (explain)

AIR KNIFE/OVEN PROCESS STEP	
Air pressure:	psi.
Air temperature:	oF
Processing time per panel:	min.
Contained unit (circle one):	Yes No

6.2 Initial Chemical Bath Make-Up Composition

Complete the chart below for each chemical component of the bath type listed. Provide the manufacturer name if the chemical used is known only by trade name. If more room is needed, please attach another sheet with the additional information. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH		CHEMICAL NAME	MANUFACTURER (if applicable)	WORKING VOLUME [a] (gallons)	CONCEN-TRATION [b]	ANNUAL QTY. USED[c] (gallons)
CLEANER	1.					
	2.					
	3.					
	4.					
CONDITIONER	1.					
	2.					
	3.					
	4.					
CARBON	1.					
	2.					
	3.					
	4.					
POST-CLEAN ETCH	1.					
	2.					
	3.					
	4.					
ANTI-TARNISH/ ANTI-OXIDANT	1.					
	2.					
	3.					
	4.					
OTHER (specify)	1.					
	2.					
	3.					
	4.					

[a] **Working Volume**- Enter the volume of the chemical used in the initial make-up of the bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] **Concentration** - Enter the concentration of the chemical in the working volume and specify units (e.g. molarity, grams/litre, etc.) of the chemical used.

[c] **Annual Quantity Used**- If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

6.3 Chemical Bath Replacement

Complete the chart below by providing information on the process of replacing, treating, and disposing of a spent chemical bath.

Bath Type	Criteria for Replacement[a]	Frequency[b]	Duration of Replacment Procedure[c]	Number of People	Personal Protective Equipment[d]	On-Site Method of Treatment or Disposal[e]	Annual Volume Treated or Disposed[f]	Off-Site Method of Treatment or Disposal[e]
Cleaner								
Conditioner								
Carbon								
Post-Clean Etch								
Anti-Tarnish/ Anti-Oxidant								
Other (specify)								

On-Site Method of Treatment or Disposal

[P]— Precipitation Pretreatment on-site
[N]— PH Neutralization Pretreatment on-site
[S]— Disposed directly to sewer with no treatment
[D]— Drummed for off-site treatment or disposal
[R]— Recycled on-site
[O]— Other (specify)

Off-Site Method of Treatment or Disposal

[R]— Sent to Recycle
[P]— Discharged to POTW
[O]— Other (specify)

Criteria for Bath Replacement

[S]— Statistical process control
[P]— Panel Sq.Ft. processed
[C]— Chemical testing
[T]— Time
[O]— Other (specify)

Personal Protective Equipment

[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

---

[a] Criteria for Replacement- Consult the key at right and enter the letter for the criteria typically used to determine when bath replacement is necessary.

[b] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[c] Duration of Replacement- Enter the elapsed time from the beginning of bath removal until the replacement bath is finished.

[d] Personal Protective Equip.- Consult key at right and enter the letters of all the protective equipment worn by the workers physically replacing the spent bath.

[e] Methods of Treat. or Disp.- Consult keys at right and enter the letter of the method used.

[f] Annual Vol. Treat. or Disp.- Enter the yearly amount of the specific bath treated or disposed.

6.4 Chemical Handling Activities:Chemical Bath Replacement

Complete the table below by indicating the options your facility uses to replace each type of spent chemical bath. If the same options are used to replace each of the various chemical baths, enter 'ALL' as the type of bath and fill out only one table. Otherwise, please photocopy and attach additional charts, as necessary.

TYPES OF BATHS *

REMOVAL OF SPENT BATH			CLEANING OF EQUIPMENT			NEW BATH MAKE-UP		
Method of Removing Spent Bath	Pump:		Tank Cleaning Method	Chemical Flush:		Chemical Retrieval from Stock into Container	Pump:	
	Siphon :			Hand Scrub:			Pour:	
	Drain/ Spigot:			Other (specify):			Scoop (solid):	
	Other (specify):						Other (specify):	
Remove Spent Bath	Directly to Wastewater Treatment:		CHEMICALS USED IN CHEMICAL FLUSH			Container Type	Open-top container:	
	Directly to sewer:		Chemical	Gallons Per Year			Closed-top container:	
	To open-top container:						Safety container:	
	To closed-top container:						Other (specify):	

---

* Types of Baths- Enter the types of baths where the activities are used. If the chemical handling activities are the same for each bath type, enter 'ALL'.

6.5 Chemical Bath Sampling

Provide information on the chemical bath sampling procedures used in your facility. Duration of sampling and personnel involved should include only the portion of the testing procedure involving the manual sampling of the chemical baths, not automated sampling or the testing that may occur in another part of the facility, such as the lab.

BATH TYPE	TYPE OF SAMPLING [a]	FREQUENCY [b]	DURATION OF SAMPLING [c]	NUMBER OF PEOPLE [d]	PROTECTIVE EQUIPMENT [e]
CLEANER			min.		
CONDITIONER			min.		
CARBON			min.		
POST-CLEAN ETCH			min.		
ANTI-TARNISH/ ANTI-OXIDANT			min.		
OTHER (specify)			min.		

[a] **Type of Sampling**- Consult the key at right and enter the letter for the type of sampling performed on the specific chemical bath.

[b] **Frequency**- Enter the average amount of time elapsed or number of panel sq. ft. processed between samples. Clearly specify units (e.g., hours, square feet, etc.)

[c] **Duration of Sampling**- Enter the average time for manually taking a sample from the specific chemical tank. Consider only time spent at the chemical bath.

[d] **Number of People**- Enter the number of people actually involved in manually taking the chemical samples. Exclude people doing the testing but not the sampling.

[e] **Personal Protect. Equip.**- Consult key at right and enter the letters for all protective equipment worn by the people performing the chemical sampling.

<u>Type of Sampling Key</u>

[A]— Automated Sampling
[B]— Both
[M]— Manual Sampling
[N]— None

<u>Personal Protective Equipment Key</u>

[E]— Eye Protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory Protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

6.6 Chemical Handling Activities:Chemical Sampling

Complete the table below by indicating what method your facility uses to manually collect bath samples and the type of container used.

Method of Obtaining Samples	Drain/Spigot:	
	Pipette:	
	Ladle:	
	Other (Specify):	
Chemical Sample Container	Open-top container:	
	Closed-top container:	

6.7 Chemical Bath Additions

Complete the following chart detailing the typical chemical additions that are made to maintain the chemical balance of each specific process baths. If more than four chemicals are added to a specific bath, attach another sheet with the additional information. If chemical additions to a bath are made automatically, do not complete the last three columns for that bath. If two tanks of the same type are used within the process, list the data for a single tank only.

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
CLEANER	1.						min.		
	2.								
	3.								
	4.								
CONDITIONER	1.						min.		
	2.								
	3.								
	4.								
CARBON	1.						min.		
	2.								
	3.								
	4.								
POST-CLEAN ETCH	1.						min.		
	2.								
	3.								
	4.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for all of the protective equipment worn by the people physically making the addition.

Chemical Addition Method Key
[A]— Automatic*
[M]— Manual

* If additions are automatic [A] then do not complete the last 3 columns.

Personal Protective Equipment Key
[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

6.7 Chemical Bath Additions- CONTINUED

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
ANTI-TARNISH/ ANTI-OXIDANT	1.						min.		
	2.								
	3.								
	4.								
OTHER (specify)	1.						min.		
	2.								
	3.								
	4.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for all of the protective equipment worn by the people physically making the addition.

Chemical Addition Method Key
[A]— Automatic*
[M]— Manual

* If additions are automatic [A] then do not complete the last 3 columns.

Personal Protective Equipment Key
[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

6.8 Chemical Handling Activities: Chemical Additions

Complete the following table by indicating the methods your facility uses while performing chemical additions.

ACTIVITY	OPTIONS	
Chemical Retrieval from Stock into Container	Pump:	
	Pour:	
	Scoop (solid):	
	Other (specify):	
Container	Open-top container:	
	Closed-top container:	
	Safety container:	
	Other (specify):	
Method of Chemical Addition	Pour directly into tank:	
	Stir into tank:	
	Pour into automated chemical addition system:	
	Other (specify):	

6.9 Other Bath Related Activities

Complete the following table for any other bath related activities that your facility engages in.

BATH TYPE	TYPE OF ACTIVITY (describe)	FREQUENCY[a]	DURATION OF ACTIVITY[b]	NUMBER OF PEOPLE	PROTECTIVE EQUIPMENT[c]
CLEANER					
CONDITIONER					
CARBON					
POST-CLEAN ETCH					
ANTI-TARNISH/ ANTI-OXIDANT					
OTHER (specify)					

[a] Frequency- Enter the average amount of time elapsed or number of panel sq. ft. processed since the last time the activity was performed. Clearly specify units (e.g., hours, square feet, etc.)

[b] Duration of Activity- Enter the average time for performing the specified activity. Clearly specify units.

[c] Personal Protect. Equip.- Consult key on the previous page and enter the letters for all protective equipment worn by the people performing the activity.

Section 7. Palladium-Based Process

The information requested below will allow us to generate an exposure assessment and risk characterization profile for each of the following baths and the associated activities involved in the operation and upkeep of the palladium-based process.

NOTE: You need to complete this section only if your facility uses a palladium-based process for making the holes conductive during the PWB manufacturing process.

7.1 Physical, Process, and Operating Conditions
Complete the table below by entering the data requested for each specific type of chemical bath listed. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH	PHYSICAL DATA			PROCESSING DATA		OPERATING CONDITIONS		
	LENGTH (inches)	WIDTH (inches)	NOMINAL VOLUME	IMMERSION [a] (seconds)	DRIP TIME [b] (seconds)	TEMP °F	AGITATION [c]	VAPOR CONTROL [d]
CLEANER/ CONDITIONER	in.	in.	gal.	sec.	sec.	°F		
PRE-DIP	in.	in.	gal.	sec.	sec.	°F		
CATALYST	in.	in.	gal.	sec.	sec.	°F		
ACCELERATOR	in.	in.	gal.	sec.	sec.	°F		
ENHANCER	in.	in.	gal.	sec.	sec.	°F		
POST-CLEAN ETCH	in.	in.	gal.	sec.	sec.	°F		
ANTI-TARNISH/ ANTI-OXIDANT	in.	in.	gal.	sec.	sec.	°F		
OTHER(specify)	in.	in.	gal.	sec.	sec.	°F		

[a] Immersion Time- Enter the average elapsed time a rack of panels is immersed in the specific process bath.

[b] Drip Time- Enter the average elapsed time that a rack of panels is allowed to hang above the specific bath to allow chemical drainage from panels.

[c] Agitation - Consult the key at right and enter the letter for the agitation method used in the specific chemical bath.

[d] Vapor Control- Consult key at right and enter the letter of the vapor control method used for that specific chemical bath.

Agitation Methods Key
[P]— Panel Agitation
[F]— Fluid Circulation Pump
[A]— Air Sparge
[O]— Other (explain)

Vapor Control Methods Key
[P]— Push-Pull
[C]— Bath Cover (when not in use)
[B]— Plastic Balls (floating)
[E]— Fully Enclosed
[O]— Other (explain)

HIGH PRESSURE WATER RINSE	
Water pressure:	psi.
Water flow rate per day:	gal.
Processing time per panel:	min.
Contained unit (circle one):	Yes No

7.2 Initial Chemical Bath Make-Up Composition

Complete the chart below for each chemical component of the bath type listed. Provide the manufacturer name if the chemical used is known only by trade name. If more room is needed, please attach another sheet with the additional information. If two tanks of the same type are used within the process, list the data for a single tank only.

BATH		CHEMICAL NAME	MANUFACTURER (if applicable)	WORKING VOLUME [a] (gallons)	CONCENTRATION [b]	ANNUAL QTY. USED[c] (gallons)
CLEANER/	1.					
CONDITIONER	2.					
	3.					
	4.					
PRE-DIP	1.					
	2.					
	3.					
	4.					
PALLADIUM	1.					
CATALYST	2.					
	3.					
	4.					
ACCELERATOR	1.					
	2.					
	3.					
	4.					
ENHANCER	1.					
	2.					
	3.					
	4.					

[a] Working Volume- Enter the volume of the chemical used in the initial make-up of the bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration - Enter the concentration of the chemical in the working volume and specify units (e.g. molarity, grams/litre, etc.) of the chemical used.

[c] Annual Quantity Used- If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

7.2 Initial Chemical Bath Make-Up Composition- <u>CONTINUED</u>

BATH		CHEMICAL NAME	MANUFACTURER (if applicable)	WORKING VOLUME[a] (gallons)	CONCEN-TRATION[b]	ANNUAL QTY. USED[c] (gallons)
POST-CLEAN ETCH	1.					
	2.					
	3.					
	4.					
ANTI-TARNISH/ ANTI-OXIDANT	1.					
	2.					
	3.					
	4.					
OTHER (specify)	1.					
	2.					
	3.					
	4.					

---

[a] Working Volume- Enter the volume of the chemical used in the initial make-up of the bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration - Enter the concentration of the chemical in the working volume and specify units (e.g. molarity, grams/litre, etc.) of the chemical used.

[c] Annual Quantity Used- If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

7.3 Chemical Bath Replacement

Complete the chart below by providing information on the process of replacing, treating, and disposing of a spent chemical bath.

Bath Type	Criteria for Replacement[a]	Frequency[b]	Duration of Replacment Procedure[c]	Number of People	Personal Protective Equipment[d]	On-Site Method of Treatment or Disposal[e]	Annual Volume Treated or Disposed[f]	Off-Site Method of Treatment or Disposal[e]
Cleaner/ Conditioner								
Pre-Dip								
Palladium Catalyst								
Accelerator								
Enhancer								
Post-Clean Etch								
Anti-Tarnish/ Anti-Oxidant								
Other (specify)								

[a] Criteria for Replacement- Consult the key at right and enter the letter for the criteria typically used to determine when bath replacement is necessary.
[b] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).
[c] Duration of Replacement- Enter the elapsed time from the beginning of bath removal until the replacement bath is finished.
[d] Personal Protective Equip.- Consult key at right and enter the letters of <u>all</u> the protective equipment worn by the workers physically replacing the spent bath.
[e] Methods of Treat. or Disp.- Consult keys at right and enter the letter of the method used.
[f] Annual Vol. Treat. or Disp.- Enter the yearly amount of the specific bath treated or disposed.

<u>On-Site Method of Treatment or Disposal</u>
[P]— Precipitation Pretreatment on-site
[N]— PH Neutralization Pretreatment on-site
[S]— Disposed directly to sewer with no treatment
[D]— Drummed for off-site treatment or disposal
[R]— Recycled on-site
[O]— Other (specify)

<u>Off-Site Method of Treatment or Disposal</u>
[R]— Sent to Recycle
[P]— Discharged to POTW
[O]— Other (specify)

<u>Criteria for Bath Replacement</u>
[S]— Statistical process control
[P]— Panel Sq.Ft. processed
[C]— Chemical testing
[T]— Time
[O]— Other (specify)

<u>Personal Protective Equipment</u>
[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

7.4 Chemical Handling Activities:Chemical Bath Replacement

Complete the table below by indicating the options your facility uses to replace each type of spent chemical bath. If the same options are used to replace each of the various chemical baths, enter 'ALL' as the type of bath and fill out only one table. Otherwise, please photocopy and attach additional charts, as necessary.

TYPES OF BATHS*

REMOVAL OF SPENT BATH			CLEANING OF EQUIPMENT			NEW BATH MAKE-UP		
Method of Removing Spent Bath	Pump:		Tank Cleaning Method	Chemical Flush:		Chemical Retrieval from Stock into Container	Pump:	
	Siphon :			Hand Scrub:			Pour:	
	Drain/ Spigot:			Other (specify):			Scoop (solid):	
	Other (specify):						Other (specify):	
Remove Spent Bath	Directly to Wastewater Treatment:		CHEMICALS USED IN CHEMICAL FLUSH			Container Type	Open-top container:	
	Directly to sewer:		Chemical	Gallons Per Year			Closed-top container:	
	To open-top container:						Safety container:	
	To closed-top container:						Other (specify):	

* Types of Baths- Enter the types of baths where the activities are used. If the chemical handling activities are the same for each bath type, enter 'ALL'.

7.5 Chemical Bath Sampling

Provide information on the chemical bath sampling procedures used in your facility. Duration of sampling and personnel involved should include only the portion of the testing procedure involving the manual sampling of the chemical baths, not automated sampling or the testing that may occur in another part of the facility, such as the lab.

BATH TYPE	TYPE OF SAMPLING [a]	FREQUENCY [b]	DURATION OF SAMPLING [c]	NUMBER OF PEOPLE [d]	PROTECTIVE EQUIPMENT [e]
CLEANER/ CONDITIONER			min.		
PRE-DIP			min.		
PALLADIUM CATALYST			min.		
ACCELERATOR			min.		
ENHANCER			min.		
POST-CLEAN ETCH			min.		
ANTI-TARNISH/ ANTI-OXIDANT			min.		
OTHER (specify)			min.		

[a] **Type of Sampling**- Consult the key at right and enter the letter for the type of sampling performed on the specific chemical bath.

[b] **Frequency**- Enter the average amount of time elapsed or number of panel sq. ft. processed between samples. Clearly specify units (e.g., hours, square feet, etc.)

[c] **Duration of Sampling**- Enter the average time for manually taking a sample from the specific chemical tank. Consider only time spent at the chemical bath.

[d] **Number of People**- Enter the number of people actually involved in manually taking the chemical samples. Exclude people doing the testing but not the sampling.

[e] **Personal Protect. Equip.**- Consult key at right and enter the letters for __all__ protective equipment worn by the people performing the chemical sampling.

__Type of Sampling Key__

[A]— Automated Sampling
[M]— Manual Sampling
[B]— Both
[N]— None

__Personal Protective Equipment Key__

[E]— Eye Protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory Protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

7.6 Chemical Handling Activities:Chemical Sampling

Complete the table below by indicating what method your facility uses to manually collect bath samples and the type of container used.

Method of Obtaining Samples	Drain/Spigot:	
	Pipette:	
	Ladle:	
	Other (Specify):	
Chemical Sample Container	Open-top container:	
	Closed-top container:	

7.7 Chemical Bath Additions

Complete the following chart detailing the typical chemical additions that are made to maintain the chemical balance of each specific process baths. If more than four chemicals are added to a specific bath, attach another sheet with the additional information. If chemical additions to a bath are made automatically, do not complete the last three columns for that bath. If two tanks of the same type are used within the process, list the data for a single tank only.

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
CLEANER/	1.						min.		
CONDITIONER	2.								
	3.								
	4.								
PRE-DIP	1.						min.		
	2.								
	3.								
	4.								
PALLADIUM	1.						min.		
CATALYST	2.								
	3.								
	4.								
ACCELERATOR	1.						min.		
	2.								
	3.								
	4.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for all of the protective equipment worn by the people physically making the addition.

Chemical Addition Method Key
[A]— Automatic*
[M]— Manual

* If additions are automatic [A] then do not complete the last 3 columns.

Personal Protective Equipment Key
[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

7.7 Chemical Bath Additions- CONTINUED

Bath Type		Chemical Added	Average Volume Added [a]	Concentration[b]	Frequency [c]	Chemical Addition Method [d]	Duration of Addition [e] (minutes)	Number of People	Personal Protective Equipment [f]
ENHANCER	1.						min.		
	2.								
	3.								
	4.								
POST-CLEAN ETCH	1.						min.		
	2.								
	3.								
	4.								
ANTI-TARNISH/ ANTI-OXIDANT	1.						min.		
	2.								
	3.								
	4.								
OTHER (specify)	1.						min.		
	2.								
	3.								
	4.								

[a] Average Volume Added- Enter the average volume in gallons of each chemical added to maintain the specific bath. If the amount of a particular chemical used is measured by weight (i.e., crystalline chemicals) instead of volume, enter the weight in pounds and clearly specify the units (Lbs).

[b] Concentration- Enter the concentration (e.g. molarity, volume %, grams/litre, etc.) of the chemical in the volume being added.

[c] Frequency- Enter the average amount of time elapsed or number of square feet processed between bath replacements. Clearly specify units (e.g., hours, sq.ft., etc.).

[d] Chemical Addition Method- Consult key at right and enter the appropriate letter for the method used for that specific bath.

[e] Duration of Addition- Enter the average elapsed time from the retrieval of the chemical stock through the completion of the addition of all chemicals.

[f] Personal Protective Equipment- Consult key at right and enter the letters for <u>all</u> of the protective equipment worn by the people physically making the addition.

Chemical Addition Method Key

[A]— Automatic*
[M]— Manual

*** If additions are automatic [A] then do not complete the last 3 columns.**

Personal Protective Equipment Key

[E]— Eye protection
[L]— Labcoat/Sleeved garment
[R]— Respiratory protection
[Z]— All except Respiratory Protection
[G]— Gloves
[A]— Apron
[B]— Boots
[N]— None

7.8 Chemical Handling Activities: Chemical Additions

Complete the following table by indicating the methods your facility uses while performing chemical additions.

ACTIVITY	OPTIONS	
Chemical Retrieval from Stock into Container	Pump:	
	Pour:	
	Scoop (solid):	
	Other (specify):	
Container	Open-top container:	
	Closed-top container:	
	Safety container:	
	Other (specify):	
Method of Chemical Addition	Pour directly into tank:	
	Stir into tank:	
	Pour into automated chemical addition system:	
	Other (specify):	

7.9 Other Bath Related Activities

Complete the following table for any other bath related activities that your facility engages in.

BATH TYPE	TYPE OF ACTIVITY (describe)	FREQUENCY[a]	DURATION OF ACTIVITY[b]	NUMBER OF PEOPLE	PROTECTIVE EQUIPMENT[c]
CLEANER/ CONDITIONER					
PRE-DIP					
PALLADIUM CATALYST					
ACCELERATOR					
ENHANCER					
POST-CLEAN ETCH					
ANTI-TARNISH/ ANTI-OXIDANT					
OTHER (specify)					

[a] Frequency- Enter the average amount of time elapsed or number of panel sq. ft. processed since the last time the activity was performed. Clearly specify units (e.g., hours, square feet, etc.)

[b] Duration of Activity- Enter the average time for performing the specified activity. Clearly specify units.

[c] Personal Protect. Equip.- Consult key on the previous page and enter the letters for all protective equipment worn by the people performing the activity.

Definitions and Abbreviations

Direct discharge	Wastewater discharge directly to a stream or river
Indirect discharge	Wastewater discharge to a publicly owned treatment works (POTW)
Zero discharge	No industrial wastewater discharge

Cu	copper
cu.ft.	cubic feet
DfE	Design for the Environment
EPA	U.S. Environmental Protection Agency
F	Fahrenheit
ft.	feet
gal.	gallons
gal./day	gallons per day
gpm	gallons per minute
hrs.	hours
lbs.	pounds
MHC	making holes conductive
min.	minutes
mg/l	milligrams per liter
OEM	Original equipment manufacturer
Pd	palladium
PWB	printed wiring board
sec.	seconds
sq. ft.	square feet
sq. in.	square inch
Sn	tin
TDS	Total dissolved solids
TSS	Total suspended solids
TTO	Total toxic organics
yr.	year

APPENDIX B

ENVIRONMENTAL RELEASES AND OCCUPATIONAL EXPOSURE ASSESSMENT: SCREEN PRINTING CTSA

Specific quantities for environmental releases and occupational exposure to chemicals can be determined for a particular system used in screen reclamation. This summary provides an overview of the releases and exposure and methodology used in determining the releases and exposure for the traditional ink remover, emulsion remover, and haze remover products.

While the greatest environmental releases and occupational exposure occur during the actual process of screen reclamation, releases and exposure also occur from volatilization from open containers, transfer operations, sampling operations, and waste rags. Air releases and the inhalation exposures occur as a result of volatilization during these operations. Releases to air occur by volatilization of chemicals from open containers, from the surface of the screen as it is being cleaned, and from rags used in the cleaning process. Estimation of releases to land and water is based on a mass balance relationship. Dermal exposures can also be estimated based on operations, formulation concentrations, and established dermal exposure models.[1]

It is assumed that workers perform the following activities during each step of the screen reclamation process. Some of these steps are not necessary or are altered for certain methods assessed here. (See Figure 2-7 in Chapter 2 for an outline of the steps involved in each method.)

Step 1. Ink removal

- Open 55-gallon drum of ink remover;
- Pour ink remover into 5-gallon pail;
- Dip rag or brush into pail;
- Remove ink from screen;
- Toss rag into laundry pile; and
- Drum waste ink for disposal.

Step 2. Emulsion removal

- Open container of emulsion remover;
- Dip brush into container;
- Remove emulsion from screen; and
- Rinse screen.

Step 3. Haze removal

- Open container of haze remover;
- Dip brush into container;
- Remove haze from screen; and
- Rinse screen.

To support the assessments, numerous sources of information were used in gathering data. Preliminary information was collected from the 11-page Screen Printing Workplace Practices Questionnaire. Meetings with printers to discuss the basic data assumptions used in the assessment were held at Screen Print '93 in New Orleans in October 1993 and at the SPAI

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[1] U.S. EPA. *Dermal Exposure Assessment: Principles and Applications.* Office of Health and Environmental Assessment, Jan. 1992, Document no. EPA/600/8-9/011F.

Environmental Committee Meeting in January 1994. Information was also verified though facilities participating in the Screen Printing Performance Demonstration from February to May 1994. These operation assumptions and data are presented in Table B-1.

TABLE B-1: ASSUMPTION AND DATA FROM INDUSTRY AND TRADE GROUPS

Type of Data	Average value	
	Number	Units
Number of employees involved in ink removal	3	employees
Hours per employee per day in ink removal	1	hours
Number of employees in screen reclamation	2	employees
Hours per employee per day in screen reclamation	1.5	hours
Average number of screens cleaned per day	6	screens
Average screen size	2, 127	in^2
Size of combined screen reclamation/ink removal area	80	ft^2
Amount of ink remover per screen	8 (traditional) 4 (alternative)	oz
Amount of haze remover per screen	3.5	oz
Amount of haze remover per screen	3	oz

a) Normalized from Workplace Practices Questionnaire to remove printing establishments larger than 20 employees.

ESTIMATION METHODOLOGY

In general, in evaluating traditional and alternative screen reclamation systems, it is assumed that all releases to air, land, or water occur via the four scenarios described below. Using this assumption cleaning fluid usage has been partitioned to air, land, and water with concentrations of mass. Volatilization is estimated using a number of established models as documented below. Water and land releases are estimated to be all cleaning fluids not volatilized. The exposure/release scenarios are defined as follows:

- Scenario I. Actual screen cleaning operations. Air releases are due to volatilization of chemicals from the screen surface. Unvolatilized material is assumed to be disposed to land or water. Ink, emulsion, and haze removal for 6 screens a day; each screen is approximately $2100m^2$.

- Scenario II. Releases to the atmosphere from pouring of 1 oz of material for sampling. This is assumed to take place over 15 minutes each day.

- Scenario III. Releases to the atmosphere from pouring of cleaning mixtures from a 55-gallon drum into a 5-gallon pail.

- Scenario IV. Releases from rags stored in a two-thirds empty drum. The water releases in this case occur in a commercial laundry. The drum is opened to add more rags once per day and to transfer the rags from the storage drum to a laundry. Rags are used only for the ink removal step.

Releases shown in the above scenarios will occur during the use of Reclamation Methods 1, 2, and 4 of Exhibit 1-2. In addition to these releases, in Method 3 (SPAI Workshop Process), an ink degradant is applied after the ink remover, followed by a water rinse; a screen degreaser is then applied prior to use of the emulsion remover. For the purposes of this assessment, Method 3 is evaluated only in conjunction with system Omicron.

Assumptions for Environmental Releases

The environmental releases model prepared for this report assumes that releases to air equal the total airborne concentration of chemicals from:

- Volatilization of solvents from screens;
- Emissions from transfer operations;
- Emissions from sampling operations; and
- Volatilization from waste dirty rags.

The following assumptions and sources of information were used in the model:

- Typical airborne concentrations;
- Typical ventilation rates;
- Emission factors from EPA (AP-42) (an EPA compendium of emission factors from the Office of Air);
- Formulation data and physical properties; and
- Average amounts of ink, haze, and emulsion remover used per site-day of 36 ounces, 21 ounces, and 18 ounces.

The model addresses releases to three media: air, water, and land. Releases to air result from volatilization from the screens during cleaning and fluid sampling and transfers. Releases for all systems studied were associated with ink removal, emulsion removal, and haze removal.

Water releases result primarily from the emulsion removal phase which is typically a rinse step using a water and sodium hypochlorite or sodium periodate solution for the traditional systems, and a water and sodium periodate solution for the alternative systems. The emulsion removal phase may also generate a contaminated rinsewater. In either phase, waste water results from screen rinsing and the spray or rag application of haze and emulsion removers.

Off-site releases to land result from the cleaning of non-disposable rags and the landfilling of disposable rags. It is assumed that rags are used only to remove the ink. The model assumes that non-disposable rags sent to a laundry contain 0.75 grams of ink remover per

18 rags. This assumption is based on:

- Limited data on how much material stays on a damp shop rag with mineral spirits;
- The average number of rags used to remove ink per screen (3 per screen); and
- The average number of screens cleaned per day (6 screens).

The model assumes weekly laundering of non-disposable shop rags and 250 days of use per year. Similarly, rags sent to a landfill are assumed to contain 0.75 grams of ink remover per 18 rags.

For systems Omicron and Beta, which have ink remover products that are water-miscible, it was assumed that nonlaunderable rags were used and the discharge to water occurred at the screen printing facility. This assumption was made given that a water rinse is used with these products in removing ink.

For aqueous solutions, the density of all components is assumed equal to 1 g/cm^3. For nonaqueous solutions, ideal solution behavior is assumed and the density of each component is used to find the amount of the component in 4 ounces of ink remover.

Assumptions for Occupational Exposure

In order to estimate occupational exposure to chemicals during the screen cleaning process, an inhalation model and a dermal exposure model was developed. The assumptions underlying each model are described below.

Inhalation Model

The inhalation model used in the CTSA is a mass balance model. It assumes that the amount of a chemical in a room equals the amount leaving the room minus any generated in the room. The model is valid for estimating the displacement of vapors from containers, and the volatilization of liquids from open surfaces. Assumptions include:

- Incoming room air is contaminant-free;
- Generation and ventilation rates are constant over time;
- Room air and ventilation air mix ideally;
- Raoult's law is valid (i.e., the volatilization and interaction of vapors);
- Ideal gas law applies (i.e., the interaction of vapors);
- Inhaled doses of each chemical were based on "typical case" ventilation parameters, since these seem to give the best fit to the highest observed values (see below). Actual ventilation conditions are unknown; and
- Median values were used for the composition; worst case evaluation for air releases would include the most volatile compound at its maximum concentration.

We used the following assumptions for the frequency and duration of inhalation exposure for ink, emulsion, and haze removal:

- 6 screens cleaned per day;
- 1 to 3 workers per site;
- 3 hours per day exposure total; and
- 250 days per year.

The four scenarios described on pages B-3, 4 were modelled for assessing inhalation exposure. Inhalation exposures occur as a result of volatilization during these scenarios. The model assumes that shop workers do not wear respirators in any of the four scenarios.

Dermal Model

Dermal exposure is caused by contact with the material. Contact with the material includes touching damp rags, dipping hand(s) into a pail of ink remover, and manually applying the brush or rag to the screen to loosen the ink. Two scenarios, routine contact with two hands and routine immersion with two hands, were modelled for assessing dermal exposure. Routine contact occurs from touching rags and manually applying the brush or rag to the screen. Routine immersion occurs from dipping hand(s) into a pail or ink, haze, or emulsion remover.

Dermal contact models from the CEB handbook (CEB, 1991) were used by adjusting the concentration of the chemical in the mixture. Dermal exposure assumes no gloves or barrier creams will be used. Although exposure was estimated for the emulsion removers or haze removers containing sodium hypochlorite or sodium hydroxide, it is usually expected that use of these chemicals would result in negligible exposure given that use of these solutions without gloves causes irritation and corrosivity effects.

OVERVIEW OF METHODOLOGY

CEB (Chemical Engineering Branch) models the evaporation of chemicals from open surfaces, such as the surface of a screen, using the following model:

$$G = \frac{\mathbf{0.02}\boldsymbol{MP}}{\boldsymbol{RT}} \sqrt{\frac{\boldsymbol{D_{ab}}\, V}{\pi\, z}} \qquad \mathbf{(1)}$$

where:

G = Volatilization rate, $g.m^{-2}.s^{-1}$
M = Molecular weight, $g.mol^{-1}$
P = Vapor pressure, mm Hg
R = Gas constant, 0.0624 $mmHg.m^3.mol^{-1}.K^{-1}$
T = Temperature, K
D_{ab} = Diffusivity, $cm^2.s^{-1}$
v_z = Air velocity, $m.s^{-1}$
z = Distance along pool surface, m

The air velocity is assumed to be $v_z = 100\ ft.min^{-1}$. Since D_{ab} is not available for many of the chemicals of interest to CEB, the following estimation equation is used:

$$\boldsymbol{D_{ab}} = \frac{4.09x10^{-5}T^{1.9}(1/29+1/M)^{0.5}M^{-0.33}}{\boldsymbol{P_t}} \quad \textbf{(2)}$$

where:

D_{ab} = Diffusion coefficient in air, cm^2.sec^{-1}
T = Temperature, K
M = Molecular weight, g.mol^{-1}
P_t = Total pressure, atm

This equation is based on kinetic theory and generally gives values of D_{ab} that agree closely with experimental data. The value of G computed from eqs (1) and (2) above is used in the following mass balance expression to compute the airborne concentration in the breathing zone:

$$C_v = \frac{1.7x10^5TG\boldsymbol{A}}{M\boldsymbol{Q}k} \quad \textbf{(3)}$$

where:

C_v = Airborne concentration, ppm
T = Ambient temperature, K
G = Vapor generation rate, g.m^{-2}.sec^{-1}
M = Molecular weight, g. mol^{-1}
A = Area of surface, m^2
Q = Ventilation rate, ft^3.min$^{-'}$
k = Mixing factor, dimensionless

The mixing factor accounts for slow and incomplete mixing of ventilation air with room air. CEB sets this factor to 0.5 for the typical case and 0.1 for the worst case. CEB commonly uses values of the ventilation rate Q from 500 ft^3.min^{-1} to 3,500 ft^3.min^{-1}. An effective ventilation rate of 250 ft^3/min was used, which was equal to the mixing factor of 0.5 multiplied by the lowest ventilation rate (500 ft^3/min). The value of C_v from equation (3) is converted to mass/volume units as follows:

$$C_m = C_v \frac{M}{V_m} \quad \textbf{(4)}$$

where:

C_m = Airborne concentration, $mg.m^{-3}$
C_v = Airborne concentration, ppm
M = Molecular weight, $g.mol^{-1}$
V_m = Molar volume of an ideal gas, $l.mol^{-1}$

At 25 °C, V_m has the value 24.45 $l.mol^{-1}$. Since a worker can be assumed to breathe about 1.25 m^3 of air per hour, it is a straightforward matter to compute inhalation exposure once C_m has been determined. Equations (3) and (4) can be combined to yield the following, given the "typical case" choice of ventilation parameters:

$$I = 0.48GAt \tag{5}$$

where:

I = Total amount inhaled, $mg.day^{-1}$
G = Vapor generation rate, $g.\ m^{-2}.s^{-1}$
A = Area of surface, m^2
t = Duration of exposure, s

The advantage of equation (5) is that the quantity *GAt* is often known beforehand, since it is equal to the total amount of the chemical released to the atmosphere. It is also useful when computing the total dose due to a sudden release of material, such as occurs when a container is opened. In this case, it is difficult to ascertain the duration of exposure, but it is a simple matter to estimate the amount of vapor in the container's headspace.

Example 1. *Estimate the vapor generation rate and worker exposure during removal of ink from a printing screen using l00 percent toluene. The worker cleans screens for I hour each day in a room with a ventilation rate of 3, 000* $ft^3.\ min^{-l}$*. The screen area is 2,217* in^2*. Assume a mixing factor of k = 0.5.*

Toluene has the following physical properties:

Molecular weight:	92. 14 $g.\ mol^{-1}$
Vapor pressure:	28 mmHg at 25 °C
Diffusion coefficient:	0.076 $cm^2.sec^{-1}$

Using these values in equation (1) gives:

Generation rate G:	0.28 $g.s^{-1}.m^{-2}$
Airborne concentration:	141 ppm (C_v)
	534 $mg.m^{-3}$ (C_m)
Exposure over 1 hour:	667 mg

If the CEB worst-case parameters are used in equation (2), i.e., a mixing factor of $k = 0.1$ and a ventilation rate of 500 $ft^3.min^{-1}$, then the estimated airborne concentration is $C_v = 4{,}216$ ppm. Exposures and volatilization rates are calculated by multiplying the pure-component values from Exhibit 4 by the mole fraction of that component in the liquid phase. A typical screen has an area of 2127 $in^2 = 1.37\ m^2$. Each worker cleans screens for 1 hour per day. Amounts released should be checked against amount used to ensure mass balance.

Example 2. *If a worker cleans 6 screens using 8 oz/screen of mineral spirits, the amount of spirits used will be:*

6 x 8 x 29.57 fluid oz/cc x 0.78 g/cc = 1107 g

The amount volatilized will be:

0.01087 $g.m^{-2}.s^{-1}$ x 3600 s x 1.37 m^2 = 53 g

Thus, the amount volatilized is not limited by the amount used. For the case of the traditional haze remover, however, volatilization is limited by the amount used. If 3 oz of haze remover containing 30 wt percent (32 volume percent or 21 mole percent) acetone is used per screen, the total amount available is:

6 x 3 x 0.32 x 29.57 fluid oz/cc x O.79 = 133g

The amount that would volatilize over 1 hour is:

1.49 x 1.37 x 3600s = 7,350g

UNCERTAINTIES

Occupational Exposure: Uncertainties

Determining occupational exposure levels associated with screen cleaning requires making assumptions about the cleaning process, the workplace environment, health and safety practices, and waste management practices. This section describes the uncertainties involved in assessing occupational exposure for screen cleaning. It also explains the assumptions underlying the exposure assessment model developed for the CTSA.

EPA has published Guidelines for Exposure Assessment in the Federal Register. These are guidelines for the basic terminology and principles by which the Agency is to conduct exposure assessments. There are several important issues relevant to this assessment. If the methodology is one which allows the assessor to in some way quantify the spectrum of exposure, then the assessor should assess typical exposures, as well as high end exposures or bounding exposures. Typical exposures refer to exactly that, how much the typical person is exposed to the particular substance in question. High end refers to a person exposed to amounts higher than 90 percent of the people (or ecological species of interest) exposed to the substance. Bounding estimates are judgements assuming that no one will be exposed to amounts higher than that calculated amount. However, in many cases, all we can do is give a picture of what the exposure would be under a given set of circumstances, without characterizing the probability of these circumstances actually occurring. These are called "What if" scenarios. They do not try to judge where on the exposure scale the estimate actually falls. All of the exposure assessments fall into the "What if" category for this assessment.

Although the screen cleaning process is relatively straightforward, occupational exposure levels will differ in actual shop environments because of many variables such as variations in:

- Toxicity of the chemicals used;
- Amount of chemicals applied;
- How the chemicals are applied;
- Compliance with health and safety and waste management procedures;
- Equipment operating time;
- Ventilation conditions and shop lay-out; and
- Temperature conditions (ambient and solvent).

All of these variables will influence the impacts of chemicals used in the screen cleaning process on shop workers. Based on studies of screen printing operations conducted by the National Institute for Occupational Safety and Health (NIOSH), it appears that many of the small to medium sized operations do not follow health and safety precautions.[2] Specifically, workers were observed performing screen reclamation without protective gloves or proper breathing apparatus. Nor did shop workers wear protective aprons to reduce dermal exposure. According to one study, some workers used solvent to wash their arms and hands after completing the screen cleaning process. In another study, rags and paper towels contaminated with solvent were placed in an open trash can. Both of these practices will also increase exposure levels significantly.

There are also differences in how screen printers wash the screens; this affects occupational exposure. Some shops use automated screen washers which blast the screens with solvent or hot water in an enclosed system. Others use a hose in a sink to flush the screens by hand or the cleaner is spread on the screen by hand, and the worker uses a rag or paper towel to wipe down the screen. Exposure levels will differ if individual workers use more (or less) cleaner than specified, and if they allow it to remain on the screen longer than specified.

During research to support this assessment a NIOSH Health Hazard Evaluation (HHE) document on screen washing was located and used to validate exposure estimates. CEB initially estimated occupational exposures by applying the relatively conservative models that are normally used for review of new chemicals. The resulting exposure estimates were high in comparison to actual monitoring data. These data indicated that, after necessary corrections were

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[2] Sources: Health Hazard Evaluation Report No. HETA 84-299-1543, (Chicago, IL: Impressions Handprinters). Health Hazard Evaluation Report No. HETA 81-3 83- I 151, (Chicago, IL: Main Post Office).

made, the exposures predicted by the CEB model were within the range of the NIOSH observations, as long as the "typical case" ventilation parameters were chosen. Use of the "worst case" ventilation parameters in the CEB model leads to results that exceed the range of the experimental data by about an order of magnitude. The theoretical basis of the CEB model was investigated and a standard engineering formula for mass transfer in laminar boundary layers was found to provide a closer approximation to the upper end of NIOSH data when used with the same "worst case" ventilation parameters.

Both the CEB model (when used with the "typical case" ventilation parameters) and the boundary-layer approach can provide estimates of inhalation exposures which agree with the experimental data within one order of magnitude or better. It is difficult to obtain better agreement than this without knowing a great deal more about each exposure scenario, such as the details of the screen cleaning process at each site, the solvent temperature, the air temperature, and the ventilation pattern in the screen cleaning area. These items are not routinely recorded by NIOSH investigative teams.

Dermal Exposure Model

The dermal exposure model is based on the concentration of material contacting the skin and the surface area contacted. Dermal exposure levels will differ in actual shop environments because of many variables such as variations in:

- Type of worker activity;
- Likelihood or type of contact (i.e., routine or immersion);
- Frequency of contact (i.e., routine or incidental);
- Potential surface area contacted;
- Likelihood and effectiveness of protective equipment being used;
- Amount of chemical remaining on the skin; and
- Evaporation rate of the chemical.

In estimating dermal exposure, it was assumed that gloves were not worn. However, assuming that gloves are worn, dermal exposure is assumed to be negligible to none depending on the chemical in question. In situations where the chemical is corrosive (e.g., sodium hypochlorite), dermal exposure to shop workers using gloves is zero. The model assumes that one hand (surface area 650 cm^2) is routinely exposed during the screen cleaning process (1 to 3 mg/cm^2 typically remaining on the skin).[3]

Environmental Releases: Uncertainties

Determining environmental releases associated with screen cleaning requires making assumptions about the cleaning process, the workplace environment, and waste management practices. This section describes the uncertainties involved in assessing environmental releases associated with screen cleaning. It also explains the assumptions underlying the environmental

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[3] Source: U.S. Environmental Protection Agency, *Chemical Engineering Branch Manual for the Preparation of Engineering Assessments*, (February 28, 1991), p. 4-36.

release assessment model developed for the CTSA.

Uncertainties

Uncertainties related to environmental releases overlap with the uncertainties associated with occupational exposure. They include variations in:

- Toxicity of the chemicals used;
- Amount of chemicals applied;
- How the chemicals are applied;
- Compliance with waste management procedures;
- Equipment operating time;
- Ventilation conditions and shop lay-out; and
- Temperature conditions (ambient and solvent).

RELEASE AMOUNTS VS. OCCUPATIONAL EXPOSURES

Air releases were computed in two different ways, depending on the particular scenario under consideration. For Scenario I (evaporation from a screen) and Scenario II (evaporation during sampling), the equations used for computing the total mass of material volatilized can be condensed into the following expression:

$$GAt = \frac{8.24x10^{-8}M^{0.835}P(\frac{1}{29}+\frac{1}{M})^{0.25}v_z^{0.5}\boldsymbol{At}}{T^{0.05}z^{0.5}P_t^{0.5}} \qquad \textbf{(6)}$$

where:

GAt = Mass released (= flux x area x time)
M = Molecular weight ($g.mol^{-1}$)
P = Vapor pressure (mmHg)
v_z = Air velocity ($ft.min^{-1}$)
A = Area of surface (cm^2)
t = Duration of release (s)
T = Air temperature (K)
z = Length of surface (cm)
P_t = Total pressure (atm)

For all cases of interest here, the temperature T, total pressure P_t, and air velocity v_z are assigned fixed values. These are 298 K, 1 atmosphere, and 100 $ft.min^{-1}$, respectively. In addition, the surface is taken to be square, so that $z = A^{0.5}$. Thus, the mass of material released has the following dependencies:

$$G\boldsymbol{A}t\ {}_{DC}M^{0.835}\left(\frac{1}{29}+\frac{1}{M}\right)^{0.25} \tag{7}$$

$$G\boldsymbol{A}t_{DC}P \tag{8}$$

$$Q\boldsymbol{A}t_{DC}\boldsymbol{A}^{\mathbf{0.75}} \tag{9}$$

For Scenario III (releases from pouring) and Scenario IV (releases from drum of rags), the vapor space of the container was assumed to be saturated. The model used can be represented

$$Q\boldsymbol{A}t=\frac{MPV}{(24.45)(760)} \tag{10}$$

where:

M = Molecular weight (g.mo^{-1})
P = Vapor pressure (mmHg)
V = Volume of container (1)

For each scenario, the container volume is fixed, so that:

$$Q\boldsymbol{A}t_{DC}M \tag{11}$$

$$Q\boldsymbol{A}t\ {}_{DC}P \tag{12}$$

Releases to water and/or land disposal are computed by a mass balance approach; any chemical not volatilized is assumed to be disposed to one of these two media.

The amount of each chemical inhaled by workers is given by the following expression:

$$I=\frac{719}{Qk}\,G\boldsymbol{A}t \tag{13}$$

where:

I = Inhaled dose (mg.day^{-1})
Q = Ventilation rate (ft^{3}.min^{-1})
k = Mixing factor (dimensionless)

In this report, Q is fixed at 3,000 $ft^3.min^{-1}$ and $k = 0.5$. Thus,

$$I = 0.48\,G\boldsymbol{A}t \qquad \textbf{(14)}$$

Thus, the inhaled dose has the same dependencies as the amount released, no additional variables being introduced.

Based on the above expressions, the amount released to the atmosphere in Scenarios I and II is approximately proportional to $\boldsymbol{M}^{0.835}\boldsymbol{P}$. For Scenario III and IV, the dependence is approximately $\boldsymbol{MP}$. The vapor pressure is generally lower for compounds with higher molecular weights. An idea of the sensitivity of vapor pressure to molecular weight can be obtained from a molecular model of the liquid state. According to Fowler and Guggenheim (*Statistical Thermodynamics*, Cambridge, 1956), for a liquid whose intermolecular potential energy can be represented by the Lennard-Jones function:

$$U(r) = 4\epsilon[\,(\frac{\sigma}{r})^6 - (\frac{\sigma}{r})^{12}] \qquad \textbf{(15)}$$

the vapor pressure can be estimated to be:

$$p = 1158\frac{\epsilon}{\sigma^3}e^{-8.136(\epsilon/kT)} \qquad \textbf{(16)}$$

As noted in the development of an expression for D_{ab}, the diffusivity, in Appendix K of the CEB Manual, the quantities ϵ and σ can be roughly correlated with molecular weight. When these parameters are regressed against experimental data for C_1-C_9 and substituted into the expression for vapor pressure, a relationship of the following form is observed:

$$\boldsymbol{p} \propto M^{0.23}\boldsymbol{e}^{-\boldsymbol{M}^{\mathbf{0.51}}} \qquad \textbf{(17)}$$

Somewhat different dependencies will be found with different sets of experimental data, but all of the resulting expressions will show that vapor pressure falls off rapidly with molecular weight within a homologous series of compounds. Thus, the amount of chemical volatilized and the resulting inhaled dose will be approximately proportional to:

$$M^{0.69}\boldsymbol{e}^{-\boldsymbol{M}^{\mathbf{0.51}}} \qquad \textbf{(18)}$$

APPENDIX C

POPULATION EXPOSURE ASSESSMENT FOR SCREEN RECLAMATION PROCESSES: SCREEN PRINTING CTSA

The purpose of a general population exposure assessment is to account for amounts of chemicals with which people who are not directly involved in the screen printing process may be in contact. There are several ways that the general population may be exposed to substances used in the screen reclamation process. People may breathe the air containing vapors which have been carried away by air currents from a screen printing facility. The vapors would be environmental releases stemming from evaporation of products at the screen printing facility. People may drink water which contains residues from the reclamation products, which can originate with the facility discharging the products down the drain. People may also drink well water that contains contaminants which have migrated from a landfill where wastes are disposed. The amount which a person may come in contact with varies with how far away they are located from the facility, how many of the different routes of contact they actually have (such as drinking, breathing, touching), how long the chemical has been in the environment, and how the chemical moves through the environment. The amounts also depend on such environmental conditions as the weather or the amount of water that is flowing in the receiving stream or river where the facility’s discharges go.

EPA has published Guidelines for Exposure Assessment in the Federal Register. These are guidelines for the basic terminology and principles by which the Agency is to conduct exposure assessments. There are several important issues relevant to this assessment. If the methodology is one which allows the assessor to in some way quantify the spectrum of exposure, then the assessor should assess typical exposures, as well as high end exposures or bounding exposures. Typical exposures refer to exactly that, how much the typical person is exposed to the particular substance in question. High end refers to a person exposed to amounts higher than 90 percent of the people (or ecological species of interest) exposed to the substance. Bounding estimates are judgments assuming that no one will be exposed to amounts higher than that calculated amount. However, in many cases, all we can do is give a picture of what the exposure would be under a given set of circumstances, without characterizing the probability of these circumstances actually occurring. These are called "What if" scenarios. They do not try to judge where on the exposure scale the estimate actually falls. All of the exposure assessmenst fall into the "What if" category for this assessment.

The fate of the chemical in the environment is how we refer to the breakdown (transformation) and mobility of the chemical through air, water, and land. There is a different chemical fate for release through a waste water treatment facility as opposed to an air release or a landfill release. There are also different processes by which degradation may occur. For example, in air, a chemical may be broken down by sunlight (by either direct photolysis or photooxidation) or by reaction with water in the atmosphere (hydrolysis). In water and soil, an important degradation process is biodegradation, where the substance may be decomposed by bacteria and other biota in the environment.[1] Each of these processes will have its own rate (speed) at which it occurs, and this may vary with the concentration of the chemical in the system. Often the way we present the fate for a chemical is by giving a half-life value. This term simply means the amount of time it takes for one-half of the substance initially present to be lost by degradation. There are

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[1] Note: Hydrolysis and photolysis may also be important depending on the chemical and the environmental compartment.

other ways to present fate. If we are interested in how much of a chemical is removed from water during its trip through a waste water treatment facility (such as a POTW - Publicly Owned Treatment Work), we will give a removal amount, usually in percent. The Screen Printing CTSA has summaries of the chemical fate of all of the chemicals identified as being used in screen reclamation products.

There are two perspectives to address when handling exposure concerns for any commercial process. The first is best described as a local point of view, i.e., a single facility in normal operation will have certain releases which affect a specific area and specific local population. Since we do not have information for each screen printing facility, we use a "model facility" approach to calculate typical releases and environmental concentrations. This will not allow us to specify the number of people around the facility, because the population varies considerably depending on the location of the screen printing facility. The other perspective is to view the overall impact, i.e., what is the impact of all of the printing facilities for the general population. While one facility may not be releasing very much of any given chemical, the cumulative effect of all of the printers in an area could be serious.

For this assessment, we have tried to present a view of the local concerns by presenting exposures for a standard set of conditions, by which we are trying to simulate a single facility for all of the methods and systems. The overall perspective is presented only for the traditional systems, which are the systems which are considered to already be in common use. It was felt that it would be far too hypothetical to do an overall perspective for the alternative formulations since we do not have a basis for predicting how many screen printers might use any given formulation.

The effects of a chemical may be a short-term (acute) effect, such as the effect a poison would have on the body, or it could be long-term, such as a carcinogen. For long-term (chronic) effects, it is most helpful to have average, or typical, exposures, since the effect will vary with the cumulative exposure. For acute effects, a peak exposure estimate would be more helpful. This can then be compared to levels at which the chemical is known to give immediate health problems. In general for this assessment, average concentrations are calculated.

OVERVIEW BY MEDIA

Air

Releases to air are from evaporation of chemicals during the process. This may be from allowing screens to dry during reclamation, or from rags or open drums of chemicals located around the facility. These vapors are then carried and mixed with outside air. The air concentration will depend on weather conditions. Stagnant conditions will not move vapors away quickly, so local concentrations will be higher than the concentrations of the chemical farther from the plant. There is the potential that everyone outside the facility could be affected. The chemical concentrations will decrease with distance, but the number of people may increase with distance, depending on the location of the screen printing facility. Usually the exposure assessor will use a computer program to determine the number of people around a known facility by using census data. Since the locations of all the screen printing facilities across the country are not known to us, we use the model facility approach, and do not count population for the model facility.

For our model facility, we assume a building height of three meters, and a width of ten meters. This is a building approximately the size of a garage. We then pick sample weather conditions, usually from San Bernardino, to determine what the air concentration of a chemical will be at a set distance from the printing facility. We use San Bernardino because the weather conditions there will give the highest average concentrations around the facility of any of the approximately 500 weather stations in the United States. However, none of the average concentrations across the country will be even ten times less than the average concentrations at San Bernardino. If the highest concentration were 10 ug/m^3, then anywhere in the country the concentration would be greater than 1 ug/m^3. We would say that there is less than an order of magnitude difference.

Methodology References

Air Modeling Parameters for ISCLT90

MODEL - Industrial Source Complex, Long Term: U.S. EPA, Office of Air and Radiation, Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711, Version 90, as implemented by the Office of Population Prevention and Toxics in the Graphical Exposure Modeling System, GEMS Atmospheric Modeling Subsection.

The following default parameters were used:

- Regulatory default setting for ISCLT;
- Facility location at 34^o latitude, 117^o longitude;
- The Star Station (meteorological) data from the station closest to the point of release, San Bernardino, CA:
- Urban Mode (U3);
- Standard Polar grid, with 3 calculations per segment;
- Single point of release at the facility location; and
- Release height of 3 meters for fugitive releases from an area source of 10 meters by 10 meters (100 m^2).

Surface Water

Releases to surface water are those releases discharged through a drain at a screen printing facility that end up going to public sewers or POTW. This discharge is treated before being released, and the effectiveness of the treatment determined, so that the amount actually getting through to the receiving water body can be calculated. The receiving water will dilute the discharge from the POTW, and a stream concentration can be calculated using stream flow information.

We use average stream concentrations to calculate average drinking water consumption. We assume that people actually drink the two liters a day that is recommended for good health. If the chemical is one that will accumulate in animals or plants, we calculate ingestion of the chemical from eating fish.

The other issue for surface water is the effect that a chemical may have on aquatic organisms, from algae to fish. If the food chain is broken in a stream, the consequences are dire. No algae, no fish. A healthy stream with numerous organisms will also have a better ability to handle chemical releases than one whose quality is already compromised. The organisms lower on the food chain, such as algae, tend to have shorter lives, making shorter exposure time periods more critical. Since concentrations will vary with the stream flow, there may be periods of lower flow conditions where the same amount released as on a regular flow situation will cause problems. We use historical stream data to try to predict how often this will happen.

Cumulative releases to the same POTW may be estimated by counting the number of screen printers in an area and distributing the releases across all the POTWs in the area. We have to assume that the releases are for the same products, or very similar products. As for air, this cumulative number is expected to be far more significant than the amount for any single screen printer.

Methodology Reference

Single Site

Concentration = Chemical Loading / Streamflow

In general, the concentration will be in ug/L, and the chemical loading is in grams or kilograms. The streamflow used is the harmonic mean streamflow in Million Liters per Day (MLD) for drinking water concerns, if the location is known. Otherwise, the streamflow will be assumed to be 1000 MLD.

US-Wide Water Releases

The methodology used is outlined in its entirety in a report from VERSAR, Inc. For Task I-11, subtask 101, from Contract 68-D3-0013. Copies of this report are available from either VERSAR, Inc. or from Sondra Hollister at EPA.

Septic Systems

There appears to be a significant minority of screen printers who do not release water to a waste water treatment plant. These printers are assumed to release to septic systems. The releases of this type are not modeled in this assessment. There are some general guidelines that may be used to determine if there will be exposure to any of the screen reclamation chemicals from septic system seepage. Each chemical will have an estimated potential migration to ground water, which is usually used for landfill assessments. This can be directly applied to septic systems, because the potential to migrate to ground water will be the same. Of course the individual characteristics of the system will determine the actual speed that each chemical travels into the ground water. If the septic system is relatively leaky, and the ground water table is relatively high, the time that a chemical takes to get into the ground water will be shorter than for a septic system which is sealed well and where the ground water table is low.

Landfill

Our usual techniques for estimating exposures from landfill releases are not applicable to printing. For a typical situation, we would assume one facility sending waste to a landfill. For the printing industry, the use of landfills cannot be so simplified. A lack of data limits the determination of exposures. We do not know how many printers are sending a portion of their wastes to a hazardous waste handler, and sending another portion to the county landfill, or how many printers will be sending to any given landfill. For these reasons, even though the exposures from landfill releases may be significant, we will not be able to calculate exposures from landfill seepage and migration into ground water. However, we can give the expected fate of the chemical in the landfill -- will the chemical migrate to ground water rapidly, moderately, or negligibly.

APPENDIX D

BACKGROUND ON RISK ASSESSMENT FOR SCREEN RECLAMATION PROCESSES: SCREEN PRINTING CTSA

HUMAN HEALTH RISK

Assessment of the human health risks presented by chemical substances includes the following components of analysis:

- **Hazard Identification** is the process of determining whether exposure to a chemical can cause an adverse health effect and whether the adverse health effect is likely to occur in humans.

- **Dose-response Assessment** is the process of defining the relationship between the dose of a chemical received and the incidence of adverse health effects in the exposed population. From the quantitative dose-response relationship, toxicity values are derived that are used in the risk characterization step to estimate the likelihood of adverse effects occurring in humans at different exposure levels.

- **Exposure Assessment** identifies populations exposed to a chemical, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the chemical.

- **Risk Characterization** integrates hazard and exposure information into quantitative and qualitative expressions of risk. A risk characterization includes a description of the assumptions, scientific judgments, and uncertainties embodied in the assessment.

Quantitative Expressions of Hazard and Risk

The manner in which estimates of hazard and risk are expressed depends on the nature of the hazard and the types of data upon which the assessment is based. For example, cancer risks are most often expressed as the probability of an individual developing cancer over a lifetime of exposure to the chemical in question. Risk estimates for adverse effects other than cancer are usually expressed as the ratio of a toxicologic potency value to an estimated dose or exposure level. A key distinction between cancer and other toxicologic effects is that most carcinogens are assumed to have no dose threshold; that is, no dose or exposure level can be presumed to be without some risk. Other toxicologic effects are generally assumed to have a dose threshold; that is, a dose or exposure level below which a significant adverse effect is not expected.

Cancer Hazard and Risk

EPA employs a "weight-of-evidence" approach to determine the likelihood that a chemical is a human carcinogen.[1] Each chemical evaluated is placed into one of the five weight-of-evidence categories listed below.

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[1] The "Proposed Guidelines for Carcinogen Risk Assessment" (EPA, 1996b) propose use of weight-of-evidence descriptors, such as "Likely" or "Known," "Cannot be determined," and "Not likely," in combination with a hazard narrative, to characterize a chemical's human carcinogenic potential - rather than the classification system described above.

- Group A - human carcinogen;
- Group B - probable human carcinogen. B1 indicates limited human evidence; B2 indicates sufficient evidence in animals and inadequate or no evidence in humans;
- Group C - possible human carcinogen;
- Group D - not classifiable as to human carcinogenicity; and
- Group E - evidence of noncarcinogenicity for humans.

When the available data are sufficient for quantitation, EPA develops an estimate of the chemical's carcinogenic potency. EPA "slope factors" express carcinogenic potency in terms of the estimated upper-bound incremental lifetime risk per mg/kg average daily dose. "Unit risk" is a similar measure of potency for air or drinking water concentrations and is expressed as risk per µg/m^3 in air or as risk per µg/l in water for continuous lifetime exposures.

Cancer risk is calculated by multiplying the estimated dose or exposure level by the appropriate measure of carcinogenic potency. For example an individual with a lifetime average daily dose of 0.3 mg/kg of a carcinogen with a potency of 0.02/mg/kg/day would experience a lifetime cancer risk of 0.006 from exposure to that chemical. In general, risks from exposures to more than one carcinogen are assumed to be additive, unless other information points toward a different interpretation.

Chronic Health Risks

Because adverse effects other than cancer and gene mutations are generally assumed to have a dose or exposure threshold, a different approach is needed to evaluate toxicologic potency and risk for these "systemic effects." "Systemic toxicity" means an adverse effect on any organ system following absorption and distribution of a toxicant to a site in the body distant from the toxicant's entry point. EPA uses the "Reference Dose" approach to evaluate chronic (long-term) exposures to systemic toxicants. The Reference Dose (RfD) is defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime" and is expressed as a mg/kg/day dose. The RfD is usually based on the most sensitive known effect; that is, the effect that occurs at the lowest dose . EPA calculates a comparable measure of potency for continuous inhalation exposures called a Reference Concentration or RfC, expressed as a mg/m^3 air concentration. Although some RfDs and RfCs are based on actual human data, they are most often calculated from results obtained in chronic or subchronic animal studies. The basic approach for deriving an RfD or RfC involves determining a "no-observed-adverse-effect level (NOAEL)" or "lowest-observed-adverse-effect level (LOAEL)" from an appropriate toxicologic or epidemiologic study and then applying various uncertainty factors and modifying factors to arrive at the RfD/RfC.

RfDs and RfCs can be used to evaluate risks from chronic exposures to systemic toxicants. EPA defines an expression of risk called a "Hazard Quotient" which is the ratio of the estimated chronic dose/exposure level to the RfD/RfC. Hazard Quotient values below unity imply that adverse effects are very unlikely to occur. The greater the Hazard Quotient exceeds unity, the greater is the level of concern. However, it is important to remember that the Hazard

Quotient is not a probabilistic statement of risk. A quotient of 0.001 does not mean that there is a one-in-a-thousand chance of the effect occurring. Furthermore, it is important to remember that the level of concern does not necessarily increase linearly as the quotient approaches or exceeds unity because the RfD/RfC does not provide any information about the shape of the dose-response curve.

An expression of risk that can be used when an RfD/RfC is not available is the "Margin-of-Exposure (MOE)." The MOE is the ratio of a NOAEL or LOAEL (preferably from a chronic study) to an estimated dose or exposure level. Very high MOE values such as values greater than 100 for a NOAEL-based MOE or 1000 for a LOAEL-based MOE imply a very low level of concern. As the MOE decreases, the level of concern increases. As with the Hazard Quotient, it is important to remember that the MOE is not a probabilistic statement of risk.

Developmental Toxicity Risks

Because of the many unique elements associated with both the hazard and exposure components of developmental toxicity risk assessment, these risks are treated separately from other systemic toxicity risks.

EPA defines developmental toxicity as adverse effects on the developing organism that may result from exposure prior to conception, during prenatal development, or postnatally to the time of sexual maturation. Adverse developmental effects may be detected at any point in the life span of the organism. The major manifestations of developmental toxicity include: (1) death of the developing organism, (2) structural abnormality, (3) altered growth, and (4) functional deficiency.

There is a possibility that a single exposure may be sufficient to produce adverse developmental effects. Therefore, it is assumed that, in most cases, a single exposure at any of several developmental stages may be sufficient to produce an adverse developmental effect. In the case of intermittent exposures, examination of the peak exposure(s) as well as the average exposure over the time period of exposure is important.

EPA has derived Reference Doses and Reference Concentrations for developmental toxicants in a similar manner to the RfDs and RfCs for other systemic toxicants. The RfD_{DT} or RfC_{DT} is an estimate of a daily exposure to the human population that is assumed to be without appreciable risk of deleterious developmental effects. The use of the subscript DT is intended to distinguish these terms from the more common RfDs and RfCs that refer to chronic exposure situations for other systemic effects.

Developmental toxicity risk can be expressed as a Hazard Quotient (dose or exposure level divided by the RfD_{DT} or RfC_{DT}) or Margin-of-Exposure (NOAEL or LOAEL divided by the dose or exposure level), with careful attention paid to the exposure term, as described above.

NOTE: *The closely related area of reproductive toxicity is also an important aspect of systemic toxicity. For purposes of this report, toxicity information on adult male and female reproductive systems will be assessed as part of the chronic toxicity risk.*

Assumptions and Uncertainties

Estimated doses assume 100 percent absorption. The actual absorption rate may be significantly lower, especially for dermal exposures to relatively polar compounds. The assessment used the most relevant toxicological potency factor available for the exposure under consideration. In some cases the only potency factor available was derived from a study employing a different route of exposure than the exposure being evaluated. For example, oral RfD values were sometimes used to calculate Hazard Quotients for inhalation and dermal exposures. For the occupational risk assessment, RfC values were converted to units of dose assuming a breathing rate of 20 m^3/day and a body weight of 70 kg. This conversion was done because occupational inhalation exposures were calculated as a daily dose rather than as an average daily concentration. The general population risk estimates compare RfC values directly to average daily concentrations because continuous exposure is assumed for the general population. Most of the Margin-of-Exposure calculations presented in the assessment are based on toxicity data that have not been formally evaluated by the Agency. Simple esters of glycol ethers were assumed to present the same hazards at approximately the same potencies as the corresponding alcohol. The same potency data were used in risk estimates for each alcohol and its corresponding ester unless specific data for each compound were available.

All risk estimates are based on release and exposure values estimated from information on product usage and work practices obtained from industry surveys. No actual measures of chemical release or exposure levels were available.

Certain formulation components are described in the CTSA by their category name, such as propylene glycol series ethers. However, all risk calculations in the CTSA are based on chemical-specific hazard and exposure data. Thus, risk values may appear for some category members but not others because of limitations in available data.

ECOLOGICAL RISK

The basic elements of ecological risk assessment are similar to those employed in human health risk assessment. This report will address only ecological risks to aquatic species. Quantitative evaluation of aquatic risks involves deriving an "ecotoxicity concern concentration (ECO CC)" for chronic exposures to aquatic species. The ECO CC may be based either on valid toxicologic test data on the subject chemical or on quantitative structure-activity relation analysis of test data on similar chemicals. The ECO CC is typically expressed as a mg/l water concentration. Concentrations below the ECO CC are assumed to present low risk to aquatic species. A notation of "N.E.S." rather than a numeric estimate of the ECO CC indicates that no adverse effects are expected in a saturated solution during the specified exposure period.

APPENDIX E

BACKGROUND AND METHODOLOGY FOR PERFORMANCE DEMONSTRATION: LITHOGRAPHY CTSA

E-1 BACKGROUND AND OVERVIEW OF METHODOLOGY

This section of the lithography CTSA summarizes performance information collected during laboratory and production run performance demonstrations with substitute blanket washes carried out between November 1994 and January 1995. Performance data collected included information such as quantity of wash used, time spent to wash the blanket, ink coverage, and the effectiveness of the wash. Data from the performance demonstrations, in conjunction with risk, cost and other information presented in other sections of the CTSA, provides a more complete assessment of substitute blanket washes than has otherwise been available from one source.

In a joint and collaborative effort, EPA worked with the Printing Industries of America (PIA), the Graphic Arts Technical Foundation (GATF), and other industry representatives to organize and conduct the performance evaluations of 36 substitute blanket washes and the baseline. The demonstration methodology was developed by consensus and was designed to allow the evaluation of the maximum number of blanket washes given the resources available to the project. Performance data were collected for each product in two distinct phases: (1) a laboratory test of the chemical and physical properties and the efficacy of the substitute products, and (2) evaluations conducted in a production setting at volunteer printing facilities. The intent of the laboratory evaluations was to independently measure some of the properties of the washes, such as volatile organic compound (VOC) content, and to assure that the blanket washes sent to volunteer printers would provide an acceptable level of performance. Facility demonstrations were undertaken at the request of printers participating in the DfE project so that blanket washes could be evaluated under the more variable conditions of production runs at printing facilities. It should be noted that the performance demonstrations are not rigorous scientific investigations. Instead, much of this chapter documents the printers' experiences with and opinions of these products as they were used in production at their facilities.

Participation in the demonstration project was open to all blanket wash manufacturers. Prior to the start of the demonstrations, the DfE project staff contacted nearly 100 blanket wash manufacturers to explain the project goals and request their submission of a product. All those who responded and submitted blanket washes were included in the first phase of the demonstrations.

Methodology

The performance evaluation methodology developed by the workgroup is described below and covers both the laboratory testing protocol and the on-site demonstrations methodology. In developing the methodology, the workgroup agreed that product names would be masked. Neither the volunteer printers nor the DfE observers knew the manufacturer of the products being evaluated. Trade names are not listed in this report, instead the blanket washes are referenced by a numerical code and a genericized chemical formulation. This agreement to mask product names was made for several reasons:

- The chemical formulations of commercial products containing distinct chemicals are frequently considered proprietary. Manufacturers of these products typically prefer not to reveal their chemical formulations because a competitor can potentially use the disclosed formulation to sell the product, often at a lower price, since the competitor did not have to invest in research and development.

- The performance of products may vary depending on use and shop conditions, and suppliers were concerned about the characterization of the performance of their products.

- The EPA was concerned about appearing to endorse brand name products that fared well in the CTSA evaluation.

In the initial stages of the Lithography Project the Project partners chose VM&P Naphtha as the baseline against which to compare the 36 substitute blanket washes. VM&P Naphtha, composed of 100 percent solvent naphtha, light aliphatic and referred to as formulation 28 in certain sections of the text, was chosen primarily because it is well known among lithographers as an effective blanket wash. Many lithographers have used VM&P in their shops and know how it works in their applications and what it costs. VM&P is known to be highly effective at very low cost, however, because of its high VOC content (100 percent) printers are searching for formulations to replace it.

As the Performance Demonstration was being conducted, some suppliers who had submitted blanket washes chose to withdraw. Their reasons included not wishing to reveal to EPA their complete formulations or concern over the potential results of the performance tests. The formulations that were withdrawn after work had already begun were numbers 2, 13, and 15. For this reason, those numbers are missing from all the tables in the CTSA.

Laboratory Evaluations

Laboratory testing was carried out by GATF in Pittsburgh, Pennsylvania. A total of 36 products were submitted plus the baseline. For each wash, the flash point, VOC content, and pH were tested. The vapor pressure of the product was not tested, but was submitted by the supplier. Two additional tests, a blanket swell test and a wipability test, were conducted to determine the efficacy of each wash prior to sending it out for field demonstrations. Only products that passed this functional demonstration stage were used in the field demonstration portion of the project. For both of these tests, GATF followed the manufacturer's instructions for diluting or mixing the product.

The blanket swelling potential of each product was tested to determine the effect of the wash on the blankets. The procedure used (detailed in Section E-3) involved measuring the thickness of the blanket test square (2 x 2 inches), maintaining contact between the test square and the wash for one hour, and taking another thickness measurement to calculate the percent swell. Another measurement is taken after 5 hours. Any wash where the blanket swell exceeded 3 percent after 5 hours indicated that the wash may dimensionally distort the blanket and was eliminated from field demonstrations.

Washability of each blanket wash was evaluated using both a wet and a dry ink film (detailed in Section E-4). To measure the washability, a standard volume of ink was evenly applied to a section of a new, clean test blanket. A measured volume of the wash was applied to a cleaning pad. The pad was attached to a mechanized scrubber and the number of strokes required to remove the wet ink were recorded. The procedure was repeated for a dry ink film where the ink was dried with a blow dryer for 20 minutes prior to the cleaning. The dry ink and wet ink tests were repeated for each alternative blanket wash submitted. Any wash where more than 100 strokes were required to clean the blanket (with cleanliness determined by using a reflective densitometer) was eliminated from the field demonstrations.

Based on the results of the blanket swell and the washability tests, 22 of the original 36 products submitted (plus the baseline) qualified for further evaluation through field demonstrations. Prior to shipping substitute blanket washes to printers for these on-site evaluations, each wash was repackaged into a generic container so that those printers demonstrating the products did not know the manufacturer or product name. Masked Material Safety Data Sheets (MSDSs) were also developed and shipped along with the substitute blanket washes to be evaluated.

Printing Facility Demonstrations

PIA affiliates recruited printers located in the Boston, Baltimore, and Washington, D.C. areas, who volunteered their facilities and their time to conduct the field demonstrations of the substitute products. A total of 17 facilities participated. Each substitute product was demonstrated at two facilities and each facility demonstrated a minimum of two and up to five different blanket washes. The product brand name was replaced with a blanket wash number so that the demonstration facilities did not know what product they were using. In addition, the facility names have been replaced with a facility number. A list of participating facilities appears at the front of this document.

To start the on-site demonstration, an "observer" from the DfE project visited each of the volunteer facilities. DfE observers were not EPA employees, but were drawn from staff of the contractor, Abt Associates, Inc. The observers called each facility to review the details of their operation, discuss the goals of the project, and to schedule a site visit. The substitute products, a baseline product, MSDSs, application instructions, and a measuring device were shipped to each facility prior to the DfE observer's arrival.

During each one-day site visit, the observer collected information on the background of the facility, as well as data specific to blanket wash performance. Background data included information on the size of the presses, the number of employees, and current blanket washing practices. After collecting the initial background data, the observers documented information on three types of blanket washes: the blanket wash currently used at the facility, a baseline blanket wash, and the substitute wash. All information was recorded on an Observer's Evaluation Sheet (see Sections E-7 and E-8). Starting with their standard wash, the press operator cleaned the blanket while the observer recorded the quantity of wash used, the time required to clean the blanket, the length of the run, the type and color of the ink on the blanket, and the number of wipes used. After restarting the press, the press operator was asked to comment on the effectiveness of the blanket wash and to determine if there were any changes in subsequent print quality that could be attributed to the blanket wash. This procedure was then repeated using Blanket Wash 28, VM&P Naphtha, the selected baseline. Naphtha was used at all participating facilities. By comparing the differences in the performance of the baseline at the two different facilities, any significant effects of facility-specific operating conditions (e.g., the type of ink, size of blanket, and operator's effort) on the performance of the substitute wash were more apparent. After cleaning the blanket with the baseline wash, the press operator then used the substitute wash provided. The observer recorded the same type of information as was recorded for both the current wash and the baseline wash. The total number of washes required varied from one facility to the next, since the observer was on-site for one day and recorded information on as many washes as were required during production that day.

After the observer's visit, the facility continued to use the substitute wash for one week. During the week, the printer at each volunteer print shop was asked to record information on product performance. The data recorded were similar to that collected by the on-site observer. However, the Printer's Evaluation Sheets (Section E-9) were simplified in an effort to minimize volunteer printers' burden and production disruptions. Facility background information such as the press size and type of shop towel used were recorded by the observer only. At the end of the week, the observer interviewed the press operator to obtain an overall opinion of the product. The exit interview information was recorded on another standardized form (Section E-10).

Data Collection, Summary, and Analysis

The information summarized in the following section comes from five sources.

- *Laboratory results:* the chemical characteristics and the results of the blanket swell and washability tests were reported for each wash.
- *Facility background information:* the observer collected information on operating conditions while on-site at each volunteer print shop.
- *Observer's data:* DfE observers recorded information on the performance of the facility's current blanket wash, a baseline wash, and the substitute blanket wash.
- *Printer's data:* press operators recorded performance data for each blanket wash completed during the week-long demonstration of the substitute blanket wash.
- *Follow-up interviews:* observers interviewed the press operators at the end of the week-long demonstration on their overall opinion of the substitute blanket wash.

For each of the 22 substitute blanket washes in the field demonstrations, data from the sources mentioned above were analyzed and are summarized in this section. The experiences of the two facilities who demonstrated each product are presented individually. As part of the analysis, a number of correlations were attempted for each facility but the results were typically not statistically significant due to small sample size. These analyses were run to determine if variations in the printer's opinion of the effectiveness of the blanket depended on any other variables such as ink coverage, effort and time spent on blanket washing, or run length. Where appropriate, these results were included within the text summaries of each substitute blanket wash. Additionally, some summary statistics, such as average amount of product used, were presented in accompanying tables.

Limitations

The widely variable conditions between and within printing facilities, the limited number of facilities, and the short duration of the performance demonstrations do not allow the results to be interpreted as definitive performance testing of the blanket washes. In addition, some facilities did not provide the full complement of evaluation forms because they found the performance of the substitute wash to be unacceptable and they discontinued use before the end of the week.

As mentioned previously, the performance demonstrations are not scientifically rigorous but are subjective assessments which reflect the conditions and experience of two individual print shops. There are a number of reasons why the results of performance demonstrations for any given blanket wash may differ from one facility to another. Among these reasons are:

- *Variability in operating conditions.* Because performance demonstrations were carried out during production runs, many factors which affect the performance of the blanket washes were not controlled during the evaluations including: ink type, ink coverage, condition of the blanket, the length of the run prior to blanket cleaning, and the ambient conditions such as temperature, humidity, and ventilation.
- *Variability of print jobs.* Different types of jobs had different requirements for blanket cleanliness. Observers noticed that what one facility considers to be a clean blanket another facility may find unacceptable.
- *Variability of staff involved in performance demonstrations.* Press operators' attitudes towards alternative blanket washes differ from one operator to the next and can affect their perception of performance. As previously mentioned, some of the information recorded was subjective and varied depending on a variety of factors including the attitude, perception, and previous experiences of the operator. For example, many of the substitute products were low in VOC content and did not evaporate as quickly as some of the more traditional blanket washes. Often, an extra step was needed to wipe the blanket with a dry rag to remove a residue left by some of the substitute washes. While extra cleaning steps can be time consuming and lead to increased production costs, even a minimal extra effort was regarded as an unacceptable burden by some operators. Other operators understood that some changes in their procedures and even some extra effort may be needed in order to effectively clean the blanket with an alternative product.
- *Variability in application method.* Press operators' overall opinion of the blanket wash could have been affected by their current application method. For example, operators who are accustomed to using high solvent blanket washes where little effort is required may differ in their opinion of "moderate effort" from operators who are currently using an alternative where some extra effort is already required. All manufacturers were asked to supply application procedures for their product. When instructions were supplied, the observer reviewed the procedures with the press operators, verified the correct procedure was used when the observer was on-site, and asked in the interview at the end of the week if the application procedures had been modified in any way. If any changes were made, the type of change and the reason for the change were described in the performance summary.

- *Short term nature of the demonstrations.* Printers used the substitute blanket washes in their facilities for one week. Any long term effects such as premature blanket wear or corrosion would not have been apparent.

Blanket Wash Summaries

A summary of the performance of each of the 22 substitute blanket washes is presented in Chapter 4 of the lithography CTSA. Since the trade names of the substitute blanket washes are not given in the lithography CTSA, each blanket wash is identified by a numerical code and a generic chemical formulation. The specific types of chemicals that make up each of the generic formulations are explained in greater detail in Chapter 2 of that document. In addition, the facility names have been replaced with a facility number.

Performance of each product is presented separately for the two facilities, and includes a description of the facility's current blanket wash, their past experience in testing alternative blanket washes, their overall opinion of the substitute wash performance, and, if applicable, a summary of the factors that may have influenced performance. A table is also included for each blanket wash which presents the results of the laboratory test of both the substitute blanket wash and the baseline wash. Averages of the volume of wash used, time required, and effort required, as recorded by the printers during field demonstrations are also included in each product performance table.

E-2 METHODOLOGY DETAILS

This section presents information on the methods that were used to gather the performance demonstration data at the print shops and in the laboratory, as presented in Chapters 4 and 7 of the Lithography CTSA. Specifically, this section includes:

- Characteristics to be Reported Out of the Performance Demonstration.
- Demonstration Methodology.
- Blanket Swell Test (laboratory test).
- Washability/wipe Test (laboratory test).

CHARACTERISTICS TO BE REPORTED OUT OF THE PERFORMANCE DEMONSTRATION

Cost of Each Product as Utilized

Product Cost

Interested product suppliers should include the manufacturer's suggested retail price (to the end user) of their products ($ per 5 gallon drum) upon submission of samples for demonstration so that the cost per volume used in a cleaning cycle can be determined and reported.

Disposal/Spoilage Costs

Suppliers should provide specific recommendations for the disposal or treatment of wastes associated with using their products. Based upon these recommendations and the wastes determined in the field tests, disposal or treatment costs will be estimated.

Labor/Down-time Costs

This information will be based on the time required to wash a standard 19" x 26" blanket (based on two measures: button-push to completion of wash excluding time for other activities, such as refilling paper; and, after washing, zero the counter and count the number of sheets to get back to salable printing), a standard press operator wage, and standard press time costs. The costs of time and paper losses while returning to salable printing following the wash should be included here as well as any costs that may be associated with changes in or destruction of the blanket or other printing system components. The standard press operator wage information will be obtained from the wage and hourly survey developed by the National Association of Printers and Lithographers.

Storage Costs

These costs will include any special storage required due to hazardous components present in the blanket wash materials.

Product Constraints

The blanket wash supplier should provide information about product compatibility with specific inks (e.g. petroleum or vegetable oil based, UV water based), if known. If the supplier does not provide information regarding product incompatibilities, it will be assumed that there are none.

Special Safety Storage Requirements

Suppliers should provide information about the flammability (as measured by flash point) of the product. This will be confirmed by the laboratory test in the pre-screening procedure.

Ease of Use

The physical effort required to effectively clean the blanket using the test product will be evaluated and reported. This is a subjective judgement based on the experience of the press operator.

Duration of the Cleaning Cycle

The measured time will be the entire cleaning cycle from press shut down to completion of the cleaning process (this excludes any activity unrelated to blanket cleaning). This information when correlated with labor and press-time costs will attempt to measure the total costs associated with the use of the product.

Effectiveness of the Blanket Wash Solution

This will be the subjective judgement of the press operator. The basic criteria will be whether the blanket is sufficiently clean to resume printing based on the judgement of the operator. VM&P Naphtha will be used as the baseline blanket wash to measure a test solution's efficacy, and the operator should also compare against what is normally used on the press.

Printing Equipment and Ink

Information will include the manufacturer, type and age of the press, the blanket and the ink, and the length of press run prior to blanket wash. This is basically descriptive information that may assist in discovering and reporting incompatibilities between the blanket washes and equipment or inks. Additionally, the type of printing job, type of fountain solution, paper size relative to press size, paper type, brief description of blanket condition (Note: the blanket used should be runable with no smashes or repairs) along with a general description (light, medium, and heavy) of ink coverage will also be reported.

DEMONSTRATION METHODOLOGY

Product Pre-Screening and Masking

The project will demonstrate alternative blanket washes. Products, product information and MSDSs will be submitted by suppliers in properly labeled generic commercial containers to an independent laboratory (e.g., GATF or university). The independent laboratory will test the flash point and VOC content of the alternative blanket washes. The vapor pressure of the product will be submitted by the supplier (the supplier will note whether the vapor pressure is based on a calculation or test data.) The pH of the product will be provided by the supplier and will be verified by the laboratory. Suppliers wishing to participate in the performance demonstration will have to make direct arrangements with the independent laboratory.

The laboratory will mask all products by removing the trade names and manufacturer from the containers and assign each sample a random ID number. Suppliers will provide a masked MSDS in addition to the standard MSDS sent for shipping. They will also give directions for use of the product without any identifying names, labels or characteristics.

The laboratory will perform a standard test for blanket swelling potential of each product. They will also perform a washability/wipe test for cleaning effectiveness on all of the products submitted. The blanket swell test and the washability/wipe test proposed methodologies are described in Sections E-3 and E-4. The directions for each specific product will be used as much as possible, including the manufacturer's directions for dilution or mixing. Any deviation from the manufacturers directions will be noted along with the reasons for the deviation. Only products that pass this functional demonstration stage will be used in the field demonstration portion of the project.

Based on the results of the product pre-screening, products will be grouped into categories based on their formulation and/or chemical parameters. These categories should be consistent with the categories used in the EPA risk assessment. One or more products successfully completing the screening will be chosen to "represent" each of the categories; these representatives (one or two per category) will be from the average of the class. The selection of masked products will be sent to volunteer printers for field demonstration. The selection of printers will take into account the type of inks being used as well as the sizes and types of blankets. The variety of inks and blankets used for the demonstration will depend on the number of demonstration sites. Each printer will test a limited number of products. This number will be determined when the number of volunteer printers is established. Although contingent upon the number of categories, the number of volunteer printers, and available resources, each representative blanket wash will be field demonstrated by at least two.

Documentation of Existing Conditions at Volunteer Facility

Once the products have been shipped to the volunteer printing facilities, an observer[1] will record the type, color, and manufacturer of the ink currently being used on the press. The observer will also document the type, model, and condition of the press and blanket being used for the demonstration and the type of paper being run on the press. The observer will also briefly describe the experience of the press operators participating in the test and will document any past experiences that the printer has had with the demonstration of blanket washes; the observer will note any potential biases. The current waste and wipe disposal practices and costs will be documented by the observer. **NOTE:** Presence of observer should be cleared with insurance carrier if necessary, and the purpose of the observer should be carefully explained to the personnel in the pressroom.

The observer will record the product name and cleaning procedure for the blanket wash currently used by the company. The observer will record the cost of the current blanket wash solution. The observer will also record how the product is being stored (in bulk and at the press) and disposed of as waste.

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[1] A contract is currently being prepared by EPA to staff this function. This observer will not provide technical assistance to the printers. The observer will serve to document the demonstration and record the operators observations. The observer will ensure the operator performs the demonstration according to the final approved methodology. The observer will additionally serve as the press operators conduit to the technical assistance personnel. This conduit is necessary so as to clearly document the direction given and the actions taken.

The observer will document the current practices by observing the clean up of a blanket, utilizing the company's current product. This will include any pre-application dilution of the product. The observer will measure the quantity used for the cleaning with the company's current blanket wash solution and record the time required for the cleanup. The pressman will use a clean rag to clean the blanket, and the observer will record the size and weight of the rags used for cleaning before and after the cleaning. This will provide an estimate of the retention factor of the product.

The observer will describe the density of the image currently being printed and will record information on the relative frequency of blanket cleaning. The observer will document the number of images required to obtain an acceptable print.

Establishing Evaluation Baseline at Volunteer Facility

The blanket will be cleaned by the press operator using the baseline solution (VM&P Naphtha). This initial cleaning will serve to familiarize the press operator with the baseline product performance. The printer will compare the baseline solution with the blanket wash that is typically used. It has been suggested that this initial cleaning should not be used for comparative purposes, but the information noted in each of the sections below should be noted for reference in any case.

Demonstration

The press will then be restarted for printing and then stopped for cleaning according to the company's standard procedures. The observer will measure the time of cleaning from button push to completion of wash excluding time for other activities, such as refilling paper, and will ask the press operator to zero the counter in order to count the number of sheets to get back to salable printing. The observer will document the volume of baseline solution used and describe the procedure used to ensure the directions were adhered to by the operator. This procedure will be followed for three complete cleaning cycles.

Press Operator Evaluation

At the completion of these cycles the press operator will subjectively evaluate the condition of the blanket, i.e., scaling, picking, etc. Additionally, the operator will evaluate the ease of use and performance of the baseline solution. The observer will describe the density of the image currently being printed. The observer will document the number of images required to obtain an acceptable print image for each of the cleaning cycles.

Resetting the Blanket

The blanket will be cleaned by the press operator using the test blanket wash solution. This initial cleaning will serve to familiarize the press operator with the product and to avoid complications with the previously used solutions. The press operator should measure the volume after each cleaning (the volume used in the initial cleaning may not be used for comparative purposes).

Demonstration

The press will be restarted for normal operation and then be stopped for cleaning according to the company's standard practice. The observer will measure the time of cleaning from button push to completion of wash excluding time for other activities, such as refilling paper, and will ask the press operator to zero the counter in order to count the number of sheets to get back to salable printing. The observer will document the volume of solution used and describe the procedure used to ensure the directions were adhered to by the operator. This procedure will be followed for five complete cleaning cycles.

Press Operator Evaluation

At the completion of these cycles the press operator will subjectively evaluate the condition of the blanket, i.e., scaling, picking etc. Additionally, the press operator will document the density of the last printed image. The press operator will document the number of images required to obtain an acceptable print image for each of the cleaning cycles. The press operator will compare the relative performance of the test solution as compared to the baseline solution.

Long Term Test

After completion of the above demonstration, a longer term test will be performed by the printer. This test will consist of continued use of the supplied product for a period of one week. The blanket will not be cleaned with any other solutions until the observer returns. The press operator will record the total number of copies printed, the number and relative frequency of blanket washes performed, the volume of product used for each blanket wash, the total amount of product used, and the number of images required to obtain an acceptable print quality for each cleaning cycle.

At the completion of this phase, the observer will return to the shop and will record the press operator's data. The observer will then document the procedures used in a final cleaning of the blanket by the press operator. This will indicate whether there has been any deviation from the initial cleaning procedure by the press operator. If there has been a deviation the observer shall record the reasons for the deviation.

The press operator will then evaluate the condition of the blanket and describe the density of the product currently being printed.

If at any time during this phase of the demonstration there is problem with the solution or the press, the press operator or company point of contact will document the problem as specifically as possible and call the technical assistance provider[2] for guidance. Any corrective action will be documented by both the technical assistance provider and the press operator. The observer will record the actions documented by the press operator.

Trouble Shooting

If problems arise during the field demonstration of the blanket solutions, the following procedures will be followed. If the observer is present, the problem will be documented and the observer will call the technical assistance provider for guidance. If the observer is not present the press operator will document the problem and contact the technical assistance provider.

The technical assistance provider will first review the procedures used by the press operator to ensure they are in compliance with the instructions provided with the product. If the procedures are correct then the technical assistance provider will contact one of the printers currently using a product in that category for assistance. Names of these support printers will be provided by the suppliers of the products. The technical assistance provider will relay and filter the recommendation of the support printer to the press operator. The technical assistance provider will ensure the confidentiality of the products is maintained during this period. The identity of the product in the field will remain masked, and the identity of the specific product being used by the support printer providing guidance will not be asked or provided by the printer.

The observer and/or the technical assistance provider will document all actions recommended and taken.

If the recommendations provided by the technical assistance provider are unsuccessful, the press operator will then attempt to solve the problem. The observer and/or the technical assistance provider will document the actions taken by the press operator and the success or failure of the actions.

The above procedures will be repeated for each product tested at the printer test site.

Results and Final Report

Final results will be assembled from the test sites and provided to a contractor to develop into a final report. The report will be developed so that the blanket wash products submitted for testing are grouped according to their formulations/chemical parameters (e.g., VOC content, vapor pressure). The results from similar products in a grouping will be reported in ranges so that the scope of performance from each group can be reported in the information provided to printers. The parameters delineating the grouping will be clearly defined so that both printer and supplier can determine the grouping for any particular blanket wash of interest. Special attention will be paid to the report-out of information on water-miscible products so that printers realize

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[2] A contract will be prepared by EPA to staff this function. The technical assistance provider (i.e., GATF, university, etc.) will be available to trouble-shoot during the field demonstration portion of the project.

that the category characteristics are based on the use of proper amounts of water. (Note: No results will be provided for individual/named products, but blanket washes participating in the study will be listed in the report, along with their grouping.) Results from the field demonstration will be evaluated and assembled so that for any particular group the "average" experience with the products in the group is presented, along with the extreme reactions.

The report will thus have two parts. One part that presents the independent laboratory's screening and other information founded in essentially concrete or quantitative data and a second part that gives experiential anecdotes derived from the subjective evaluations of the demonstration site personnel. Both types of information can be used to develop a second type of information product: case studies of individual demonstration locations that discuss specific actions, changes in techniques, attitude adjustments or other factors that could be significant to a printer that is contemplating product substitution. The products would continue to be masked in the case study. It may be possible to combine several sites with similar experiences into a single report focussing on a single group of products.

E-3 BLANKET SWELL TEST

The purpose of this test is to determine the effect of blanket washes on lithographic blankets by measuring any change in thickness by the use of a micrometer.

Equipment:

Crystallization Dish
Cady Gauge (gauge +/- 0.0005 inch)
Swell Test Clamp
2 x 2 inch squares compressible blankets
VM&P Naphtha, Varnish Makers' and Painters' Naphtha; petroleum fractions meeting ASTM specifications. (Distillation range, at 760mm Hg 5 percent at 130 ^{o}C; greater than 90 percent at 145 ^{o}C)
Various Blanket Washes

Experimental Procedure:

This procedure involves measuring and adding 10 ml of the blanket wash to a crystallization dish using a graduated cylinder. An initial caliper measurement is taken of the 2 x 2 inch blanket sample and then it is placed over the mouth of the dish. The dish and blanket are placed into the swell clamp where the blanket is tightened down onto the mouth of the dish until a leak proof seal is formed. The various washes are kept in contact with the blanket for one hour. Caliper readings are taken and the percent swell is calculated. The blanket is re-tightened, exposed for an additional five hours, and the caliper is measured again. This same procedure will be repeated for each blanket wash. The VM&P Naphtha will be used as a control.

$$\text{Percent Swell} = \frac{\text{Final Caliper} - \text{Initial Caliper}}{\text{Initial Caliper}} \times 100$$

Sample	% Caliper Change After 1 Hour	% Caliper Change After 6 Hours
1. Control (VM&P Naphtha)		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

Temperature ____________________________

Relative Humidity ______________________

Blanket Type ____________________________

E-4 WASHABILITY/WIPE TEST

Equipment:

Ink - Sheetfed Process Black
Blanket - Compressible Blanket Cut Into Squares
Quickpeek Brayer Apparatus
Gardner Scrubber Apparatus
Graduated Cylinder
Control Blanket Wash - VM&P Naphtha
Playtex® Panty Shield
Status T Reflective Densitometer
Standard 1200-1500 Watt Blow Dryer
Various Candidate Blanket Washes

Experimental Procedure:

The procedure involves an initial evaluation by using both a dry and wet ink film drawn down on separate pieces of blanket using a quickpeek brayer apparatus. The ink stripes will measure 2 inches wide and 5 inches in length. The amount of ink applied will be determined by using one small or large hole on the Quickpeek apparatus. The blanket will be new and cleaned with the standard prior to applying the ink films. One of the ink films will be dried with a standard blow dryer.

The piece of blanket will then be placed into the holder of the Gardener Scrubber Apparatus. A measured volume of standard and candidate washes will be evaluated. The number of strokes necessary to clean the blanket with the standard will be determined. Once the area has been cleaned with the standard, the densitometer will be used to evaluate the cleanliness of the blanket. Each candidate wash will be placed onto a clean Playtex® Panty Shield and the cleanliness of the blanket will be measured after the same number of strokes found necessary by the standard. If the blanket is not clean, the number of strokes necessary to clean the blanket will be noted. Any residue or other unusual conditions will be indicated.

One of the wet ink films will be dried for 20 minutes with the blow dryer. The same volume of standard and blanket wash as used for the wet ink will be use. The above procedure will be repeated.

The following represents a more detailed review of the step-by step procedure for the Gardner Scrubber Apparatus:

1. A piece of blanket is cut to fit into the holder of the Gardener Scrubber apparatus and the section to be scrubbed is drawn on the blanket. A measured quantity of ink is spread evenly onto the surface of the blanket, ensuring that the thickness of the ink is uniform in the area to be scrubbed. Inking should be done on a counter or other level surface - inking in the holder will result in an uneven surface.

2. The wooden block is used to hold the sample collector, in this case a Playtex® Panty Shield. A new, dry shield should be weighed, without the coated paper that protects the adhesive. Solvent will be placed on the shield, not on the inked surface. The initial weight of the shield should be noted and the shield placed on the wooden block. Affix the shield on the side of the block not marked "top" block using the shield's adhesive, and place the block in its holder. Make sure the shield ends are inside the metal holder. They can be forced in by hand or held with thumbtacks. Use the side screw to ensure the block is held securely.

3. Prepare a pipet with 0.4 mL of standard solvent. Ensure that the Scrubber counter is reset and that the holder is in a position where it can be stopped after the test. The far right hand side of the tray is suggested.

4. Place the inked blanket into the tray. Hold the wooden block with the panty shield up and away from the inked surface so that no ink gets on the panty shield. Pipet the wash onto the pad using a swirling motion to evenly distribute the solvent over the surface.

5. Turn the pad over and start the scrubber. It should be allowed to go back and forth 20 times. At the completion of the last cycle, lift the pad off the blanket surface.

6. Lift the tray and blanket out of the apparatus.

7. Remove the block holder and remove the panty shield. Place in a 110 C forced draft oven for 2 hours to drive off the solvent. Weigh the dried panty shield and note the weight.

8. Clean the piece of blanket and re-ink to perform more tests.

9. Complete the tests for the blanket wash materials being tested with 2 replications each. Repeat the test using the standard solvent upon completion of the test series.

Note: A modified method may need to be developed for aqueous cleaners.

E-5 CATEGORIZATION FOR LITHOGRAPHIC BLANKET WASHES

Table E-1 presents the following categories and classification of formulations that were developed by the DfE Lithography Project Core Group and reviewed by the blanket wash suppliers. The categorization was developed to assist with the development of the Performance Demonstrations.

TABLE E-1: CATEGORIES AND CLASSIFICATIONS OF FORMULATIONS

Category	Mix	Washes	
		All	Pass[a] to Demo
1.	Vegetable fatty ester	1 26 29	1 26 29
1a.	Vegetable fatty ester (+glycol)	14 19	14 19
2.	Ester/Petroleum	3 21 36 38	21 36 38
2a.	Ester/Petroleum (+surfactant)	6 11 18 40	6 11 40
3.	Ester/Water	9 10	9 10
4.	Petroleum	31 32 35	31 32
5.	Petroleum/Terpene	13 15	13
6.	Petroleum/Water	5 8 20 37 39	20 37 39
6a.	Petroleum/Water (diluted for use)	12 30 33	30 12
7.	Water/Petroleum/Ester	22 34	22 34
8.	Terpene	16 24 27	24
8a.	Terpene (+ additives)	4 7 23 25	
9.	Detergent	17	

a) 1 indicates formulations passed blanket swell test ($\leq$3.0%) and basic washability.

E-6 PERFORMANCE DEMONSTRATION FORMS

The following four forms (shown on the following pages) were used by the observers and printers to record information for the performance demonstrations:

- Observer's Evaluation Sheet
- Observer's Performance Evaluation Sheet
- Printer's Evaluation Sheet
- End-of-Week Follow-up Questionnaire

E-7 OBSERVERS EVALUATION SHEET

FACILITY NAME: ____ **DATE:** __________

Ask each participating printer in the substitute blanket wash performance demonstrations to answer these questions when you call to schedule your visit to their facility. Once on-site, verify the answers.

1. Printing Process

Approximately what percentage of your business (based on annual sales) is in the following segments? Please check all boxes that apply.

	<50%	**50 - 95%**	**95 - 100%**
Lithography/Offset	☐	☐	☐
Gravure	☐	☐	☐
Flexography	☐	☐	☐
Screen printing	☐	☐	☐
Letterpress	☐	☐	☐
Other (specify)	☐	☐	☐

2. Products

What percentage of your *lithography* business (based on annual sales) is in the following products? Please check all boxes that apply.

	<50%	**50 - 95%**	**95 - 100%**
Commercial Printing	☐	☐	☐
Direct-mail Products	☐	☐	☐
Business Forms	☐	☐	☐
Publications (other than news)	☐	☐	☐
Packaging	☐	☐	☐
News	☐	☐	☐
Other (specify)	☐	☐	☐

3. General Facility Information

How many employees are at this location? __________

How many employees work in the press room? __________

How many shifts does your facility run per day? __________

4. Press Type(s)

Describe the press(es) that will be used for the performance demonstrations. The required press size is in the 19" x 26" class.

1. **Press size:** __________ *(in. x in.)*	**# of print units:** ___________	**Print speed:** __________ *(# impressions/hour)*
2. **Press size:** __________ *(in. x in.)*	**# of print units:** ___________	**Print speed:** __________ *(# impressions/hour)*

5. Blanket information

On the press(es) that will be used for the demonstration, what is the average number of times a blanket is washed per shift? ________________

What type of blanket do you use on the press(es) that will be used for the demo:

- Manufacturer: ______________________________

- Type (e.g., 3-ply compressible, etc.) _________________________________

- Number of impressions on this blanket prior to the demonstrations:
  1 week or less...☐ 1 week to 3 months...☐ 3 months or more...☐

- Do you have any automatic blanket washers in your facility? ____________

6. Blanket Washes

Press Used in Demo.	Trade Name of Blanket Wash/Manufacturer	Cost ($/gallon)	Dilution Ratio (wash:water)	Ink Type(s)
				conventional ☐ vegetable oil-based ☐ UV ☐ waterless ☐ other___________ ☐
				conventional ☐ vegetable oil-based ☐ UV ☐ waterless ☐ other___________ ☐

7. Experience with Substitute Blanket Washes

a. Have you tried any substitute blanket washes for environmental or worker health and safety reasons?
- Did the substitute wash work better, the same, or worse than your old wash? Why?
b. Besides substitute washes, have you changed any equipment, procedures or work practices that reduced your use of blanket wash solution or reduced the time required to wash the blanket? Yes.....☐ No.....☐ - If yes, please describe:

8a. Cleaning Procedure - CURRENT PRODUCT

Record blanket cleaning procedure using the chart below and the space at the bottom of the page for additional comments. In each column, check all that apply.

Method for Applying Blanket Wash	Type of Wipe Used to Clean the Blanket	Avg. No. of Wipes Used/Cleaning (cleaning+excess)	Method for Removing Excess Wash from Blanket	Wipes Management
Use squirt bottle to spray directly on blanket ☐	**Disposable** ☐	1-2 ☐	Clean dry rag ☐	Send off-site for laundering ☐
	Size:________			
Use squirt bottle to spray on wipe and apply wipe to blanket ☐	Wet ☐ Dry ☐	2-4 ☐	Clean wet rag ☐	Launder on-site ☐
		4-6 ☐	Allow to evaporate ☐	Dispose of as hazardous waste
Dip wipe in blanket wash and apply to blanket ☐	**Reusable** ☐			
Use safety plunger can ☐	Size:_________			
	Wet ☐ Dry ☐	6-8 ☐	No excess ☐	Dispose of as non-hazardous waste ☐
None Used ☐		8-10 ☐	Other (specify) ☐	
Other (specify) ☐	**Other** (specify) ☐	Other (specify) ☐		Other (specify) ☐

- Was the rotation of the blanket during washing *(circle one):* **manual** or **automatic**?

- Note any other steps taken in washing the blanket:

- For the current blanket wash product, ask the press operator if there are ever any variations in the cleaning procedure, and if so, under what circumstances?

8b. Cleaning Procedure - BASELINE PRODUCT

Clean the blanket using the baseline product, VM&P Naphtha, recording the required information on the observer's evaluation sheet for each cleaning.

- Note the condition of the blanket **before** cleaning:

- Weigh the Naphtha container before use. Record weight: ___________
- Pour Naphtha onto a clean, dry wipe.
- Weigh the Naphtha container again. Record weight: ____________
- Record the difference in weight on the evaluation sheet.
- Clean the blanket.
- Was the rotation of the blanket during washing *(circle one):* **manual** or **automatic**?
- Note any other steps taken in washing the blanket:

8c. Cleaning Procedure - SUBSTITUTE PRODUCT # ________

Clean the blanket using the substitute blanket wash. Follow the manufacturers instructions and record the required information on the observer's evaluation sheet for each cleaning.

- Note the condition of the blanket **before** cleaning:
- Describe the cleaning procedure:
- Was the rotation of the blanket during washing *(circle one):* **manual** or **automatic**?

E-8 OBSERVER'S PERFORMANCE EVALUATION SHEET

Facility Name____ Date____________

Demo Type: *(Check one and enter wash #)*

Current Wash ______

Baseline Wash ______
Wash # ______ (1 - 3)

Substitute Wash ______
(enter code # ______)
Wash # ______ (1 - 5)

Ink used before wash-up	Specify ink color, type, and manufacturer: conventional .... ☐ vegetable oil-based.... ☐ other (specify) _________________
Run length	Record length of run (# impressions) ________________
Ink coverage *(obtain a sample sheet for each level of coverage)*	*(check one)*: Heavy______ Medium______ Light______
Substrate	*Record substrate printed:*
Drying time	Time from end of press run to start of blanket wash: ____________ minutes
Dilution	_____________ *(enter wash:water ratio* or *"none" if used at full strength)*
Quantity of wash used	_____________ ounces *(pour wash on wipe; record volume of wash poured)*
Cleaning time	______________ minutes *(time for blanket cleaning only)* ______________ rotations *(corresponding number of blanket rotations)*
Ease of cleaning	*(check one for each question):* • Compared to your standard wash, was the effort needed: Lower______ Same______ Higher______ • Compared to the baseline wash, was the effort needed: Lower______ Same______ Higher______ • Did the wash cut the ink: Well____ Satisfactorily____ Unsatisfactorily____
Excess wash	Did you have to remove excess wash? *(check one)* Yes _______ No_______ If "Yes", how was it removed? *(check all that apply)*: Wet wipe____ Dry wipe____ Allow to evaporate____
Wipes used	Enter the total number of fresh wipes used for blanket washing *(includes both wipes used for washing and for removing excess wash)* : __________

Odor	*(check one):* Odor not noticed______ Odor detected______ Strong odor______
Printer's opinion of the wash performance?	The wash **performance** was *(check one):* Good______ Fair______ Poor______
Examine the blanket	Evaluate the blanket appearance after the wash:
Printing after the wash	Specify the ink color and type used after the wash: How many impressions were run to get back to acceptable quality? ____________ Does the printer think the wash caused problems with the print quality? Yes *or* No If yes, explain:

E-9 PRINTER'S EVALUATION SHEET

Facility name: _______________________________________ Date: _________

Press Operator's Initials: ________

Answer these questions for the BLANKET WASH ONLY (do not include the roller cleaning)	
Ink used before wash-up	Specify ink color: _______________ Specify ink type: conventional..........☐ other_____________________ vegetable oil-based...☐
Run length	Record length of run: *# impressions =* _________________
Ink coverage	*circle one*: Estimate the image coverage: Heavy Medium Light
Quantity of wash used for this cleaning	_________ # of ounces from Portion Aid dispenser provided
Cleaning rotations	_______________ rotations *(record the number of blanket rotations completed during the blanket cleaning)*
Ease of cleaning	*circle one*: The effort needed to clean the blanket was: Low Medium High
Wipes used	Number of fresh wipes used for blanket washing: __________
What is your opinion of this blanket wash?	*circle one*: The wash performance was: Good Fair Poor
Examine the blanket condition after the wash	Is there any residue, debris, etc. on the blanket? Yes..... ☐ No.....☐ If yes, please explain:
Printing after the wash	How many impressions were run to get back to acceptable print quality? Did the blanket wash cause problems with the print quality? Yes... ☐ No...☐ If yes, please explain:
Comments or suggestions - Use the back of this sheet or the space below for any comments:	

E-10 END-OF-WEEK FOLLOW-UP QUESTIONNAIRE

End of Week Follow-Up to Lithographers

At the end of the week-long demonstration, contact the press operator who used the blanket wash either in-person or by phone. Interview the operator to determine if there were any problems, changes, or concerns since your visit. If you are contacting them by phone, remind them to send in the completed forms immediately.

Facility Name ________________________________ Substitute Wash # ________

1. In your opinion, was the performance of the substitute wash better, worse, or about the same as your standard wash? Why?

2. Did you find any conditions where the wash did not work? (e.g., a certain ink type, ink color, or especially heavy coverage). If so, describe the condition(s).

3. Have you changed the ampliation procedure in any way?
    - Do you use more wash?
    - Have you changed the dilution?
    - Have you changed the method for removing excess wash?

4. Do you think the number of impressions required to get back to acceptable print quality is greater, the same, or less than were required using your standard blanket wash? Why?

5. Did you use any other blanket washes during the week on this blanket? Why?

6. Note the condition of the blanket

7. Do you have any other comments, concerns or problems regarding the substitute blanket

APPENDIX F

CHEMICAL VOLUME ESTIMATES: SCREEN PRINTING CTSA

Volumes for chemicals used within screen reclamation were estimated. Volumes of the chemicals produced within the nation, export volumes, and import volumes were estimated from information obtained from the following sources: Chemical Economics Handbook[1], US ITC[2], Manville[3], US EPA reports[4], Kirk-Othmer[5], and industry sources. In some cases, volumes reported represent broader categories than the individual chemical. Volumes for the portion of the chemicals used within screen reclamation was not readily available.

The Workplace Practices Questionnaire[6], SPAI's 1990 Survey[7], and expert opinion estimates were used to develop an estimate of the chemical volumes. The following methodology summarizes the assumptions and calculations used to estimate the annual national totals of chemicals used in screen reclamation.

The information needed to develop the estimates included the average screen size, the per screen volume of each type of reclamation product, market shares, the number of screens cleaned yearly, and the number of screen printing operations. This information is summarized in Table F-1.

The screen size, in conjunction with the amount of product used or purchased and the number of screens cleaned, was used to determine the per screen product usage. Typical formulations were then used to determine the chemical breakdown of the reclamation products. Combining this information resulted in estimates of the volumes of chemicals used for screen reclamation. Additional detail of the methodology is given below.

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[1] SRI. Selected reports from 1985 to 1993. *Chemical Economics Handbook*. SRI International, Menlo Park, CA.

[2] USITC. 1993 and 1994. Synthetic Organic Chemicals: United States Production and Sales, 1991. U.S. International Trade Commission, Washington, DC.

[3] Manville. Selected reports from 1990 - 1993. Manville Chemical Products Corporation, Ashbury Park, NJ.

[4] US EPA reports, including the Toxic Substances Control Act Chemical Substance Inventory (1985), "Aqueous and Terpene Cleaning" (1990), "Economic analysis of final Test Rules for DGBE and DGBA" (1987), "Glycol Ethers: An Overview" (1985).

[5] Kirk-Othmer, 1981, "Oils, essential." Kirk-Othmer Encyclopedia of Chemical Technology, 3rd ed., vol 16. New York: Wiley.

[6] The Workplace Practices Questionnaire was developed by EPA, SPAI and the University of Tennessee in 1993. It contains information on 115 screen printing facilities' operating and work practices characteristics. See Appendix B for a reproduction of the blank questionnaire and Appendix C for a summary of responses.

[7] Screen Printing Association International, 1990 Industry Profile Study, Fairfax, VA 1991.

AVERAGE SCREEN SIZE

Estimated from the Workplace Practices survey, observations were weighted by the number of screens cleaned per day. This is a normalization technique which incorporates the frequency of screen cleaning as well as the size of the screens. The average screen size was estimated to be 2,916 square inches. This value differs from the average in the appendix due to this normalization to incorporate incomplete responses.

PER SCREEN PRODUCT USAGE

Usage levels for three types of reclamation products were calculated using information collected through the Workplace Practices survey: ink remover, emulsion remover, and haze remover. Information used included average screens printed per day, volumes of products purchased each year, and the unit price of the products. Certain observations such as those from facilities carrying out in-plant recycling, were excluded from the calculations as these would distort the average volume used per screen of one-time ink removal operations. The average volume used per screen was calculated by dividing the annual amount of product purchased by the number of screens cleaned per year (assuming 252 working days and the midpoint of the range of screens cleaned per day).

DERIVATION OF MARKET SHARE OF TRADITIONAL AND ALTERNATIVE SCREEN RECLAMATION PRODUCTS

Current use of screen reclamation products is divided between *traditional* products, generally high VOC solvents, and *alternative* products, usually low or no VOC content products. To calculate the market share represented by each type of product, data was collected from the Work Practices Survey for Screen Printers (see Appendix A). In the calculation, market share is not based on volume used but rather on total screen area cleaned since traditional and alternative products may require very different quantities to clean the same screen area.

The formula used to calculate market share is as follows:

$$\text{Market Share}_{\text{Alt}} = A_{\text{Alt}}/A_{\text{Alt + Tra}} \qquad \text{Market Share}_{\text{Tra}} = A_{\text{tra}}/A_{\text{Alt + Tra}}$$

where:

$_{\text{Alt}}$ denotes Alternative Product
$_{\text{Tra}}$ denotes Traditional Product
$A = $ total screen area cleaned daily $= \sum_{N}^{F}$ [# of screens cleaned daily x area of screens]
F = number of facilities cleaning screens

Ink Removers

A simplistic decision rule, based on expert opinion, was used to classify ink removers as alternative or traditional. If the price of an ink remover in the Work Practices survey was below \$5.60/gallon then it was considered traditional. If the unit price was above \$18.90/gallon then the product was considered to be alternative. An additional seven ink removal products were assigned as traditional or alternative based on having a brand name in common with a product assigned using the price thresholds.[8] As the Work Practices Survey collected brand names, we did not know the composition of the product and had no other method to determine which category the products fit into. Once facilities were identified as using either traditional or alternative products, the screen area cleaned per day for each facility was estimated.[9] The screen area cleaned per day is then summed across facilities within product types. To estimate market share, the screen area cleaned using each type of product was then divided by the total screen area cleaned daily with both types of products. The results indicate that the percentage of total screen area cleaned using traditional products equals 65.6 percent and the percentage of total screen area cleaned using alternative products equals 34.4 percent.

Emulsion Removers

As there is little difference among emulsion removers used in the Work Practices survey, no distinction was made between traditional and alternative emulsion removers.

Haze Removers

The market share of haze removers used by printing operations that is considered to be traditional and the market share that is considered to be alternative is not known. Consequently, in the cost analysis, it was assumed that all haze removers currently used are traditional products.

NUMBER OF SCREENS CLEANED

The number of screens cleaned per year was taken from SPAI's 1990 survey, where facilities reported which range they fit into. In order to use this information for our calculations, an average value was chosen to represent each range. For the top range of 41 screens or more, 50 screens per day was used. The remaining figures are reported in Table F-1.

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[8] A substantial portion (~ 70 percent) of screen area reported in the Work Practices survey could not be assigned to traditional or alternative products and were, therefore, not included in the above calculation .

[9] Data reported in the Work Practices Survey was limited to the total volume of alternative and traditional products purchased annually and the total number of screens cleaned per day at the facility. The number of screens cleaned per day with each type of product was not indicated. As a result, the average price of the ink remover was calculated and used to establish which type of product the facility was using.

Using an SPAI estimate of 20,000 screen printing facilities (excluding textile printers), the total number of screens cleaned per day can be estimated. For example, 57 percent of facilities clean one to ten screens, or an average of 5.5 a day, resulting in 62,700 screens a day for that particular range. Continuing the analysis results in an estimate of 272,710 screens cleaned per day.

TABLE F-1: INFORMATION FOR SCREEN RECLAMATION CHEMICAL VOLUME ESTIMATES

Description	Data		
Average screen size [a]	2916 sq. in.		
Per screen product usage [a]	Product	Oz./Screen (Gal./Screen)	
	Ink remover (traditional)	98 (0.7663)	
	Ink remover (alternative)	22 (0.1731)	
	Emulsion remover	8.8 (0.0685)	
	Haze remover	2 (0.0160)	
Ink remover market share [a,d]	Traditional - 65.6% Alternative - 34.4%		
Screens cleaner per day [b]	Range of # of Screens	Value Used	% of Facilities
	1 to 10	5.5	57.0
	11 to 20	15.5	23.2
	21 to 30	25.5	9.8
	31 to 40	35.5	4.1
	41 or more	50	5.9
Number of Screen Printing Facilites [c]	20,000		
Number of Screens Cleaned Per Day [d]	272,710		

a) Based on raw data from WPQ for screen printing adjusted for incomplete responses.
b) SPAI's 1990 Industry Profile.
c) SPAI estimate.
d) Calculated value.

NATIONAL ESTIMATES OF SCREEN RECLAMATION PRODUCTS

Multiplying product usage per screen by market share by the total number of screens cleaned per year provides estimates of the amount of screen reclamation products used nationally. All facilities are assumed to use ink remover, emulsion remover, and haze remover; this may result in an overestimate of chemicals used as not all facilities use haze remover, at least not on all screens. Market share estimates, developed by EPA in consultation with industry experts, are provided in Table F-2.

TABLE F-2: ESTIMATED MARKET SHARE FOR SCREEN RECLAMATION PRODUCTS

Chemical	Market Share (%)
Ink Remover, Traditional Formulations	
Xylene	20
Mineral spirits	20
Acetone	20
Lacquer thinner[a]	40
Ink Remover, Alternative Formulations	
Propylene glycol methyl ether	10
Methoxypropanol acetate	10
Dibasic esters[b]	30
Diethylene glycol	3
Propylene glycol methyl ether acetate	5
Perpineols/d-limonene (50/50)	7
Propylene glycol	5
Pripropylene glycol methyl ether	15
Diethylene glycol butyl ether	10
Cyclohexanone	5
Emulsion Remover	
Bleach (sodium hypochlorite) (12% solution in water)	10
Sodium metaperiodate (4% solution in water)	80
Periodic acid (10% solution in water)	5
Sodium bisulfate (50% solution in water)	5
Haze Remover	
Sodium hydroxide (20% solution in water)	25
Potassium hydroxide (20% solution in water)	25
Sodium hydochlorite (12% solution in water)	10
Mixture of 65% glycol ethers c and 35% N-methylpyrrolidone	10
Mixture of 10% d-limonene, 20% sodium hydroxide, and 70%	10
Mixture of 10% xylene, 30% acetone, 30% mineral spirits	20

a) The formulation for lacquer thinner is as follows:

(1)	Methyl ethyl ketone	78933	30%
(2)	N-butyl acetate	123-86-4	15%
(3)	Methanol	67561	5%
(4)	Solvent naphtha, light aliphatic	64742-89-8	20%
(5)	Toluene	108883	20%
(6)	Isobutyl isobutyrate	97858	10%

b) This category includes dimethyl glutarate, dimethyl adipate, dimethyl succinate in a 2:1:1 ratio.

c) This category includes propylene glycol methy ether, methoxypropanol acetate, propylene glycol methyl ether acetate, tripropylene glycol methyl ether, and diethylene glycol mono butyl ether in equal portions.

ESTIMATES OF CHEMICAL USAGE FOR SCREEN RECLAMATION

To estimate the amount of individual chemicals used, the product volumes estimated earlier were combined with the market share estimates to determine the amount of individual chemicals used. Chemicals that are solids at room temperature are reported in units of mass (pounds) and those that are liquids are reported in units of volume (gallons). The estimated amount of chemicals is reported in Table F-3. Many of the chemicals do not have estimates; the chemical's specific information provided for this analysis (reported in Table F-1) is an overview and, therefore, did not cover all of the chemicals used in screen reclamation. We were unable to collect volume information directly from reclamation product manufacturers.

TABLE F-3: ESTIMATED ANNUAL AMOUNT OF CHEMICALS CURRENTLY USED IN SCREEN RECLAMATION
(Liquids are reported by volume, solids by weight)

Chemical	Volume (gallons)	Weight (pounds)
Acetone	6,920,000	
Alcohols, C8 - C10, ethoxylated	NA a	NA
Alcohols, C12 - C14, ethoxylated	NA	NA
Benzyl alcohol	NA	NA
2-Butoxyethanol	NA	NA
n-Butyl acetate	1,920,000	
Butyrolactone	NA	NA
Cyclohexanol	NA	NA
Cyclohexanone	270,000	
Diacetone alcohol	NA	NA
Dichloromethane	NA	NA
Diethyl adipate	NA	NA
Diethyl glutarate	NA	NA
Diethylene glycol	122,000	
Diethylene glycol monobutyl ether	420,000	NA
Diethylene glycol butyl ether acetate	NA	NA
Diisopropyl adipate	NA	NA
Dimethyl adipate		2,700,000
Dimethyl glutarate	609,000	5,500,000
Dimethyl succinate	304,000	
Dipropylene glycol methyl ether	NA	NA
Dipropylene glycol methyl ether acetate	NA	NA
Dodecyl benzene sulfonic acid, triethanol amine salt	NA	NA
Ethoxylated castor oil	NA	NA

TABLE F-3: ESTIMATED ANNUAL AMOUNT OF CHEMICALS CURRENTLY USED IN SCREEN RECLAMATION
(Liquids are reported by volume, solids by weight)

Ethoxylated nonylphenol	NA	NA
Ethyl acetate	NA	NA
Ethyl lactate	NA	NA
Ethyl oleate	NA	NA
Fumed silica	NA	NA
Furfuryl alcohol	NA	NA
Isobutyl isobutyrate	2,630,000	
Isobutyl oleate	NA	NA
Isopropanol	NA	NA
d-Limonene		1,100,000
Methoxypropanol acetate	420,000	
Methanol	610,000	
Methyl ethyl ketone	3,720,000	
Methyl Lactate	NA	NA
Mineral spirits	6,920,000	
N-methyl pyrrolidone	38,000	
2-octdecanamine, N, ndimethyl, noxide	NA	NA
Phosphoric acid, mixed ester w/isopropanol & ethoxylated tridecanol	NA	NA
Potassium hydroxide		1,060,000
Propylene carbonate	NA	NA
Propylene glycol	203,000	
Propylene glycol ethyl ether	418,000	
Propylene glycol methyl ether acetate	217,000	
Silica	NA	NA
Silica, fumed (amorphous, crystalline-free)	NA	NA
Sodium bisulfate		2,350,000
Sodium hexametaphosphate	NA	NA
Sodium hydroxide		1,450,000
Sodium hypochlorite	68,000	
Sodium lauryl sulfate	NA	NA
Sodium metasilicate	NA	NA
Sodium periodate		11,700,000
Sodium salt, dodecylbenzene sulfonic acid	NA	NA
Solvent naphtha, heavy aromatic	NA	NA
Solvent naphtha, light aliphatic	2,160,000	

TABLE F-3: ESTIMATED ANNUAL AMOUNT OF CHEMICALS CURRENTLY USED IN SCREEN RECLAMATION
(Liquids are reported by volume, solids by weight)

Solvent naphtha, light aromatic	NA	NA
Special tall oil	NA	NA
Terpineols		1,100,000
Tetrahydrofurfuryl alcohol	NA	NA
Toluene	2,670,000	
1,1,1-trichloroethane	NA	NA
1,2,4-trimethylbenzene	NA	NA
Triethanolamine salt, dodecyl benzene sulfonic acid	NA	NA
Tripropylene glycol methyl ether	623,000	
Trisodium phosphate	NA	NA
Xylene	6,800,000	

a) Not available. Some chemical amounts were not estimated; sufficient information on the use of those chemicals in the screen printing industry was not available.

APPENDIX G

COST ANALYSIS METHODOLOGY: LITHOGRAPHIC BLANKET WASHES CTSA

BLANKET WASH COST ANALYSIS METHODOLOGY

The methodology described below was used to estimate the cost of using the baseline blanket wash as well as the cost of using 22 substitute blanket washes. The primary source of information for the cost estimates was the performance demonstration conducted during production runs at 17 volunteer facilities in late 1994 and early 1995. This information was supplemented by several other sources, including: (1) industry statistics collected by trade groups; (2) lease prices for cloth printer's wipes from a large east coast industrial laundry; and (3) EPA's risk assessment work.

The performance demonstration collected data on the use of donated, substitute blanket wash products and the baseline, VM&P Naptha. Substitute products were screened for blanket swell and washability; each was then sent to two printing facilities. Each facility also tested the baseline product; results are presented comparing the substitute products to the baseline. Although each facility was to use the substitute product for one week, performance problems and scheduling conflicts resulted in some products being used more than others.

Certain assumptions were used in this analysis to smooth out the differences among the various facilities participating in the performance demonstration in order to make the results comparable and to remain consistent with assumptions used in other parts of this CTSA. For example, it was assumed that there are four blankets or "units" per press, each of which is washed 10 times per shift. Additionally, it was assumed that work is performed for one 8-hour shift per day, 5 days per week, 50 weeks per year. Using these assumptions, the following costs were estimated for individual facilities involved in the performance demonstrations for the baseline blanket wash and each substitute blanket wash:

- Total cost/wash.
- Total cost/press.
- Total cost/press/shift/year.

A general description of the cost estimation methodology and data sources used is below, followed by a more detailed description of the methodology.

General Description of Costing Methodology

In general, the cost estimate for each reclamation method combines product cost and product performance data. Variations in the sample sizes, the value for 'n', found in the labor rate (time), the number of wipes per cleaning, quantity of wash used and number of cleanings used to determine performance are due to differences in the way the data for each factor was collected. For example, in the case of the time required to clean the blanket, only the data collected by the observer on the first day of the demonstration were used in the assessment. In determining the average quantity of blanket wash used, data collected during the entire week were utilized in the assessment resulting in a higher sample size. The final cost estimates are a combination of the three distinct cost elements listed below:

Labor

The time spent to clean the blanket was recorded in the performance demonstrations by the observer on the first day of the demonstration for each product, as it was not feasible for press operators to time themselves while cleaning. Therefore, estimates of time to clean the blanket recorded by observers were used to calculate the labor cost.[1] The labor cost was calculated as the total time spent multiplied by (1) the average wage rate for lithography press operators of $15.52/hour; (2) an industry fringe rate (to account for holiday and vacation) of 1.07; and (3) an industry multiplier of 1.99 to account for overhead costs. All of these cost elements were calculated from industry statistics reported in NAPL's *1993 Cost Study* and are explained in more detail in the next section.

Blanket wash products

The quantity of blanket wash used per blanket was recorded during the observer's visit and by the press operator during the week of demonstrations. Average usage per blanket was calculated at each facility for both the baseline product and the 22 substitute products. Multiplying usage per wash, accounting for dilution where necessary, by the unit cost of each product (provided by each participating manufacturer and summarized in Table G-1) yielded the blanket wash costs.

Materials (i.e., wipes)

The only materials consumed in manual blanket washing are the wipes used by the press operator to wash the blanket. All but one of the print shops participating in the performance demonstration used cloth wipes; the other used disposable wipes. Materials costs were therefore calculated by multiplying the number of wipes used, as recorded in the performance demonstrations, by the lease price of a cloth printer's wipe. (A representative of Standard Uniform Services, one of the largest industrial laundries in Massachusetts, provided an estimated lease price of $0.11 per wipe.)

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[1] An alternative method of determining the labor time was examined, apart from using the average time estimates compiled by observers. Within each facility, observers and press operators collected data on the number of blanket rotations per wash. Because only observers compiled time estimates, the rotations data included more observations and was, therefore, considered as an alternative method for estimating labor time. However, this approach was abandoned after further analysis found poor correlation between time and number of rotations. Although occasionally high correlation was found to exist, the majority of facilities did not show a high degree of correlation. Eight facilities with the greatest number of observations were analyzed separately to determine if time and number of rotations were correlated. Again, poor correlation was found. This is interpreted to mean that there was not a preset cleaning speed for the rotation of the cylinders; we were not, therefore, able to use the number of rotations multiplied by the average time per rotation recorded by the observer to determine the labor time involved with cleaning the cylinders. In addition, the ink coverage changed from one cleaning to the next, adding a variation which affected the cleaning time. However, poor correlation between time and number of rotations was also found to exist for facilities that reported consistent ink coverage.

The trend in the number of rotations necessary to clean a cylinder was also examined to determine if there was a learning curve involved with using the alternative cleaners. While it is believed that there is a learning curve, the demonstration timetable was too short for this observation, which was further complicated by variable ink coverage.

TABLE G-1: SUBSTITUTE BLANKET WASHES, MANUFACTURER PRICING

Blanket Wash Number and Type	Product Cost per Gallon ($)** (based on the 55 gallon drum price)($)
Baseline - VM&P Naphtha	5.88
1 - Vegetable Fatty Ester	20.00
6 - Ester/Petroleum + Surfactant	12.35
9 - Ester/Water	10.26
10 - Ester/Water	9.55
11 - Ester/Petroleum + Surfactant	12.15
12 - Petroleum/Water Diluted for Use	16.40
14 - Vegetable Fatty Ester + Glycol	9.55
19 - Vegetable Fatty Ester + Glycol	11.80
20 - Petroleum/Water	10.80
21 - Ester/Petroleum	10.08
22 - Water/Petroleum/Ester	13.15
24 - Terpene	17.85
26 - Vegetable Fatty Ester	12.24
29 - Vegetable Fatty Ester	18.00
30 - Petroleum/Water Diluted for Use	5.00
31 - Petroleum	9.80
32 - Petroleum	2.85
34 - Water/Petroleum/Ester	15.00
37 - Petroleum/Water	14.80
38 - Ester/Petroleum	19.00
39 - Petroleum/Water	8.95
40 - Ester/Petroleum + Surfactant	10.25

** Unit costs supplied by manufacturers participating in the performance demonstrations.

Figure G-1 shows a graphical display of the relative cost changes (substitute compared to baseline) at each facility followed by a summary of the cost comparisons in Table G-2.[2] Figure G-1 illustrates the range of percentage cost changes (compared to the baseline) measured at each facility. Two points are plotted for each of the substitute products because each was tested at two facilities. Formulations are arranged by ascending VOC content. Cost comparisons for each blanket wash against the baseline are provided at the end of this section; summary paragraphs are followed by tables providing specific results. Absolute and relative cost variations are reported for each substitute. An increase in the time required to clean the blanket, quantity of wash

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[2] Products 9, 22, and 32 are not included within Figure G-1 because VOC content for these products was not available.

solution used, number of wipes expended, and costs of labor and materials is preceded by a plus sign; conversely, decreases are denoted by a minus sign.

FIGURE G-1: BLANKET WASH COSTS CHANGES ARRANGED BY LOWEST TO HIGHEST VOC CONTENT OF FORMULATIONS

Details Related to Data Sources and Methodological Approach

As mentioned above, the blanket wash cost comparison considered three cost elements when comparing the performance of baseline and substitute blanket cleaners: labor costs (time x wage rate); blanket wash use (quantity x unit price), adjusting for dilution; and material and equipment costs # wipes x cost per wipe). Each element is described in more detail below. Also, Figure G-2 presents a graphical display of the relative contribution of labor, product use, and material use to the overall cost differences (compared to the baseline) for each of the substitute products. For example, performance results for product 1, tested at facility 6 indicate that overall costs per wash were $0.41 greater for Blanket Wash 6 compared to the baseline. The 40.41 difference is divided up as follows: costs associated with labor were $0.19 higher than the baseline, costs associated with product use (i.e., price x quantity) were $0.11 greater than the baseline, and costs associated with material and equipment use were $0.11 greater than the baseline.

FIGURE G-2: COST DIFFERENCE BETWEEN SUBSTITUTE AND BASELINE BLANKET WASHES

Labor Costs

The hourly wage and overhead rate for press operators was calculated from the *NAPL 1993 Cost Study*. The NAPL study presents a number of facility-specific characteristics, including: annual wages and overhead costs by press type and brand, number of shifts per day, length of work week, and vacations and holidays allowed. Because of the many variables impacting hourly wages and overhead rates, several assumptions were made to facilitate comparisons along the various alternatives.

Assumptions

- Based on a review of press sizes used in the performance demonstrations as well as discussions with performance demonstration observers, wage rates and overhead expenses for a 26-inch, 2-unit press were used in this analysis.

- The *NAPL 1993 Cost Study* presents three possible employment scenarios (referred to as areas A, B, and C), each with differing wages and overhead costs. The "areas" are defined as follows: (1) area A: 35 hours/week, 4 weeks paid vacation, and 11 paid holidays; (2) area B: 37.5 hours/week, 3 weeks paid vacation, and 10 paid holidays; and (3) area C: 40 hours/week, 2 weeks paid vacation, and 8 paid holidays. It was assumed that press operations at performance demonstrations shops operate under a 40 hour work week and are offered 2 weeks paid vacation and 8 paid holidays per year.

- Annual wages and overhead rates vary according to the number of (eight hour) shifts the press facility operates per day. As the number of shifts increase, the wage rate for all shifts increases and the overhead rate decreases. To estimate average wage and overhead rates for this analysis, hourly wage estimates and overhead rates were weighted according to the proportion of facilities participating in performance demonstrations operating one, two or three shifts per day.

- The NAPL cost study provides overhead expenses for seven brands of presses within the 26-inch, 2-unit press category. Overhead rates were calculated by averaging across the seven brands. Annual wages do not vary across the seven brands of presses.

Hourly wage rate for a press operator

As mentioned above, annual wage rates, presented in the NAPL cost study, do not vary across press type; however, wages do vary according to the number of shifts operated per day. In this analysis, a weighted average of $15.52/hour was calculated given that nine of the facilities that participated in the performance demonstration operate one shift per day, four facilities operate two shifts per day, and four facilities operate three shifts per day. Calculations of the average hourly wage are presented in Table G-3 below.

TABLE G-3: CALCULATION OF AVERAGE HOURLY RATE				
# Shifts (8 hrs.)	**Annual Wage**	**Hourly Wage**	**Weight (Facilities × shifts)**	**Wage × Weight**
1	$31,200	$15.00	9	$135
2	$64,740	$15.56	8	$124
3	$99,060	$15.88	12	$191
Totals:			29	$450
Total wage × weight:				$450.04
Total/29:				**$15.52**

Source: *NAPL 1993 Cost Study.*

Fringe rate

To account for costs associated with fringe benefits such as holiday and vacation time, a fringe rate was calculated. The NAPL Cost Study indicates that press operators working a 40 hour week receive eight paid holidays and two weeks vacation per year. To calculate the fringe rate, non-productive hours were subtracted from total hours of operation per year (i.e., 2,080 hours minus 144 hours = 1936 hours). The ratio of total hours to productive hours is equal to the fringe rate applied to each hour worked (2080/1936 = 1.074).

Overhead rate

Overhead rates for this analysis are calculated according to the following formula:[3]

$$\frac{\text{depreciation + rent \& heat + fire \& sprinkler insurance + pension fund + welfare benefits + payroll taxes + workmen's comp. + light \& power + direct supplies + repairs to equipment + general factory + administrative \& selling overhead}}{\text{direct labor + supervisory and misc. labor}}$$

The NAPL cost study provides overhead expenses for seven brands of presses within the 26-inch, 2-unit press category. For the purposes of this analysis, overhead rates were averaged across the seven brands. As with the hourly wage calculations, a weighted average was calculated, accounting for the variability in the number of shifts a facility may operate per day. The overhead rate was estimated to be 1.99.

Total Labor Cost

The total labor cost associated with the use of an individual blanket wash was calculated by multiplying the average cleaning time by the press operator's hourly wage, overhead rate, and fringe rate. For example, the total labor cost for Blanket Wash 1, tested by facility 3, was

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[3] Overhead cost elements were taken directly from the NAPL 1993 Cost Study.

calculated by multiplying the average time spent cleaning (37.5 seconds) by the wage per second ($15.52/60min/60sec[4]), overhead rate (1.99), and fringe rate (1.074) for a total cost of $0.35 per wash.

Blanket Wash Use

Costs attributable to blanket wash use were calculated by multiplying the average quantity of blanket cleaner used per wash cycle by the price of the appropriate wash. In cases where participants diluted blanket wash with water, the unit price was multiplied by the ratio of cleaner used and not the total quantity of the mixture. For example, if the dilution ratio was 1:1, the unit price of the blanket wash was multiplied by 0.5 to account for dilution and then multiplied by the volume used. As mentioned above, blanket wash prices were provided by manufacturers participating in the performance demonstrations. During the performance demonstrations it was observed that most printing facilities purchased blanket cleaner in 55-gallon quantities. This was assumed to be true of all printing facilities participating in the performance demonstration.

Material and Equipment Costs

Because the performance demonstrations were limited to manual blanket washing, the only materials or equipment affecting the cost of blanket washing were the wipes used by the press operator to remove ink and paper products. The cost of press wipes were calculated by multiplying the average number of wipes used per wash by the lease price of a cloth printer's wipe. A representative of Standard Uniform Services, one of the largest industrial laundries in Massachusetts, estimated a lease price of $0.11 per wipe.

Waste Disposal

Because blanket washing wastes may be classified as hazardous wastes by regulations implementing RCRA and therefore require more careful and costly handling and disposal, printers may reduce waste disposal costs if wastes associated with alternative blanket washes do not contain any RCRA listed wastes, eliminating the need to be handled as hazardous waste.[5] Disposal costs were not considered in this cost comparison, however, because all but one of the printers participating in the performance demonstrations use cloth wipes that are leased from an industrial laundry. Industrial laundries currently do not distinguish between hazardous and nonhazardous blanket washes when laundering wipes; it was therefore assumed that there would be no savings in waste handling or processing costs associated with switching to an alternative blanket wash product. In addition, the impact of alternative cleaners on the costs of handling and processing used wipes is unclear. For example, according to the Uniform and Textile Service Association, wipes impregnated with vegetable-oil based cleaners have a higher potential for

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[4] The wage rate of $15.52 per hour translates to $0.0043 per second.

[5] Costs of managing hazardous wastes include placing the waste in a closed and properly labeled container, manifesting shipments and using special shipping arrangements, and shipping to a permitted hazardous waste treatment or disposal facility.

spontaneous combustion when piled together in a laundry bag. Vegetable-oil based cleaners break down, creating exothermic heat and the potential for spontaneous combustion. In addition, the vegetable oil-based cleaners may make wastewater treatment and permit compliance more difficult for the industrial laundry (Dunlap, 1995).

While there is a potential for reduction in waste treatment and disposal costs attributed to the use of alternative blanket cleaners, the current state of federal regulations is in flux. Also, there are many different state and local regulations which might dictate different treatment for hazardous blanket wash wastes. Specifically, future changes to RCRA and the Clean Water Act (CWA) could potentially create a cost advantage for printers using alternative blanket cleaners. Currently, under RCRA, the mixture rule classifies a non-hazardous waste as hazardous when combined with a listed waste (F, P, K, and U listed wastes). The mixture rule was struck down by a 1991 District of Columbia Circuit Court ruling, but was temporarily reenacted while EPA conducts a review of the rule. EPA has not provided definitive guidance on the treatment of solvent contaminated shop towels, leaving it to each state to provide guidance on the identification and management of press wipes.[6] Many states have responded by recognizing a conditional exemption from the mixture rule for contaminated press wipes. EPA's Office of Solid Waste is currently considering changes to the definition of hazardous and solid wastes that could potentially exempt press wipes from hazardous waste classification. Also, EPA is currently developing categorical standards for the industrial laundry industry that could potentially impact the cost of treating press wipes.

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[6] The EPA is planning to develop guidance to the States for the use, reuse, transportation, and disposal of shop towels.

TABLE G-2: SUMMARY OF COST ANALYSIS FOR BLANKET WASH PERFORMANCE DEMONSTRATION								
Formula Number	**Test Facility**	**Total cost/wash**		**Total cost/press**		**Total cost/press/shift/year**		**Percentage Difference[a]**
		Baseline	**Alternative**	**Baseline**	**Alternative**	**Baseline**	**Alternative**	
1	Facility 3	0.55	0.69	2.20	2.76	5,500	6,900	+25
	Facility 6	0.46	0.87	1.84	3.48	4,600	8,700	+89
6	Facility 11	0.70	0.82	2.80	3.28	7,000	8,200	+17
	Facility 15	0.50	0.77	2.00	3.08	5,000	7,700	+54
9	Facility 10	0.91	2.08	3.64	8.32	9,100	20,800	+129
	Facility 15	0.50	0.92	2.00	3.68	5,000	9,200	+84
10	Facility 3	0.55	0.57	2.20	2.28	5,500	5,700	+4
	Facility 4	0.85	2.20	3.40	8.80	8,500	22,000	+159
11	Facility 1	0.59	1.29	2.36	5.16	5,900	12,900	+119
	Facility 2	0.53	0.68	2.12	2.72	5,300	6,800	+28
12	Facility 12	0.81	0.99	3.24	3.96	8,100	9,900	+22
	Facility 13	0.80	0.83	3.20	3.32	8,000	8,300	+4
14	Facility 6	0.46	1.07	1.84	4.28	4,600	10,700	+133
	Facility 16	0.66	0.82	2.64	3.28	6,600	8,200	+24
19	Facility 18	0.62	1.66	2.48	6.64	6,200	16,600	+168
	Facility 19	0.53	0.89	2.12	3.56	5,300	8,900	+68
20	Facility 11	0.70	1.13	2.80	4.52	7,000	11,300	+61
	Facility 12	0.81	1.58	3.24	6.32	8,100	15,800	+95

TABLE G-2: SUMMARY OF COST ANALYSIS FOR BLANKET WASH PERFORMANCE DEMONSTRATION

21	Facility 6	0.46	1.01	1.84	4.04	4,600	10,100	+120
	Facility 17	0.41	0.58	1.64	2.32	4,100	5,800	+41
22	Facility 12	0.81	0.82	3.24	3.28	8,100	8,200	+1
	Facility 13	0.80	1.51	3.20	6.04	8,000	15,100	+89
24	Facility 16	0.66	0.97	2.64	3.88	6,600	9,700	+47
	Facility 17	0.41	0.88	1.64	3.52	4,100	8,800	+115
26	Facility 5	0.55	0.73	2.20	2.92	5,500	7,300	+33
	Facility 15	0.50	0.47	2.00	1.88	5,000	4,700	-6
29	Facility 7	0.57	0.93	2.28	3.72	5,700	9,300	+63
	Facility 8	0.55	0.89	2.20	3.56	5,500	8,900	+62
30	Facility 18	0.62	1.01	2.48	4.04	6,200	10,100	+63
	Facility 19	0.53	0.62	2.12	2.48	5,300	6,200	+17
31	Facility 7	0.57	1.59	2.28	6.36	5,700	15,900	+179
	Facility 8	0.55	0.59	2.20	2.36	5,500	5,900	+7
32	Facility 1	0.59	1.31	2.36	5.24	5,900	13,100	+122
	Facility 5	0.53	0.43	2.12	1.72	5,300	4,300	-19
34	Facility 1	0.59	0.89	2.36	3.56	5,900	8,900	+51
	Facility 19	0.53	0.95	2.12	3.80	5,300	9,500	+79
37	Facility 3	0.55	0.48	2.20	1.92	5,500	4,800	-13
	Facility 4	0.85	0.79	3.40	3.16	8,500	7,900	-7

TABLE G-2: SUMMARY OF COST ANALYSIS FOR BLANKET WASH PERFORMANCE DEMONSTRATION

38	Facility 2	0.53	1.08	2.12	4.32	5,300	10,800	+104
	Facility 4	0.85	1.11	3.40	4.44	8,500	11,100	+31
39	Facility 5	0.55	0.69	2.20	2.76	5,500	6,900	+25
	Facility 8	0.55	0.80	2.20	3.20	5,500	8,000	+45
40	Facility 1	0.59	0.79	2.36	3.16	5,900	7,900	+34
	Facility 10	0.91	0.87	3.64	3.48	9,100	8,700	-4

a) A positive sign denotes an increase and a negative sign denotes a decrease in the cost when using the alternative blanket cleaner instead of the base product.

APPENDIX H

ENVIRONMENTAL FATE SUMMARY INITIAL REVIEW EXPOSURE REPORT

INITIAL REVIEW EXPOSURE REPORT	000075-09-2	Page 1 of:
Assessor:	Search ( )Y	Focus Date:

SAT	Health:	Focus Rep:
	Eco:	SAT Rep:

Submitter:	Max. PV		Manuf.	
	(kg/yr)		Import	

Use: PRINTING INKS CLUSTER

Consumer Exposure	( )no,	
	( )yes, see consumer exp. page	

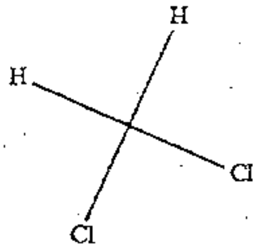
Analogs/Comments	CBI STAMP

Chemical Name:

DICHLOROMETHANE

Trade Name:

Structure:



EBR CRITERIA

Surface dw ( )y ( )n	Total rel ( )y ( )n
Ground dw ( )y ( )n	Water rel ( )y ( )n
Ambient Air( )y ( )n	Consumer ( )y ( )n

INITIAL REVIEW EXPOSURE REPORT		000075-09-2	Page 2 of:

STATE	NEAT	CLEAR, COLORLESS VOLATILE LIQUID	MW CHK
	MFG		84.93

MOL WT	84.93	% < 500		FORM	C H2 Cl2
METHOD		% < 1000		CAS	

PROPERTY	Submitted	ICB-CRSS		Method/Ref	PCGems/EPI	
MP (C)	-97.00 - -97.00				-97.00	
BP (C)	40.00		@ 760 torr		26.37	@ 760 torr
@ P (torr)						
VP (torr)	340.00			@ 20 C	7.23E+02	
S-H2O (g/L)	17.00				16309.850	mg/L
S-Org (g/L)						mg/L
Log Kow	1.25				1.25	
pH, pKa				Log Koc	1.38	
Light Absorption (nm)	> 290	No light absorption at λ ≥ 290 nm		Log BCF / BCF	0.72	
Solvent:				H (atm m3/mol)		3.01E-03
HYDRO t(1/2) @ pH 7, 25 C	1000.00		da	AERUD		

Volatilization (H2O) t(1/2)	River	1.12	hr	Lake	3.73	da
AOP t(1/2) (hr)	OH	1061.09	O3		Total	

BIODEG	Linear Prob:	0.49	Nonlinear Prob:	0.14	Survey Ult:	WK-MO	Survey Prim: DA-WK
STP (% Removal)	Tot	55.10	Biod	0.05	Ads	0.99	Air 54.06

REMOVAL IN WWT/POTW	% Overall	see below	0	25	50	75	90	=> 99

			CATEGORY			
		RATING	1	2	3	4
Sorption			[✓ low]	moderate	strong	v.strong
Stripping			[✓ extensive]	[✓ moderate]	low	negligible
Biodegradation	Removal		unknown	high	moderate	[✓ negligible]
	Destruction		unknown	complete	partial	

Comments:

AEROBIC BIODEGRADATION	Ultimate		<= days	[✓ weeks]	[✓ months]	> months
t(1/2)	Primary		<= days	weeks	months	> months

Comments: BIODEG survey model gives reasonable results.

INITIAL REVIEW EXPOSURE REPORT			000075-09-2		Page 3 of:	
-						
			CATEGORY			
		RATING	1	2	3	4
ANAEROBIC BIODEGRADATION	Ultimate		<= days	weeks	[✓ months]	[✓ > months]
	Primary		<= days	weeks	months	> months
Comments:	Primary probably faster, due to dehalogenation.					
HYDROLYSIS	A. C-Cl	4	<= mins	days	months	[✓ => years]
(pH 7, 25 C)	B.		<= mins	days	months	=> years
Comments:	A. t(1/2) = 700 years					
SORPTION TO SOIL & SEDIMENT			v.strong	strong	moderate	[✓ low]
Comments:						
MIGRATION TO GROUND WATER			negl	slow	[✓ moderate]	[✓ rapid]
Comments:	Classic GW pollutant.					
VOLATILIZATION	Rivers		negl	slow	[✓ moderate]	[✓ rapid]
(w/ sediment)	Lakes		negl	slow	[✓ moderate]	rapid
Comments:						
PHOTOLYSIS	A. Direct	1	[✓ negl]	slow	moderate	rapid
	B. Indirect	1	[✓ negl]	slow	moderate	rapid
Comments:	t(1/2) > 1 year for both processes					
ATMOSPHERIC OXIDATION	A. OH	2-3	negl	[✓ slow]	[✓ moderate]	rapid
	B. O3	1	[✓ negl]	slow	moderate	rapid
Comments:	* A. t(1/2) = 88 days					
	B. No ozone reaction possible					
exp k_{OH} = [illegible]	4.2×10^{-14} t(1/2) = 25 days at OH = 1.5×10^6 & a 12-hour daylight day					

APPENDIX I

RISK, COMPETITIVENESS & CONSERVATION DATA SUMMARY AND SOCIAL BENEFITS/COSTS ASSESSMENT: LITHOGRAPHY CTSA

Earlier sections of the lithography CTSA evaluated the risk and performance of the baseline blanket wash as well as the alternatives. These data provide the basis for comparing the benefits and costs of using the alternative blanket washes instead of the baseline. Relevant data include: worker health risks, public health risks, flammability risks, ecological risks, energy and natural resource use, volatile organic compound (VOC) content, and labor, materials, and product costs. Each is discussed in turn below.

Worker Health Risks

The majority of substitute formulations, as well as the baseline, present some concern for dermal exposure, driven primarily by high exposure levels. The dermal exposure estimates provide an upper-bound estimate which no worker is expected to exceed because the exposure assessment assumes that no gloves or barrier creams are used by workers when cleaning a blanket. Worker inhalation risks are very low for nearly all of the blanket wash products due to low or negligible exposure levels. Only one of the substitute formulations (Blanket Wash 3) triggered inhalation concerns. The components of all other substitute products present low or no concern. The baseline presents low inhalation concern. Table I-1 presents a summary of worker risks beginning with the baseline product, VM&P Naphtha. The risk assessment assumed that components of concern present a greater risk than components of low to moderate concern, and components of low to moderate present a greater risk than components of low concern, and so on (no/low concern < low to moderate concern < concern).

TABLE I-1: SUMMARY OF RISK CONCLUSIONS OF SUBSTITUTE AND BASELINE BLANKET WASH CLEANERS

Formula Number	Chemicals Identified as a Concern in the Risk Assessment	Worker Health Risk	
		Dermal	Inhalation
Baseline (28)	Hydrocarbons, petroleum distillates	concern	no/low concern
1	No individual chemicals of concern identified	no/low concern[a]	no/low concern[a]
3	Hydrocarbons, aromatic	concern	no/low concern
	Hydrocarbons, aromatic	concern	concern
	Hydrocarbons, aromatic	concern	no/low concern
4	Terpenes	concern	no/low concern
	Ethoxylated nonylphenols	no/low concern	no/low concern[b]
5	Hydrocarbons, aromatic	concern	no/low concern
	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
	Propylene glycol ethers	concern	no/low concern
6	Hydrocarbons, petroleum distillates	concern	no/low concern
	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[b]
	Fatty acid derivatives	no/low concern[b]	no/low concern[b]
	Alkyl benzene sulfonates	no/low concern[b]	no/low concern[b]

TABLE I-1: SUMMARY OF RISK CONCLUSIONS OF SUBSTITUTE AND BASELINE BLANKET WASH CLEANERS

Formula Number	Chemicals Identified as a Concern in the Risk Assessment	Worker Health Risk	
		Dermal	Inhalation
7	Terpenes	concern	no/low concern
	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
8	Propylene glycol ethers	concern	no/low concern
	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[b]
9	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
10	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
11	Hydrocarbons, petroleum distillates	concern	no/low concern
	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[b]
	Alkyl benzene sulfonates	no/low concern[a]	no/low concern[b]
12	Hydrocarbons, petroleum distillates	concern	no/low concern
	Hydrocarbons, petroleum distillates	low to moderate concern[a]	no/low concern[a]
14	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
	Propylene glycol ethers	no/low concern[a]	no/low concern[b]
16	Terpenes	concern	no/low concern
17	Glycols	no/low concern	no/low concern
	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
	Alkali/salts	no/low concern	no/low concern[b]
	Fatty acid derivatives	possible concern	no/low concern[b]
18	Hydrocarbons, petroleum distillates	concern	no/low concern
	Dibasic esters	concern	no/low concern
	Alkyl benzene sulfonates	no/low concern[a]	no/low concern[a]
	Esters/lactones	no/low concern[a]	no/low concern[a]
19	Propylene glycol ethers	no/low concern[a]	no/low concern[a]
	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
20	Hydrocarbons, petroleum distillates	concern	no/low concern
	Alkyl benzene sulfonates	no/low concern[a]	no/low concern[a]
	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[a]
21	Hydrocarbons, aromatic	concern	no/low concern
	Hydrocarbons, petroleum distillates	concern	no/low concern
	Fatty acid derivatives	no/low concern[a]	no/low concern[a]

TABLE I-1: SUMMARY OF RISK CONCLUSIONS OF SUBSTITUTE AND BASELINE BLANKET WASH CLEANERS

Formula Number	Chemicals Identified as a Concern in the Risk Assessment	Worker Health Risk	
		Dermal	Inhalation
22	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[a]
	Fatty acid derivatives	no/low concern[a]	no/low concern[a]
23	Terpenes	possible concern	no/low concern
	Nitrogen heterocyclics	possible concern	no/low concern
24	Alkyl benzene sulfonates	concern	no/low concern[b]
	Terpenes	concern	no/low concern
	Ethylene glycol ethers	possible concern	no/low concern
	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
25	Terpenes	concern	no/low concern
	Esters/lactones	possible concern	no/low concern
26	Esters/lactones	concern	no/low concern[b]
	Esters/lactones	no/low concern	no/low concern[b]
	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
27	Terpenes	concern	no/low concern
29	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
30	Hydrocarbons, aromatic	concern	no/low concern
	Propylene glycol ethers	no/low concern[a]	no/low concern[a]
31	Hydrocarbons, aromatic	concern	no/low concern
	Hydrocarbons, petroleum distillates	low to moderate concern[a]	no/low concern[a]
32	Hydrocarbons, petroleum distillates	low to moderate concern[a]	low to moderate concern[a]
33	Hydrocarbons, aromatic	concern	no/low concern
	Hydrocarbons, petroleum distillates	concern	no/low concern
	Propylene glycol ethers	no/low concern	no/low concern
34	Terpenes	concern	no/low concern
	Alkoxylated alcohols	no/low concern	no/low concern
	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
	Hydrocarbons, petroleum distillates	low to moderate concern[a]	no/low concern[a]
35	Hydrocarbons, aromatic	concern	no/low concern
	Hydrocarbons, petroleum distillates	low to moderate concern[a]	no/low concern[a]

TABLE I-1: SUMMARY OF RISK CONCLUSIONS OF SUBSTITUTE AND BASELINE BLANKET WASH CLEANERS

Formula Number	Chemicals Identified as a Concern in the Risk Assessment	Worker Health Risk	
		Dermal	Inhalation
36	Hydrocarbons, petroleum distillates	concern	no/low concern
	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[b]
	Propylene glycol ethers	no/low concern	no/low concern
	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
37	Hydrocarbons, aromatic	possible concern	no/low concern
	Hydrocarbons, petroleum distillates	low to moderate concern[a]	no/low concern[a]
	Hydrocarbons, petroleum distillates	low to moderate concern[a]	no/low concern[a]
38	Fatty acid derivatives	no/low concern[a]	no/low concern[b]
	Alkoxylated alcohols	no/low concern[a]	no/low concern
	Hydrocarbons, petroleum distillates	low to moderate concern	no/low concern[a]
39	Hydrocarbons, petroleum distillates	concern	no/low concern
	Propylene glycol ethers	concern	no/low concern
	Alkanolamines	concern	no/low concern[b]
	Ethylene glycol ethers	possible concerns	no/low concern
40	Hydrocarbons, petroleum distillates	concern	no/low concern
	Ethoxylated nonylphenol	no/low concern	no/low concern[b]
	Hydrocarbons, aromatic	moderate concern[a]	no/low concern[b]
	Fatty acid derivatives	no/low concern[a]	no/low concern[b]

a) Risks for these chemicals in this product could not be quantified; therefore, the level of concern for this chemical is based upon a structure-activity analysis of potential hazard.
b) Risks for these chemicals in this product could not be quantified; therefore, the level of concern for this chemical is based upon a low risk call based on estimates of no or extremely low exposure.

Public Health Risks

In addition to worker exposure, members of the general public may be exposed to blanket wash chemicals due to their close physical proximity to a printing facility or due to the wide dispersion of chemicals. Individuals in the general public that are exposed to blanket wash chemicals are potentially subject to health risks. The EPA risk assessment identified no concerns for the general public through ambient air, drinking water, or fish ingestion due to use of blanket washes. Using the model facility approach, the general population exposure assessment predicted that exposure levels would be extremely low for all media examined. Because of the low exposure levels, no concerns were identified for the general public from the use of blanket wash chemicals.

Flammability Risk

Some blanket wash chemicals in this assessment present risks of fire and explosion because of their flammability and high volatility. In order to assess the relative fire hazard of the substitute and baseline blanket washes, the flash points of each product is compared to OSHA and EPA definitions of flammable liquids.[1] Flammable liquids are defined by OSHA as having a flash point less than 141°F. Similarly, EPA defines RCRA ignitable wastes (40 CFR 261.21) as having a flash point of 140°F or less. Table I-2 presents the flash points of the baseline as well as the alternative blanket washes. Flash points were developed as part of the performance demonstration.

TABLE I-2: RELATIVE FLAMMABILITY RISK OF SUBSTITUTE AND BASELINE BLANKET WASHES

Blanket Wash	Flash Point (°F)	Blanket Wash	Flash Point (°F)
Baseline (28)	50	*22*	157+
1	230+	*23*	140
3	114	*24*	100
4	114	*25*	220+
5	139	*26*	230+
6	152	*27*	145
7	165	*29*	230+
8	115	*30*	100+
9	230+	*31*	105
10	230+	*32*	220
11	150	*33*	105
12	125	*34*	138
14	230+	*35*	105
16	145	*36*	175
17	220+	*37*	82
18	150	*38*	230+
19	230+	*39*	155
20	170	*40*	155
21	115		

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[1] Flash point is defined as the lowest temperature at which a liquid gives off vapor within a test vessel in sufficient concentration to form an ignitable mixture with air near the surface of the liquid.

Ecological Risk

The EPA risk assessment evaluated the ecological risks of the substitute products as well as the baseline blanket wash; in the analysis for this CTSA, only the risks to aquatic species were considered. Evaluation of aquatic risks involved comparing a predicted ambient water concentration to a "concern concentration" for chronic exposures to aquatic species using a hypothetical receiving stream (a relatively small stream at low flow conditions). The concern concentration is expressed in mg/L water. Exposure concentrations below the concern concentration are assumed to present low risk to aquatic species. Exposures that exceed the concern concentration indicate a potential for adverse impact on aquatic species. The following formulations were found to pose a risk to aquatic species: Blanket Washes 3, 5, 6, 8, 11, 18, and 20. All the chemicals of concern are amine salts of an alkybenzene sulfonate. Switching to these substitutes would likely increase aquatic risks rather than decrease them. The baseline product was not identified as creating an aquatic species risk.

Energy and Natural Resource Use

The life cycle of any product begins with the extraction of raw materials from the environment, and continues through the manufacture, transportation, use, recycle, and disposal of the product. Decisions at each stage of a product's life will impact its energy and natural resource demand. A previous section of the CTSA presented a discussion describing the issues to consider when cleaning the blanket and purchasing blanket washes but does not analyze the individual energy and natural resource requirements of the substitute and baseline washes due to various data limitations. The issues discussed include: (1) optimization of the washing technique to reduce blanket wash use, press wipe use, and waste print runs; (2) derivation of blanket wash products from non-renewable (petroleum and natural gas) and renewable (plant products) chemical raw materials (it is not clear, however, which raw materials demand the least energy and natural resources without a full life-cycle analysis); (3) lack of differentiation between products in terms of energy consumption during the product formulation process because the same basic processes are used to formulate all blanket wash products; and (4) reduction in packaging requirements and transportation/distribution energy consumption due to the use of concentrated formulations, assuming the products are diluted by the printer. A thorough quantitative evaluation of each life-cycle stage was beyond the scope of the CTSA.

VOC Releases

The VOC content of the alternative and the baseline blanket washes was independently tested by the GATF laboratory in Pittsburgh, Pennsylvania. VOCs are currently regulated under clean air legislation occupational exposure rules and toxics use and release reporting laws; therefore, substitution of high VOC cleaners has the potential to reduce the regulatory burden for printers. Table I-3 presents a summary of the relative VOC content of the baseline and alternative blanket washes.

TABLE I-3: VOC CONTENT OF THE SUBSTITUTE AND BASELINE BLANKET WASHES

Blanket Wash	VOC Content (lbs/gal;% by weight)	Blanket Wash	VOC Content (% by weight)
Baseline (28)	6.2; 100%	22	Not measured; 2.17%
1	2.3; 30%	23	0.48; 6%
3	6.4; 91%	24	1.5; 19%
4	6.4; 89%	25	4.1; 55%
5	2.5; 30%	26	1.3; 18%
6	3.5; 47%	27	7.2; 93%
7	3.0; 36%	29	2.1; 30%
8	3.3; 41%	30	0.48; 7%
9	0.11; 10%	31	6.6; 99%
10	0.16; 2%	32	6.5; 99%
11	4.3; 61%	33	3.4; 46%
12	1.3; 20%	34	2.8; 39%
14	0.97; 12%	35	6.7; 99%
16	7.2; 99%	36	3.5; 48%
17	0.051; 0.6%	37	1.0; 14%
18	4.4; 60%	38	4.9; 65%
19	1.8; 22%	39	2.9; 37%
20	2.7; 35%	40	3.8; 52%
21	3.5; 47%		

Performance

The performance of each of the substitute blanket washes as well as the baseline was demonstrated using both laboratory and production run tests. The laboratory tests determined the flash point, VOC content, and pH and demonstrated the blanket swell and wipability of each product. The production run tests, conducted at two facilities for each of the substitute products and at all facilities for the baseline, collected information such as quantity of wash used, time spent to wash the blanket, ink coverage, and the effectiveness of the wash. Summary results are presented in Table I-4. The widely variable conditions between and within printing facilities and the short duration of the production runs used for the performance demonstrations does not allow the results to be interpreted as definitive performance assessments of the blanket washes.

Prior to testing the blanket washes in a print shop, the 36 substitute blanket washes were tested in the laboratory for blanket swell potential and wipability. Of the 36 washes, 22 were deemed to be satisfactory for demonstrations at volunteer printing shops (two shops demonstrated each blanket wash). The results of the performance demonstrations were highly variable between the two print shops using a particular blanket wash and among the many blanket washes themselves. Performance varied to a great extent based on the amount of ink coverage. Excluding trials with heavy ink coverage, 11 washes gave good or fair performances at both facilities, 7 washes gave good or fair performance at one facility but not the other, and the remaining 4 washes performed poorly at both facilities.

Labor, Materials, and Product Costs

The costs of using each of the substitute blanket washes as well as the baseline depends on variations in labor costs, product use, and material and equipment use at each facility that participated in the performance demonstrations. Each substitute blanket wash product was tested by two facilities. The baseline product was tested by all facilities. Costs for each product are presented on a per wash basis, a per press basis, and a cost per press/shift/year basis. In comparing the cost data for the substitute and the baseline products, the costs of using the substitute blanket cleaners exceed the cost of using the baseline product in nearly all cases. In some cases smaller quantities of wash or less cleaning time was required, resulting in a cost savings when using the substitute instead of the baseline wash. (Blanket Washes 26, 32, 37, and 40 resulted in costs savings relative to the baseline product. Overall, however, the costs of using the substitute blanket washes exceed the costs of using the baseline wash in the large majority of cases. Costs associated with using the substitute blanket washes range from a low of \$1.72 to a high of \$8.80 per press.[2] Costs of using the baseline product range from \$1.64 to \$3.64 per press. Where costs of the alternative blanket washes exceed the baseline, percentage cost increases range from 1 percent to 179 percent.) Table I-5 presents a summary of the cost comparisons.

Disposal costs were not considered in this cost comparison because all but one of the printers participating in the performance demonstrations use cloth wipes that are leased from an industrial laundry. Many industrial laundries currently do not distinguish between hazardous and nonhazardous blanket washes when laundering wipes; therefore, it was assumed that there would be no savings in waste handling or processing costs associated with switching to a substitute blanket wash product.

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[2] Presses are assumed to have four units; therefore, four blankets are washed each time a press is cleaned.

Introduction to Social Benefit/Cost Assessment

Social benefit/cost analysis is a tool used by policy makers to systematically evaluate the impacts to all of *society* resulting from individual decisions. The decision evaluated in this analysis is the choice of a blanket wash product. Printers have certain criteria which they use to evaluate the benefits and costs of alternative blanket cleaners such as price, drying time, flexibility of use for rollers and blankets, propensity to cause blanket swell, etc. A printer might ask what impact their choice of blanket washes will have on operating costs, compliance costs, liability costs, and insurance premiums. This business planning process is unlike social benefit/cost analysis, however, because it approaches the comparison from the standpoint of the individual printing firm and not from the standpoint of *society.* A social benefit/cost analysis seeks to compare the benefits and costs of a given action, considering both the private and external costs and benefits.[3] Therefore, the analysis will consider the impact of the alternative blanket cleaners on operating costs, regulatory costs, and insurance premiums, but will also consider the *external* costs and benefits of the alternative blanket cleaners such as reductions in environmental damage and reductions in the risk of illness for the general public. External costs are not borne by the printer, however; they are true costs to society.

Benefits of the substitute blanket cleaners may include private benefits such as increased profits resulting from improved worker productivity, a reduction in employee sickness, or reduced property and health insurance costs and external benefits such as a reduction in pollutants emitted to the environment or reduced use of natural resources. Costs of the substitute blanket cleaners may include private costs such as higher operating expenses resulting from a higher priced blanket wash and external costs such as increase in human health risks and ecological damage. Several of the benefit categories considered in this analysis share elements of both private and external costs and benefits. For example, use of the substitute blanket washes may result in energy and natural resource savings. Such a benefit may result in private benefits in the form of reduced product usage and waste print runs as well as external benefits in the form of reduced consumption of non-renewable resources.

Benefit/Cost Methodology

The methodology for conducting a social benefit/cost assessment can be broken down into four general steps: (1) obtain information on the relative performance, human and environmental risk, process safety hazards, and energy and natural resource requirements of the

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[3] Private costs include any direct costs incurred by the decision maker and are typically reflected in the firm's balance sheet. In contrast, external costs are incurred by parties other than the primary participants to the transaction. Economists distinguish between private and external costs because each will affect the decision maker differently. Although external costs are real costs to some members of society, they are not incurred by the decision maker and firms do not normally take them into account when making their decisions. A common example of external costs is the electric utility whose emissions are reducing crop yields for the farmer operating downwind. The external costs incurred by the farmer in the form of reduced crop yields are not considered by the utility when deciding how much electricity to produce. The farmer's losses do not appear on the utility's balance sheet.

baseline and the alternatives; (2) construct matrices of the data collected; (3) when possible, monetize the values presented within the matrices; and (4) compare the data generated for the alternative and the baseline in order to produce an estimate of net social benefits. The Findings section presents the results of the first task by summarizing the performance data, risk data, and energy and natural resource information for the baseline and the alternative blanket washes. In Table I-5 the data required to make a determination of the relative costs and benefits of switching to an alternative blanket wash are organized according to formulation number, beginning with the baseline. Ideally, the analysis would quantify the social benefits and costs of using the substitute and baseline blanket wash products, allowing identification of the substitute product whose use results in the largest net social benefits. However, because of data limitations and production facility variations, the analysis presents instead a qualitative description of the risks associated with each substitute product compared to the baseline. Benefits derived from a reduction in risk are described and discussed, but not quantified; the information provided can be very useful in the decision making process. A few examples are provided to quantitatively illustrate some of the benefit considerations. Personnel in each individual facility will have to examine the information presented, weight each piece according to facility and community characteristics, and develop an independent choice.

The analysis is further developed in the following sections, beginning with summaries of the potential risks of the substitute and baseline blanket washes. Associated Costs provides a summary of the financial costs of the baseline and the alternative blanket washes, Costs and Benefits by Formulation compares the benefits and costs of using the substitute blanket wash products instead of the baseline wash, and Potential Benefit of Avoiding Illness Linked to Exposure to Chemicals Commonly Used in Blanket Washing provides an indication of the minimum benefits per affected person that would accrue to society if switching to substitute blanket wash products reduced cases of certain adverse health effects.

TABLE I-6: COSTS AND BENEFITS OF BASELINE AND SUBSTITUTE BLANKET WASHES

Formula Number	Private Cost [a]		Private Benefits			External Benefits
	Average Cost/Press	% Change	Worker Risk Trade-offs	Flammability Risk [b]	% VOC	Environmental Risk
Baseline (28)	[redacted]		Low to moderate concern for dermal and inhalation exposure.[d]	High risk	99%	No estimated risk
1	Alternative: 2.76 Baseline: 2.20	+25	Overall concern is low for dermal and inhalation exposure.[d]	Low risk	30%	No estimated risk
	Alternative: 3.48 Baseline: 2.20	+89				
3	Not tested		Concern for dermal exposure and inhalation.	Moderate risk	91%	Aquatic species risk
4	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	89%	No estimated risk
5	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Moderate Risk	30%	Aquatic species risk

TABLE I-6: COSTS AND BENEFITS OF BASELINE AND SUBSTITUTE BLANKET WASHES

6	Alternative: 3.28 Baseline: 2.80	+17	Concern for dermal exposure and very low concern for inhalation exposure.	Low risk	47%	Aquatic species risk
	Alternative: 3.08 Baseline: 2.00	+54				
7	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Low risk	36%	No estimated risk
8	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	41%	Aquatic species risk
9	Alternative: 8.32 Baseline: 3.64	+129	Very low concern for dermal exposure and no concern for inhalation exposure.[d]	Low risk	10%	No estimated risk
	Alternative: 3.68 Baseline: 2.00	+84				
10	Alternative: 2.28 Baseline: 8.80	+4	Very low concern for dermal exposure[c] and no concern for inhalation exposure.[d]	Low risk	2%	No estimated risk
	Alternative: 8.80 Baseline: 3.40	+159				
11	Alternative: 5.16 Baseline: 2.36	+119	Concern for dermal exposure and very low concern for inhalation exposure.	Low risk	61%	Aquatic species risk
	Alternative: 2.72 Baseline: 2.12	+28				
12	Alternative: 3.96 Baseline: 3.20	+22	Concern for dermal exposure and low concern for inhalation exposure.[c]	Moderate risk	20%	No estimated risk
	Alternative: 3.32 Baseline: 3.20	+4				
14	Alternative: 4.28 Baseline: 1.84	+133	Low concern for dermal and inhalation exposure.[c]	Low risk	12%	No estimated risk
	Alternative: 3.28 Baseline: 2.64	+24				
16	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	99%	No estimated risk
17	Not tested		Possible concern for dermal exposure and very low concern for inhalation exposure.[d]	Low risk	0.6%	No estimated risk
19	Alternative: 6.64 Baseline: 2.48	+168	Low concern for dermal and inhalation exposure.[c]	Low risk	22%	No estimated risk
	Alternative: 3.56 Baseline: 2.12	+68				
20	Alternative: 4.52 Baseline: 2.80	+61	Concern for dermal exposure and low concern for inhalation exposure.[c]	Low risk	35%	Aquatic species risk
	Alternative: 6.32 Baseline: 3.24	+95				
21	Alternative: 4.04 Baseline: 1.84	+120	Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	47%	No estimated risk
	Alternative: 2.32 Baseline: 1.64	+41				

TABLE I-6: COSTS AND BENEFITS OF BASELINE AND SUBSTITUTE BLANKET WASHES

22	Alternative: 3.28 Baseline: 3.24	+1	Moderate concern for dermal exposure[c] and low concern for inhalation exposure.[d]	Low risk	17%	No estimated risk
	Alternative: 6.04 Baseline: 3.20	+89				
23	Not tested		Possible concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	6%	No estimated risk
24	Alternative: 3.88 Baseline: 2.64	+47	Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	19%	No estimated risk
	Alternative: 3.52 Baseline: 1.64	+115				
25	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Low risk	55%	No estimated risk
26	Alternative: 2.92 Baseline: 2.20	+33	Concern for dermal exposure and no concern for inhalation exposure.[d]	Low risk	18%	No estimated risk
	Alternative: 1.88 Baseline: 2.00	-6				
27	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	93%	No estimated risk
29	Alternative: 3.72 Baseline: 2.28	+63	Low concern for dermal exposure[c] and no concern for inhalation exposure.[d]	Low risk	30%	No estimated risk
	Alternative: 3.56 Baseline: 2.20	+62				
30	Alternative: 4.04 Baseline 2.48	+63	Concern for dermal exposure and low concern for inhalation exposure.[c]	Moderate risk	7%	No estimated risk
	Alternative: 2.48 Baseline: 2.12	+17				
31	Alternative: 6.36 Baseline: 2.28	+179	Concern for dermal exposure and low concern for inhalation exposure.[c]	Moderate risk	99%	No estimated risk
	Alternative 2.36 Baseline: 2.20	+7				
32	Alternative: 5.24 Baseline: 2.36	+122	Low to moderate concern for dermal and inhalation exposure.[c]	Low risk	99%	No estimated risk
	Alternative: 1.72 Baseline: 2.12	-19				
33	Not tested		Concern for dermal exposure and very low concern for inhalation exposure.	Moderate risk	46%	No estimated risk

TABLE I-6: COSTS AND BENEFITS OF BASELINE AND SUBSTITUTE BLANKET WASHES

34	Alternative: 3.56 Baseline: 2.36	+51	Concern for dermal exposure and low concern for inhalation exposure.[c]	Moderate risk	39%	No estimated risk
	Alternative: 3.80 Baseline: 2.12	+79				
35	Not tested		Concern for dermal exposure and low concern for inhalation exposure.	Moderate risk	99%	No estimated risk
36	Not tested		Concern for dermal exposure and low concern for inhalation exposure.[c]	Low risk	48%	No estimated risk
37	Alternative: 1.92 Baseline: 2.20	-13	Low to moderate concern for dermal exposure and low concern for inhalation exposure.[c]	High risk	14%	No estimated risk
	Alternative: 3.16 Baseline: 3.40	-7				
38	Alternative: 4.32 Baseline: 2.12	+104	Low to moderate concern for dermal exposure and low concern for inhalation exposure.[c]	Low risk	65%	No estimated risk
	Alternative: 4.44 Baseline: 3.40	+31				
39	Alternative: 2.76 Baseline: 2.20	+25	Concern for dermal exposure and very low concern for inhalation exposure.	Low risk	52%	No estimated risk
	Alternative: 3.20 Baseline: 2.20	+45				
40	Alternative: 3.16 Baseline: 2.36	+34	Concern for dermal exposure and low concern for inhalation exposure.[d]	Low risk	52%	No estimated risk
	Alternative: 3.48 Baseline: 3.64	-4				

a) Cost analysis based upon product performance as determined by the performance demonstration at various testing facilities and pricing submitted by the product supplier. See Chapter 4 for a more in-depth description of the cost analysis and descriptions of the testing facilities.

b) Flammability risks are defined as follows: (1) High Risk: products with a flash point less than 100 °F; (2) Moderate Risk: products with a flash point greater than 100 °F but less than 150 °F; and (3) Low Risk: products with a flash point greater than 150 °F.

c) Risks for this chemical could not be quantified; therefore, the level of concern for this chemical is based upon a structure-activity analysis.

d) Risks for this chemical could not be quantified; therefore, the level of concern for this chemical is based solely upon estimated exposure levels.

Potential Benefits

The potential social benefits associated with the use of a substitute blanket cleaner versus the baseline wash include: reduced health risks for workers and the general public, reduced risk of fire and explosion due to lower flammability, reduced ecological risks, reduced use of energy and natural resources, and reduced VOC emissions. In order to assess the risk to workers, the EPA risk assessment combines hazard and exposure data for individual chemical components of the substitute as well as the baseline products into a single qualitative expression of risk. This qualitative expression of risk provides the basis for comparing the relative worker exposure risks associated with the use of the substitute blanket wash products as compared with the baseline. While members of the general public are also potentially at risk from blanket wash chemicals that are released to air and water, the EPA risk assessment identified no concerns for the general public through ambient air, drinking water, or fish ingestion. Due to data limitations, the exposure assessment does not estimate cumulative exposures from landfill releases or septic system releases. The relative risks of fire and explosion are determined by comparing the flash point of each blanket wash, using the OSHA definition of a flammable liquid as well as EPA's definition of an ignitable waste as a benchmark. In addition to the risks faced by workers and the general public, the risk assessment considers the potential ecological risks of using each of the alternative products and the baseline blanket wash. Several of the substitute formulations were found to present a risk to aquatic species. The energy and natural resource requirements of the substitute and the baseline blanket wash vary and a full life-cycle assessment, which was beyond the scope of this CTSA, would be needed to determine the requirements. The risks associated with VOC releases were not examined within the risk assessment; however, the relative VOC contents of the substitute formulations are discussed below since VOC releases are the primary driving factor behind current regulations affecting printers.

Reduced Worker Health Risks

Reduced risks to workers can be considered both a private and an external benefit. Private worker benefits include reductions in worker sick days and reductions in health insurance costs to the printer. External worker benefits include reductions in medical costs to workers as well as reductions in pain and suffering associated with work related illnesses. The EPA risk assessment considers two paths of worker exposure: inhalation and dermal. Inhalation exposure results from the volatilization of blanket wash chemicals from the blanket during washing and from the rags used to wipe down the blanket. Dermal exposure results from direct contact with the blanket wash chemicals during blanket cleaning. Worker dermal exposure to all products can be easily minimized by using proper protective equipment such as gloves or barrier creams during blanket cleaning. Worker health risks associated with the use of any blanket wash product are a function of both the product's toxicity as well as the degree of worker exposure which occurs during blanket cleaning. For example, the worker health risks associated with the use of a more toxic blanket wash may be reduced by the product's low volatility (i.e., reduced inhalation exposure) or workplace practices such as the use of automatic blanket cleaning technology (i.e., reduced dermal exposure). The exposure assessment estimates worker exposure (dermal and inhalation) for each of the blanket wash products. The risk assessment evaluates the toxicity of the individual blanket wash components for the substitute and baseline products and integrates the hazard and exposure information into a single qualitative expression of risk. The risk assessment does not provide a single measure of risk for the products overall, making it difficult in some cases to determine the relative risk from one product to another. For example, Blanket Wash 22 contains heavy aromatic solvent naphtha and fatty acid esters which were determined to posses moderate dermal concern and low dermal concern, respectively.

Reduced Public Health Risk

In addition to worker exposure, members of the general public may be exposed to blanket wash chemicals due to their close physical proximity to a printing facility or due to the wide dispersion of chemicals. Such releases impose an external cost on society that is typically not considered by printing facilities in selecting their blanket wash. For example, people may breath blanket wash vapors that have been released from a printing facility or people may drink water containing blanket wash residues discharged by a facility. Individuals in the general public that are exposed to blanket wash chemicals are therefore potentially subject to health risks. The EPA risk assessment identified no concerns for the general public through ambient air, drinking water, or fish ingestion. Using the model facility approach, the general population exposure assessment predicted that exposure levels would be extremely low for all media examined. Because of the low exposure levels, no concerns were identified for the general public from the use of blanket wash chemicals.

Reduced Flammability Risk

Some blanket wash chemicals in this assessment present risks of fire and explosion because of their flammability and high volatility (Tables I-2 and I-3). Reduced flammability risk may result in both private and external benefits. Private benefits may accrue to the printer in the form of lower risk of fire damage to the print shop. The population surrounding the print shop may experience external benefits in the form of lower risks of fire damage to their homes.
In order to assess the relative fire hazard of the substitute and baseline blanket washes, the flash points of each product is compared to OSHA and EPA definitions of flammable liquids.[4] Flammable liquids are defined by OSHA as having a flash point less than 141 °F. Similarly, EPA defines RCRA ignitable wastes (40 CFR 261.21) as having a flash point of 140 °F or less. The baseline product has a flash point of 50 °F, well below OSHA and EPA standards. Several of the substitute blanket washes have flash points below the OSHA and EPA thresholds: Blanket Washes 3, 4, 5, 8, 12, 21, 23, 24, 30, 31, 33, 34, 35, and 37.

Reduced Ecological Risk

Blanket wash formulations are potentially damaging to terrestrial and aquatic ecosystems, resulting in external costs borne by society. The EPA risk assessment evaluated the ecological risks of the substitute products as well as the baseline blanket wash; however, only the risks to aquatic species were considered. Reductions in aquatic species risks may create external benefits by increasing the catch per unit effort for commercial fishers as well as by increasing catch and participation rates of recreational fishers. The following formulations were found to pose a risk to aquatic species: Blanket Washes 3, 5, 6, 8, 11, 18, and 20. All the chemicals of concern are amine salts of an alkylbenzene sulfonate. Switching to these substitutes would likely increase aquatic risks rather than decrease them. The baseline product was not identified as creating an aquatic species risk.

Energy and Natural Resource Conservation

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[4] Flash point is defined as the lowest temperature at which a liquid gives off vapor within a test vessel in sufficient concentration to form an ignitable mixture with air near the surface of the liquid .

Benefits may accrue to society (external) as well as the printer (private) in the form of energy and natural resource savings if substitute blanket washes are substituted for the baseline wash. For example, Blanket Wash 34 was found to require fewer impressions to get back to acceptable print quality than with the baseline wash, thereby consuming less paper and energy. A similar situation may occur with press wipes. By switching to the substitute blanket wash, the printer might experience lower energy and resource costs. At the same time, society would also benefit from the printer's reduction in energy and natural resource use. However, the analysis of energy and resource conservation did not estimate the individual energy and natural resource requirements of the substitute and baseline washes due to various data limitations. A thorough quantitative evaluation of each life-cycle stage was beyond the scope of the CTSA.

Reduced VOC Releases

The reduction of VOCs within the pressroom can potentially result in private benefits including lower compliance costs and savings on insurance premiums, as well as external benefits including a safer work environment and reduced health effects outside of the facility.[5] VOCs are currently regulated under clean air legislation as well as toxics use and release reporting laws and, therefore, were not re-evaluated as part of the risk assessment. Because there are several sources of VOCs within any given print shop, no attempt was made to quantify the benefits associated with an incremental reduction in the release of blanket wash VOCs. However, case studies are available documenting the potential benefits of VOC reduction throughout the pressroom. For example, the Commonwealth of Massachusetts Office of Technical Assistance found that Hampden Papers of Holyoke, Massachusetts experienced savings by reducing VOCs (97 percent reduction over a ten year period).[6] Hampden Papers, by adopting a source reduction strategy, has avoided the need to purchase VOC collection and control equipment or explosion-proof mixers for inks and coatings containing VOCs. In addition, they have incurred significant savings in fire insurance premiums, and reduced their liability under Superfund, air regulations, OSHA, RCRA, and other laws (OTA, no date). VOC content of the baseline as well as the alternative formulations, as measured by the GATF laboratory, are presented in Table I-3. VOC content ranges from a low of 2 percent to a high of 99 percent. The baseline product and Blanket Wash 31 have the highest VOC content (99 percent).

Associated Costs

As discussed previously, in comparing the cost data for the alterative and the baseline

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[5] A successful VOC reduction strategy cannot be limited to blanket washes. All sources of VOC releases (i.e., inks, coatings, etc.) within the print shop must be evaluated in order to design and implement an efficient emissions control plan.

[6] For a copy or further information about this case study, contact: Office of Technical Assistance (OTA), Executive Office of Environmental Affairs, 100 Cambridge Street, Boston, MA 02202, or phone OTA at (617) 727-3260.

products, the costs of using the alternative blanket cleaners exceed the cost of using the baseline product in nearly all cases. Some cases required smaller quantities of wash or less cleaning time, resulting in a cost savings when using the substitute instead of the baseline wash. (Blanket Washes 26, 32, 37, and 40 resulted in costs savings relative to the baseline product. Overall, however, the costs of using the substitute blanket washes exceed the costs of using the baseline wash in the large majority of cases. Costs of the using the substitute blanket washes range from a low of $1.72 to a high of $8.80 per press. Costs of using the baseline product range from $1.64 to $3.64 per press. Where costs of the alternative blanket washes exceed the baseline, percentage cost increases range from 1 percent to 179 percent.)

Costs and Benefits by Formulation

The objective of a social benefit/cost assessment is to identify those products or decisions that maximize net benefits. Ideally, the analysis would quantify the social benefits and costs of using the substitute and baseline blanket wash products in terms of a single comparable unit (i.e., dollars) and calculate the net benefits of using the substitute instead of the baseline product. Due to data limitations, however, the analysis presents a qualitative description of the risks associated with each product compared to the baseline. Table I-7 compares the relative risks and costs of each substitute blanket wash to the baseline. While this table presents a comparison between the blanket washes and the substitutes, it is important to keep in mind that not all of the risk assessments are based on risk (comprised of both exposure and hazard) but that some of the assessments are based solely on a hazard call based upon a structure-activity analysis. A frowning face (☹) indicates an increase in cost, worker health risks, flammability, risk to aquatic species, or VOC content when using the substitute blanket wash instead of the baseline product. A smiling face (☺) indicates a reduction in cost, worker risk, flammability, aquatic species risk, or VOC content when using the substitute instead of the baseline product. A zero (o) indicates that the risk assessment identified no difference in relative risks when using the substitute blanket cleaner instead of the baseline. Because the risk assessment evaluated individual blanket wash components, the relative worker health risks are based upon the component that poses the highest degree of concern. For example, components of Blanket Wash 32 were determined to pose no or low concern (propylene glycol ethers) and concern (aromatic and petroleum distillate hydrocarbons); therefore, the overall dermal risk of Blanket Wash 32 is one of concern. Blanket Wash 32 is shown to have similar relative dermal risks to workers when compared to the baseline because the baseline product's component of highest concern poses concern (i.e., petroleum distillate hydrocarbons).[7]

In nearly every case the substitute product costs more to use than the baseline. There were several products whose used was determined to decrease dermal worker health risks; these were Blanket Washes 1, 9, 10, 14, 17, 19, 22, 23, 29, 37 and 38. Formulation 10 was found to increase costs by less than 10 percent for one of the facilities. The few products that did show evidence of reduced costs, had mixed results in terms of their relative health risks. For example, Blanket Wash 37, which was found to be less expensive to use than the baseline, was found to

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[7] The risk classification scheme should be interpreted as follows: no/low concern < low to moderate concern< concern.

reduce worker dermal risks but was neutral in terms of relative inhalation risk. Blanket Washes 26 and 40 showed evidence of reduced costs; in addition, the risk assessment found that worker dermal risks were similar for both products over the baseline. In addition, while Blanket Wash 32 was less expensive than the baseline at one facility, it was found to present increased dermal and inhalation risks over the baseline. All of the substitute products had lower flash points and, therefore, reduced flammability risk when compared to the baseline. Finally, three Blanket Washes (6, 11, and 20) had higher aquatic risks than the baseline.

TABLE I-7: RELATIVE BENEFITS AND COSTS OF SUBSTITUTE VS BASELINE BLANKET WASH[a]

Formula Number	Cost/Press		Worker Health Risk		Flammability Risk	Risk to Aquatic Species	VOC Content[b]
	Facility #1	Facility #2	Dermal	Inhalation			
1	☹	☹	☺	○[c]	☺	○	☺
3	Not tested		○	☹	☺	☹	☺
4	Not tested		○	○	☺	○	☺
5	Not tested		○	○	☺	☹	☺
6	☹	☹	○	○	☺	☹	☺
7	Not tested		○	○	☺	○	☺
8	Not tested		○	○	☺	☹	☺
9	☹	☹	☹	○	☺	○	☺
10	☹	☹	☺[c]	○	☺	○	☺
11	☹	☹	○	○	☺	☹	☺
12	☹	☹	○	○	☺	○	☺
14	☹	☹	☺[c]	○	☺	○	☺
16	Not tested		○	○	☺	○	○
17	Not tested		☺	○	☺	○	☺
18	Not tested		○	○	☺	☹	☺
19	☹	☹	☺[c]	○	☺	○	☺
20	☹	☹	○	○	☺	☹	☺
21	☹	☹	○	○	☺	○	☺
22	☹	☹	☺[c]	○	☺	○	NM
23	Not tested		☺	○	☺	○	☺
24	☹	☹	○	○	☺	○	☺
25	Not tested		○	○	☺	○	☺
26	☹	☺	○	○	☺	○	☺
27	Not tested		○	○	☺	○	○

TABLE I-7: RELATIVE BENEFITS AND COSTS OF SUBSTITUTE VS BASELINE BLANKET WASH[a]

29	☹	☹	☺	○	☺	○	☺
30	☹	☹	○	○	☺	○	☺
31	☹	☹	○	○	☺	○	○
32	☹	☺	☹	☹	☺	○	○
33	Not tested		○	○	☺	○	☺
34	☹	☹	○	○	☺	○	☺
35	Not tested		○	○	☺	○	○
36	Not tested		○	○	☺	○	☺
37	☺	☺	○	○	☺	○	☺
38	☹	☹	☺	○	☺	○	☺
39	☹	☹	☺	○	☺	○	☺
40	☹	☺	○	○	☺	○	☺

Potential Benefit of Avoiding Illness Linked to Exposure to Chemicals Commonly Used in Blanket Washing

As mentioned above, the risk assessment did not link exposures of concern to adverse health outcomes. Data do exist, however, on the cost of avoiding or mitigating certain illnesses that are linked to exposures to blanket wash chemicals. Such cost estimates indicate potential benefits associated with switching to less toxic products. Health endpoints potentially associated with blanket wash chemicals include: eye irritation, headaches, nausea, and asthma attacks. The following discussion presents estimates of the economic costs associated with each illness. To the extent that blanket wash chemicals are not the only factor contributing toward the illnesses described, individual costs may overestimate the potential benefits to society from substituting alternative blanket cleaners; also, this is not a comprehensive list of the potential health effects of exposure to blanket washes. For instance, inks and other pressroom chemicals may also contribute toward adverse worker health effects. The following discussion focuses on the external benefits of reductions in illness: reductions in worker medical costs as well as reductions in pain and suffering related to worker illness. However, private benefits, accrued by the decision-maker, may be incurred through increased worker productivity and a reduction in liability and health care insurance costs. While reductions in insurance premiums as a result of pollution prevention are not currently widespread, the opportunity exists for changes in the future.

Often adverse health effects are experienced when working with chemicals. For example, press operators at facility 12 experienced nausea and dizziness when using Blanket Wash 20, a petroleum based blanket wash containing petroleum distillates and aromatic hydrocarbons. In addition, Blanket Wash 20 aggravated a previously existing respiratory condition in one press operator. The economic literature provides estimates of the costs associated with eye irritation, headaches, nausea, and asthma attacks, each of which may result from exposure to blanket wash chemicals. An analysis summarizing the existing literature on the costs of illness estimates individual willingness-to-pay to avoid certain acute effects for one symptom day (Unsworth and Neumann, 1993). The estimates for eye irritation, headaches, nausea, and asthma attacks are all based upon a survey approach designed to illicit estimates of individual willingness-to-pay to avoid a given illness. Such surveys, when properly designed, should capture direct treatment costs, indirect costs, and costs associated with pain and suffering. As eye irritation, headaches, nausea, and asthma attacks typically occur as short-term, discrete incidents, cost estimates represent an individual's willingness-to-pay to avoid a single incidence and not the average lifetime cost of treating a disease. Table I-8 presents a summary of the low, mid-range, and high estimates of individual willingness-to-pay to avoid each of these health endpoints. These estimates provide an indication of the benefit per affected individual that would accrue to society if switching to a substitute blanket wash product reduced the incidence of eye irritation, headaches, nausea, and asthma attacks.

TABLE I-8: ESTIMATED WILLINGNESS-TO-PAY TO AVOID MORBIDITY EFFECTS FOR ONE SYMPTOM DAY (1995 DOLLARS)

Health Endpoint	**Low ($)**	**Mid-Range ($)**	**High ($)**
Eye Irritation[a]	20.79	20.79	46.14
Headache[b]	1.67	13.23	66.72
Nausea[a]	29.11	29.11	83.66
Asthma Attack[c]	15.62	42.96	71.16

a) Tolley, G.S., et al. January 1986. *Valuation of Reductions in Human Health Symptoms and Risks*. University of Chicago. Final Report for the U.S. EPA. As cited in Unsworth, Robert E. and James E. Neumann, Industrial Economics, Incorporated, Memorandum to Jim DeMocker, Office of Policy Analysis and Review, *Review of Existing Value of Morbidity Avoidance Estimates: Draft Valuation Document*. September 30, 1993.

b) Dickie, M., et al. September 1987. *Improving Accuracy and Reducing Costs of Environmental Benefit Assessments*. U.S. EPA, Washington, DC and Tolley, G.S., et al. *Valuation of Reductions in Human Health Symptoms and Risks*. January 1986. University of Chicago. Final Report for the U.S. EPA. As cited in Unsworth, Robert E. and James E. Neumann, Industrial Economics, Incorporated, Memorandum to Jim DeMocker, Office of Policy Analysis and Review, *Review of Existing Value of Morbidity Avoidance Estimates: Draff Valuation Document*. September 30, 1993.

c) Rowe, R.D. and L.G. Chestnut. March 1985. *Oxidants and Asthmatics in Los Angeles: A Benefit Analysis. Energy and Resource Consultants, Inc.* Report to U.S. EPA, Office of Policy Analysis. EPA-230-07-85-010. Washington, DC. Addendum March 1986. As cited in Unsworth, Robert E. and James E. Neumann, Industrial Economics, Incorporated, Memorandum to Jim DeMocker, Office of Policy Analysis and Review, *Review of Existing Value of Morbidity Avoidance Estimates: Draft Valuation Document.* September 30, 1993.

APPENDIX J

COST OF ILLNESS VALUATION METHODS

Several approaches are available to estimate the economic benefits of reduced morbidity effects associated with pollution releases, including: contingent valuation, averting behavior, hedonic valuation, and cost of illness approaches. Table J-1 provides a brief summary of each.

TABLE J-1: COST OF ILLNESS VALUATION METHODS

Valuation Method	Description
Contingent Valuation Approach	The contingent valuation approach uses a survey to illicit estimates of individual willingness-to-pay to avoid a given illness. The contingent valuation technique, when properly designed, should capture direct treatment costs, indirect costs, and costs associated with pain and suffering.
Cost of Illness Approach	The cost of illness approach estimates the direct medical costs associated with an illness and will sometimes include the cost to society resulting from lost earnings. Cost of illness studies do not account for pain and suffering, the value of lost leisure time, or the costs and benefits of preventive measures.
Hedonic Valuation Approach	Hedonic valuation studies use regression analysis to estimate the relationship between environmental improvement or reduced worker risk and other independent variables. For example, a hedonic wage study may attempt to describe the relationship between wage rates and job related risks (i.e., what is the premium required to compensate workers for the added risk they incur from their occupation). The weakness of the hedonic approach is based upon the difficulty in separating illness effects from other independent variables.
Averting Behavior Approach	The averting behavior method examines preventive measures undertaken to avoid exposure or mitigate the effects of illness. Investments made in preventive measures are then used as a proxy for individual willingness-to-pay to avoid a particular illness.

Source: Unsworth, Robert E. And James E. Neuman, Industrial Economics, Incorporated, Memorandum to Jim DeMocker, Office of Policy Analysis and Review, *Review of Existing Value of Morbidity Avoidance Estimates: Draft Valuation Document.* September 30, 1993.