Methodology for Risk-Based Prioritization Under ChAMP

Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency

Table of Contents

Introduction 3
Screening-Level Hazard Characterization 4
- **Data Sources** 4
- **Endpoints Included in the Hazard Characterization** 5
- **Data Evaluation** 5
  - **Physical Chemical Properties and Environmental Fate** 6
  - **Environmental Effects – Aquatic Toxicity** 9
  - **Human Health Effects** 10

Screening-Level Exposure Characterization 13
- **Potential Exposures to the General Population and Environment** 14
- **Potential Exposure to Workers** 15
- **Potential Exposure to Consumers** 17
- **Potential Exposure to Children** 18
- **Exposure Characterization Assumptions and Uncertainties** 19

Screening-Level Risk Characterization 19

Risk-Based Prioritizations 21

Appendices:

- **A. Public Sources Searched for Measured (Experimentally Derived) Physical-Chemical Properties** 23
- **B. Public Sources Routinely Searched for Hazard Information** 24
- **C. Public Sources Routinely Searched for Exposure/Use/Release Information** 26

Introduction

Risk-based prioritizations (RBPs) are qualitative evaluations that indicate whether the Office of Pollution Prevention and Toxics (OPPT) considers a HPV chemical or chemical category as a low, medium, or high priority for further assessment or risk management activities. RBPs are interim evaluations that neither constitute a final Agency determination as to risk, nor a determination as to whether sufficient data are available to characterize risk.

Each RBP decision is based on and contains a qualitative, screening-level hazard, exposure and risk characterization prepared by OPPT using data submitted to the Agency under the HPV Challenge Program[1] and the 2006 Inventory Update Reporting (IUR)[2], as well as data publicly available through other selected sources[3]. These characterizations are intended only to support the prioritization decision and are not quantitative risk assessments. These characterizations indicate whether the hazard, exposure, and risk elements for each chemical or chemical category are low, medium, or high, according to the criteria or rationales developed for each element. Figure 1 depicts the process for developing RBPs.

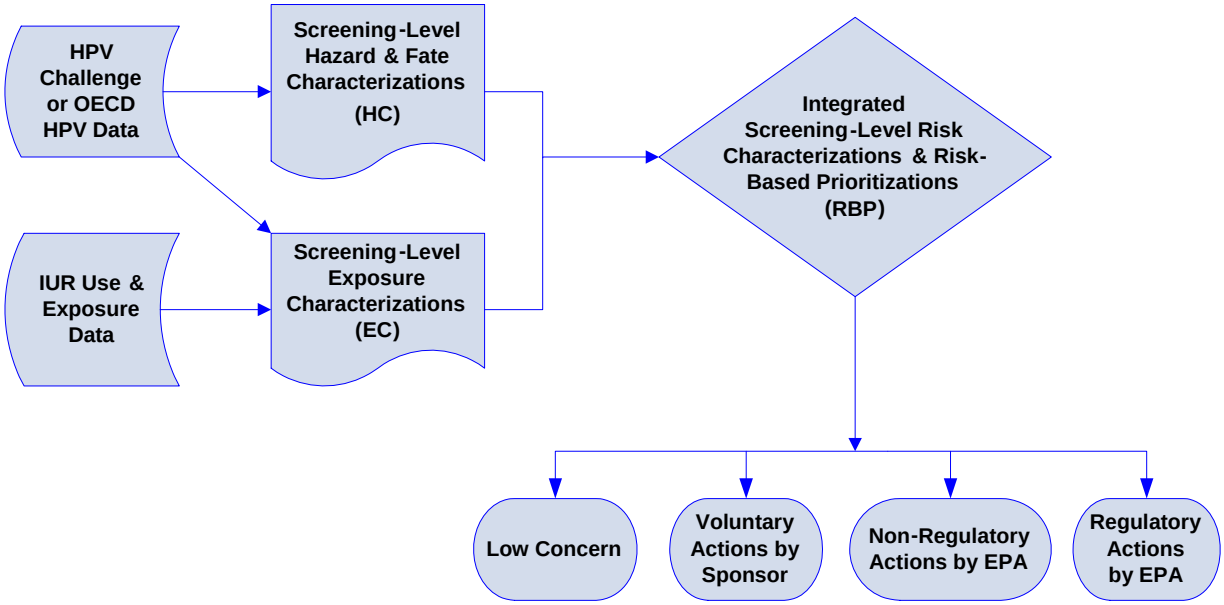

Figure 1. Process for Developing Risk-Based Prioritizations

In determining the priority of a chemical or category for further assessment or risk management activities, each RBP also incorporates policy and regulatory considerations that go beyond

[1] US EPA, HPV Challenge Program information: http://www.epa.gov/hpv/.
[2] US EPA, IUR information: http://www.epa.gov/oppt/iur/index.htm.
[3] These additional information sources are listed in this document in Appendices A, B, and C.

science issues. For example, a chemical identified as a high potential for risk may be a low priority for further assessment or risk management by the Agency if it is already subject to regulation on the basis of that risk, or if research or assessment activities are already underway to address potential concerns. Conversely, a chemical exhibiting generally low toxicity in limited available studies but with significant data gaps may be assigned a medium or high priority as a matter of policy, based on the combination of concerns regarding those data gaps and information suggesting a high potential for exposure. Each RBP explains the individual rationale for the specific prioritization decision, including the policy and regulatory considerations that were factored into the low, medium, or high priority assigned to the chemical or category.

The RBPs focus on chemical uses that fall within the jurisdiction of the Toxic Substances Control Act (TSCA). Uses regulated by other statutory authorities – for example, food, cosmetic, or pharmaceutical uses subject to the Federal Food, Drug, and Cosmetic Act, or pesticide uses governed by the Federal Insecticide, Fungicide, and Rodenticide Act – and the natural occurrence of chemicals in the environment are noted in the RBPs where such information is known, but generally do not advance a chemical's priority for further work under TSCA. OPPT may share its prioritization information on specific chemicals of potential concern with other agencies, including the Food and Drug Administration, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission.

Each RBP document has three sections: (1) the conclusion and rationale for the decision which includes subsections for the risk-based prioritization, the screening-level risk characterization, the screening-level hazard and exposure rankings, a summary of previous regulatory actions, and the assumptions and uncertainties used in making the prioritization decision; (2) the screening-level hazard characterization (generally Appendix A); and (3) the screening-level exposure characterization (generally Appendix B). For RBP cases that are determined early in the process to have a low hazard, an IUR data summary is generated and appended to the RBP in lieu of the exposure characterization. The data that are used for the screening-level hazard and exposure characterizations, the criteria used for the hazard and exposure rankings, and the criteria used for the risk rankings are provided below.

Screening-Level Hazard Characterizations

Data Sources

OPPT evaluates the HPV Challenge Program submissions and conducts a targeted search of specific reliable sources for any additional information relevant to characterizing the hazard of the chemical or category. OPPT's focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available. Furthermore, these sources typically provide information that is directly relevant to OPPT's initial hazard assessment and often include critical reviews of the relevant information provided; and in the case of OPPT documents, already follow established Agency guidance in those reviews. The public sources searched for measured (experimentally derived) physical/chemical properties data and fate information appear in Appendix A. The public databases searched for hazard information appear in Appendix B. The sources for hazard information are searched from one year prior to the date of the HPV Challenge submission to the present.

OPPT does not develop hazard characterizations (HCs) for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of ChAMP. OPPT does search its standard sources for update information covering the period between the date of the SIAR/SIAP and the development of the RBP document. Any new information which is relevant to the hazard characterization is presented.

Endpoints Included in the HC

The parameters and endpoints presented and used in characterizing hazards include the SIDS and other parameters OPPT finds useful in characterizing chemical behavior and potential hazards of chemicals. These generally include:

- *Physical/Chemical Properties and Environmental Fate Parameters*: Molecular weight, physical state at room temperature, melting point, boiling point, vapor pressure, water solubility, dissociation constant (where applicable), octanol/water partition coefficient (log K_{ow}), and Henry's Law Constant.
- *Environmental Fate Parameters*: Organic carbon normalized sorption coefficient (log K_{oc}), various measures of persistence (ability to photodegrade, hydrolyze, and biodegrade), bioconcentration/bioaccumulation factor (bioaccumulation) and fugacity.
- *Aquatic Toxicity*: Acute toxicity to fish, aquatic invertebrates and aquatic plants, and chronic toxicity as appropriate, depending on physical-chemical properties of the chemical.
- *Human Health Toxicity* (*SIDS Endpoints)*: Acute, repeated-Dose (systemic), reproductive, developmental, and genetic toxicity.

Sponsor companies were encouraged to include other endpoints in HPV Challenge Program submissions, and that information is included in the HC where it was provided by the sponsor or located by OPPT during its search of reliable sources. These endpoints may include:

- *Irritation*: Eye or Skin
- *Sensitization*: Skin or Respiratory
- *Carcinogenicity*
- *Neurotoxicity*
- *Immunotoxicity*

Data Evaluation

The HC is organized in three sections. The first section summarizes the physical-chemical properties and environmental fate of the chemical or chemical category. The second section summarizes the aquatic toxicity data, while the third section summarizes the mammalian toxicity data. In the latter two sections, each study is summarized, and where appropriate, conclusions are made regarding toxicity values (i.e. LC_{50}, EC_{50}, LOAEL, and NOAEL).

At the end of each section is a summary of the conclusions of the overall data. Conclusion statements are made for each type of study. For the aquatic toxicity section conclusions are made for fish, and aquatic invertebrates and plants. For the mammalian toxicity section conclusions are made for acute toxicity, repeated-dose toxicity, reproductive toxicity, developmental toxicity (pre- and post-natal), genetic toxicity, and when available other endpoints such as irritation or carcinogenicity.

The purpose of the conclusion paragraphs is to provide a **qualitative** hazard characterization that is then used in combination with the qualitative exposure characterization to develop a qualitative risk characterization to inform the risk-based prioritization. Thus, the hazard characterization statements for aquatic and mammalian toxicity are expressed as low, moderate, or high. The characterization statements (low, moderate, or high) are based on comparing the toxicity values (e.g., LC_{50}, EC_{50}, LOAEL) for the SIDS endpoints included in the HPV Challenge Program to the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) criteria or to OPPT guidance for determining reportability under TSCA Section 8(e). The numeric values used in the comparison may reflect those submitted by the sponsor or those derived or revised by OPPT during in-depth review of the data provided in the robust summaries. Where study results indicate borderline values, OPPT uses professional judgment and a weight of the evidence approach to adjust the value up or down, as appropriate. Criteria have not been developed for some endpoints, including mutagenicity, irritation, carcinogenicity, neurotoxicity, and immunotoxicity, and in these cases a statement is made summarizing the outcome of the study. The criteria for the qualitative conclusions are described below.

Physical/Chemical Properties and Environmental Fate

To assess physical/chemistry and environmental fate properties for use in developing hazard and exposure characterizations, OPPT uses information submitted under the HPV Challenge Program supplemented by existing data from publicly available literature and databases. The quality and acceptability of available data are evaluated by OPPT scientists. Only data determined to be of high quality are included. Where multiple values have been reported for the same parameter, all values from reliable sources are included and cited.

When acceptable data are not available, OPPT uses expert judgment and one or a combination of estimation approaches, including "read-across" of data from structurally analogous chemicals and predictive modeling tools, depending on the availability of acceptable experimental data for analogs and the reliability of available modeling tools. Estimation approaches are used consistent with practice and experience in the OPPT New Chemicals Program (http://www.epa.gov/oppt/newchems/index.htm) and the US and OECD HPV Chemical Programs, as outlined in the OECD *Guidance on Grouping of Chemicals* (http://appli1.oecd.org/olis/2007doc.nsf/linkto/env-jm-mono(2007)28).

Experimental data and/or estimated values for each physical/chemical and environmental fate endpoint are included in tables in the HC. Experimental and estimated data are also qualitatively described for some endpoints to offer interpretations of the data and provide summary

descriptions. For vapor pressure, water solubility, rate of hydrolysis, photolysis, biodegradation, mobility, volatility, adsorption and bioaccumulation, values range from negligible to high as described below

Physical/Chemical Properties

The following criteria are used to characterize experimental data for vapor pressure and water solubility. Molecular weight, physical state, melting point and boiling point are not characterized, but are used to inform judgment on the reliability of other physical/chemical and fate endpoints.

PHYSICAL/CHEMICAL PROPERTY CHARACTERIZATION CRITERIA		
Parameter	**Characterization**	**Value Range**
Vapor pressure (mm Hg)	**Negligible** **Low** **Moderate** **High**	**$< 10^{-8}$** **$\geq 10^{-8}$ up to 10^{-4}** **$\geq 10^{-4}$ up to 1** **≥ 1**
Water solubility (mg/L)	**Negligible** **Low** **Moderate** **High**	**$< 10^{-3}$** **$\geq 10^{-3}$ up to 1** **≥ 1 up to 1000** **≥ 1000**

Environmental Fate

When adequate data are identified for mobility, volatility, hydrolysis, photodegradation, and biodegradation, the following criteria will be used to characterize these parameters.

ENVIRONMENTAL FATE CHARACTERIZATION CRITERIA		
Parameter	**Characterization**	**Value Range**
Mobility (K_{oc} L/kg)	**High Mobility** **Moderate Mobility** **Low Mobility**	**< 2** **2 to 4** **> 4**
Volatility Henry's Law Constant (atm m^3/mol)	**High** **Moderate** **Low**	**> 10^{-3}** **10^{-3} to 10^{-7}** **< 10^{-7}**
Hydrolysis (Half-life)	**Rapid** **Moderate** **Slow** **Negligible**	**< 2 hours** **≥ 2 hours to 2 days** **≥ 2 days to 20 days** **> 20 days**
Photodegradation (Half-life)	**Rapid** **Moderate** **Slow** **Negligible**	**< 2 hours** **≥ 2 hours to 1 day** **≥ 1 day to 10 days** **> 10 days**
Ready Biodegradation (within 28 days)	**Readily Biodegradable** **Not Readily Biodegradable**	**≥ 70% DOC removal (OECD 301 A and OECD 301 E); ≥60% theoretical carbon dioxide ($ThCO_2$) (OECD 301 B); ≥60% theoretical oxygen demand (ThOD) (OECD 301 C, OECD 301 D and OECD 301 F).** **If results fall below the criteria above**
Environmental Biodegradation (Environmental Half-life)	**Rapid** **Moderate** **Slow to negligible**	**< 2 days** **≥2 days to 2 months** **> 2 months**

Persistence

Persistence characterization includes evaluation of the potential half-life in air, water, soil, and sediment while considering the expected partitioning characteristics of the chemicals and all potential removal pathways based on standard physical/chemical properties and environmental fate parameters. The persistence characterization in the HC (identified as P1, P2, or P3) is based on the Persistence, Bioaccumulation, and Toxic (PBT) criteria set forth in OPPT's policy statement on *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*[4].

[4] Federal Register: November 4, 1999 (Volume 64, Number 213), pages 60194-60204; http://www.epa.gov/oppt/newchems/pubs/pbtpolcy.htm).

PERSISTENCE CHARACTERIZATION CRITERIA			
Environmental Medium	Hazard Characterization		
	Not Persistent	Persistent	
Water, Soil, Sediment*	Low ("P1")	Moderate ("P2")	High ("P3")
	< 60 Days	60 - 180 days	> 180 Days
* For comparison purposes, calculations are based on 30 days in a month.			

Bioaccumulation

Bioaccumulation characterization includes evaluation of high quality bioaccumulation (measured or estimated bioaccumulation factor, or BAF) data as the most preferred data for bioaccumulation assessment. When BAF data are not available, bioconcentration data (measured or estimated bioconcentration factor, or BCF) will be used to evaluate the potential for a chemical to bioaccumulate in organisms in the aquatic environment. The bioaccumulation characterization in the HC (identified as B1, B2, or B3) is based on the PBT criteria set forth in OPPT's policy statement on *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances*[4].

BIOACCUMULATION CHARACTERIZATION CRITERIA			
	Hazard Characterization		
	Not Bioaccumulative	Bioaccumulative	
	Low ("B1")	Moderate ("B2")	High ("B3")
Bioaccumulation Factor (BAF)	< 1000	1000 - 5000	> 5000
Bioconcentration Factor (BCF)	< 1000	1000 - 5000	> 5000

Environmental Effects – Aquatic Toxicity

The hazard characterization for aquatic organisms is based on the evaluation of up to three aquatic ecotoxicity endpoints: the acute toxicity values (LC_{50} or EC_{50}) for fish, aquatic invertebrates, and algae. If chronic toxicity studies are available, they are also evaluated. When measured values are not available or are inadequate, estimated values from ECOSAR[5] may be used to support the hazard characterization. Criteria for characterization of acute toxicity are from the Globally Harmonized System (GHS) of Classification and Labeling[6]. For chronic toxicity, the GHS does not provide specific criteria for making hazard assignments. Therefore, the criteria for evaluating chronic toxicity are those used in OPPT's New Chemical Program[7].

[5] U.S. EPA. 2000. ECOSAR: Ecological Structure-Activity Relationships. Office of Pollution Prevention and Toxics, Washington, DC. http://www.epa.gov/oppt/newchems/tools/21ecosar.htm.
[6] United Nations. 2007. Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Second Revised Edition. United Nations, New York and Geneva. http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.
[7] U.S. EPA. 2005. Pollution Prevention (P2) Framework. Office of Pollution Prevention and Toxics, EPA-748-B-04-001. U.S. Environmental Protection Agency, Washington, DC. http://www.epa.gov/oppt/sf/pubs/p2frame-june05a2.pdf

AQUATIC TOXICITY CHARACTERIZATION CRITERIA			
Endpoint	Hazard Characterization		
	High	Moderate	Low
Acute LC_{50} or EC_{50} (mg/L)	≤ 1	> 1 – 10	> 10
Chronic (ChV or LOEC) (mg/L)	≤ 0.1	> 0.1 - 10	> 10

Human Health Effects

The characterization of health-related toxicity is based on the evaluation of several endpoints generally evaluated in mammalian toxicity tests. Acute, repeated-dose, reproductive, developmental, and genetic toxicity are SIDS endpoints required under the U.S. HPV Challenge Program. Additional test data, including but not limited to irritation (eye/skin), sensitization (skin/respiratory), carcinogenicity, neurotoxicity, and immunotoxicity, may also be included in Challenge Program submissions or identified in OPPT's search of reliable sources. Data for these endpoints are reviewed and summarized in the HC. The criteria OPPT uses to characterize human health hazards are provided below.

Acute Toxicity

The following criteria are used to characterize acute toxicity. These criteria are used by OPPT to determine reportability under TSCA Section 8(e)[8].

ACUTE TOXICITY CHARACTERIZATION CRITERIA			
Route (units)	Hazard Characterization		
	High	Moderate	Low
Oral LD_{50} (mg/kg)	≤ 50	> 50 – 500	> 500
Dermal LD_{50} (mg/kg)	≤ 200	> 200 – 2000	> 2000
Inhalation LC_{50} (ppm) (mg/L)	≤ 200 ≤ 2	> 200 – 5000 > 2 - 50	> 5000 > 50

Repeated-Dose (Systemic) Toxicity

The following criteria are used to characterize repeated-dose toxicity. These criteria are essentially the same as the criteria used in the GHS[6].

[8] U.S. EPA, TSCA section 8(e) Health and Environmental Effects, http://www.epa.gov/oppt/tsca8e/pubs/frequentlyaskedquestionsfaqs.htm

REPEATED-DOSE/SYSTEMIC TOXICITY CHARACTERIZATION CRITERIA*			
Route of Administration (units)	**Hazard Characterization**		
	High	**Moderate**	**Low**
Oral (mg/kg-bw/day)			
90-day (13 weeks)	**<10**	**10 – 100**	**>100**
40-50 days	**< 20**	**20 – 200**	**> 200**
28-days (4 weeks)	**<30**	**30 – 300**	**> 300**
Dermal (mg/kg-bw/day)			
90-day (13 weeks)	**<20**	**20 – 200**	**>200**
40-50 days	**<40**	**40 – 400**	**>400**
28-days (4 weeks)	**<60**	**60 – 600**	**>600**
Inhalation(vapor) (mg/L/6hrs/day)			
90-day (13 weeks)	**<0.2**	**0.2 – 1.0**	**>1.0**
40-50 days	**<0.4**	**0.4 – 2.0**	**>2.0**
28-days (4 weeks)	**<0.6**	**0.6 – 3.0**	**>3.0**
Inhalation(dust/mist/fume) (mg/L/6hrs/day)	**<0.02**	**0.02 – 0.2**	**>0.2**
90-day (13 weeks)	**<0.04**	**0.04 – 0.4**	**>0.4**
40-50 days	**<0.06**	**0.06 – 0.6**	**>0.6**
28-days (4 weeks)			
Inhalation(gas) (ppm/6hrs/day)			
90-day (13 weeks)	**<50**	**50 - 250**	**>250**
40-50 days	**<100**	**100 - 500**	**>500**
28-days (4 weeks)	**<150**	**300 - 750**	**>750**
* All values are LOAELs. The 90-day values (i.e., first line in each row) are from the GHS scheme. The other values are pro-rated estimates OPPT has calculated to accommodate the various data submitted under the HPV Challenge Program. This method is also suggested for use by the GHS program (see Section 3.9.2.5 in http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/English/03e_part3.pdf			

Reproductive/Developmental Toxicity

The following criteria are used to characterize reproductive and developmental toxicity. These criteria are the same as those used by OPPT for reviewing TSCA Section 8(e) submissions for developmental/reproductive toxicity.

REPRODUCTIVE/DEVELOPMENTAL TOXICITY CHARACTERIZATION CRITERIA*			
Route of Administration (units)	**Hazard Characterization**		
	High	**Moderate**	**Low**
Oral (mg/kg-bw/day)	**<50**	**50 – 250**	**>250**
Dermal (mg/kg-bw/day)	**<100**	**100 – 500**	**>500**
Inhalation(vapor) (mg/L/day)	**<1.0**	**1 – 2.5**	**>2.5**
Inhalation (dust/mist/fume) (mg/L/day)	**<0.1**	**0.1 – 0.5**	**>0.5**
Inhalation (gas) (ppm/day)	**<50**	**50 - 250**	**>250**
* All values are LOAELs. The oral values are taken directly from the OPPT criteria for reviewing TSCA 8(e) submissions mentioned in the text. The other values are pro-rated estimates OPPT has calculated to accommodate the various data submitted under the HPV Challenge Program. The estimates are based on the routes of administration differences noted above in the repeated-dose criteria table in Section 3.2.			

Genetic Toxicity

As available, evaluations of both the gene and chromosomal effects are evaluated. In HCs prepared for RBPs, OPPT uses the approach used in the OPPT New Chemicals program in that test results are presented as positive, equivocal or negative.

Other Human Health-Related Data

Irritation/Sensitization

Many HPV submissions include robust summaries for irritation (eye and skin) and sensitization (predominantly skin) studies. OPPT also receives this type of information under TSCA 8(e) and so may identify such studies in the sources it searches (i.e., TSCATS). When available, OPPT will report the results qualitatively (i.e., positive – with the appropriate descriptor for severity if provided in robust summary– or negative).

Carcinogenicity

When data indicating a potential for carcinogenicity are submitted or identified in the literature search, the increased incidence for tumors up to the level (dose or concentration) tested and the tumor type is summarized in the HC document, and the potential for this type of hazard is noted.

Neurotoxicity or Immunotoxicity

When neurotoxicity or immunotoxicity data are submitted, the level (dose or concentration) at which effects are observed is presented in the HC document and the potential for these effects is noted.

Screening-Level Exposure Characterizations

Screening-level exposure characterizations (ECs) are qualitative and based largely on surrogates for exposure. These include use and exposure-related information and allow OPPT to quickly prioritize potential exposures for large numbers of chemicals. The qualitative assessments are developed using a process that integrates a multitude of factors that influence the prioritization ranking, any one of which may affect the prioritization outcome, but none of which solely affect the outcome.

The ECs provide qualitative rankings (high, medium, low) of potential exposures and are not intended to provide detailed or quantitative assessments of exposure. The rankings describe only the potential that a given population could be exposed based on the limited amount of information considered. Both Confidential Business Information (CBI) and non-confidential information from the Inventory Update Rule (IUR) information and other sources are used in developing OPPT's high, medium, and low prioritization rankings for exposures. No confidential information is presented in the ECs but may be included in aggregated form with non-confidential information where the aggregation of data can preserve the confidentiality of the specific information claimed as CBI.

With rare exceptions, the IUR data set, HPV Challenge Program submissions, and other public information available to OPPT for this prioritization exercise do not include data that would allow the quantitative characterization of the magnitude, frequency, duration, or route of exposure for any potentially exposed population. Most of the available information consists only of general chemical manufacturing, importation, processing, and broad category-of-use information. Similarly, quantitative information on actual releases of chemicals to the environment is very limited, being generally available only for those chemicals that appear on the Toxics Release Inventory (TRI)[9]. Accordingly, in preparing ECs, OPPT uses the information reviewed and its assessment experience in both the new and existing chemicals programs to make inferences regarding the potential for exposure of human populations and the environment. In determining the exposure potential, OPPT considers available information including production volume, environmental releases, uses of the chemical, physical/chemical properties, environmental fate and, if available, monitoring data.

In preparing an EC, OPPT relies heavily on information provided through the 2006 IUR submissions, because the IUR provides a current, nationwide set of information on the manufacturing and importation volumes of chemicals in quantities of 25,000 pounds or more per year. For chemicals produced or imported at or above 300,000 pounds at an individual site during the reporting year, the 2006 IUR submissions also included some exposure-related information on processing and use. Prior IUR reporting years did not require the submission of that processing and use information.

Other information sources, including HPV Challenge Program submissions and public databases, generally are not as current as the IUR, and the data in these sources may not be representative of the entire country. However, these sources may contain some useful information that is not reported under the IUR, and EPA uses them to supplement the IUR data. The list of public

[9] US EPA, TRI information: http://www.epa.gov/tri/.

information sources routinely consulted for exposure, use, and release information appears in Appendix C. Only sources that contain information on a specific chemical are referenced in the EC for that chemical.

The EC provides qualitative exposure characterizations for the following populations and the environment:

Potential Exposures to the General Population and the Environment

In determining the ranking for potential exposures to the general population and in the environment, OPPT considers a wide variety of factors including the environmental releases and media of releases, chemical's physical/chemical properties (including volatility and solubility), environmental fate characteristics, particularly persistence and bioaccumulation potential, the production volume, the number of sites, and their known presence in the environment, if any, as demonstrated from monitoring data from selected sources. Combining this information with its experience in both the new and existing chemicals programs, OPPT then determines if, in total, these factors are likely to result in potential exposures. OPPT then assigns a relative ranking (low, medium, or high) to that potential for the general population and the environment to be exposed from the presence of the chemical in the environment.

Quantitative information on releases of a chemical substance to various media is generally not available for HPV chemicals. In the absence of environmental release information, EPA often has to make inferences about potential releases and media of releases based on available information including use information reported to IUR and selected data sources, experience learned from the review of new and existing chemicals, and physical/chemical properties. For example, EPA often assumes there is potential for vapor releases to air based on the vapor pressure.

EPA assumes that most facilities manufacturing, processing, or using HPV chemicals have some releases of the chemicals. Some uses may be indicative of potential for releases and/or media of releases. For example, chemicals that are processed as surfactants in industrial laundry formulations or used as a flotation agent in mining operations are inferred to have high releases (as a percentage of processed or used) to water. Chemicals that are processed as reactants to make other chemicals are generally inferred to have low releases as a percentage of volume processed; the media of these releases are usually unknown and for the purpose of determining ranking for general population exposure, these chemicals are assumed to have potential for releases to all media including land, water and air.

There may also be "down-the-drain" commercial/consumer uses (e.g., soaps, detergents) that can increase the potential for environmental releases and associated exposures of the general population and in the environment. OPPT searches selected relevant sources, including TRI reporting and certain environmental monitoring databases (air, surface, and ground water), for further information on potential releases of chemicals.

Though monitoring data do provide some indication that a chemical has been released to the environment, the data are not necessarily current or nationally representative. Therefore, without

current, chemical-specific release information, it is assumed that there is potential for exposure to the general population and the environment.

Chemicals that have low releases (e.g., some chemicals with low environmental releases reported under TRI) and/or that rapidly break down into other, low-concern substances in the environment could generally be considered to present a low potential for general population and environmental exposures, because they would not remain in the environment long enough for significant exposures to occur. However, if their breakdown products were themselves chemicals of concern, OPPT would also factor in the potential for exposure to those breakdown products.

Chemicals used solely as intermediates in the production of other products or chemicals, processed, and used in mostly closed systems could be considered to present a low potential for general population and environmental exposures because they would not be considered likely to have a high fraction of volume released into the environment during their manufacture or use.

Where there is substantial uncertainty concerning releases, OPPT will generally assume for this prioritization exercise that releases might occur and that a potential for exposure may exist. OPPT carefully evaluates the available information on manufacturing, processing, and types of uses to establish whether that assumed potential would be considered low, medium, or high.

Potential Exposures to Workers

OPPT considers a variety of information in deriving the relative ranking for potential worker exposure, including uses of the chemical, its vapor pressure, physical state, concentration, the estimated number of potentially exposed workers, production volumes, and other factors such as the chemical's corrosive, flammable, and pyrophoric characteristics. The potential for worker exposure by inhalation and dermal contact is inferred based on this information and experience from the review of new and existing chemicals.

In general, the potential for inhalation exposure by workers is inferred based on the vapor pressure, physical state, and use information from the IUR. For example, the potential for inhalation of vapors is considered low if the vapor pressure is below 0.001 mm Hg, medium if the vapor pressure is between 0.001 mm Hg and 1 mm Hg, and high if the vapor pressure exceeds 1 mm Hg. There may be potential for exposure to particulates if the chemical is a solid, and/or exposure to mist if, for example, the chemical is used in a paint formulation which is spray-applied.

OPPT also generally assumes a potential for dermal exposure to workers during manufacturing, industrial processing, and use of a chemical. Factors that may affect dermal exposure include physical state, how the chemical is used, the concentration at which the workers may be potentially exposed, worker activities, and engineering controls. For the purpose of this ranking exercise, dermal exposure is factored into the relative ranking for overall potential worker exposure using available information on use, physical state, and concentration, which is often available under the IUR.

The estimated number of potentially exposed workers, as reported under the IUR, is also a factor in deriving the relative ranking for potential worker exposure. A relatively large reported number of manufacturing workers (e.g., ≥ 1,000 workers) or the potential for commercial uses which could result in a large number of potentially exposed commercial workers, who are not specifically reported under IUR, may increase the relative ranking for potential worker exposure.

For additional information on the number of workers potentially exposed, OPPT also consults the National Occupational Exposure Survey (NOES), conducted between 1981 and 1983. Although these data are out of date, they may provide useful information. The differences in the number of workers estimated by the NOES and IUR are attributable to many factors, including time, scope, and method of the estimates. For example, NOES estimates covered all workplaces while IUR ones are for industrial workplaces only, and NOES used a survey and extrapolation method while IUR submitters simply provide their best estimates based on available information for the specific reporting year.

Available use information, primarily from the IUR, is also an important factor in deriving the relative ranking for potential worker exposure. For example, the relative ranking for potential exposure may be considered high based on industrial and commercial uses which could result in a high number of workers potentially being exposed to mist and/or particulates. The relative ranking for potential exposure may be lower if the use is limited solely to industrial use as a chemical intermediate.

OPPT also considers other factors such as corrosive, flammable, and pyrophoric characteristics in developing ECs. These characteristics often require engineering controls and/or personal protective equipment to handle the chemicals safely and could lower the relative ranking for potential worker exposure. OPPT also takes into consideration the existence of regulatory Permissible Exposure Limits (PELs) established by the Occupational Safety and Health Administration (OSHA). These mandatory limits are intended to limit worker exposures to below specific levels, hence reducing worker risks. The relative ranking for potential exposure may be adjusted downward if the chemical has an established OSHA PEL. The American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) and National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure limits (RELs) are noted but generally not considered in the exposure ranking because these limits are not enforceable. However, TLVs and RELs may be considered as part of the overall risk-based prioritization decisions.

The approach used to determine a relative ranking for potential worker exposure is described in more specific detail below. It has evolved and continues to be refined over time as EPA gains more experience. The approach takes into consideration the information (or factors) discussed above, professional judgment and experience from the new and existing chemicals programs. This approach prioritizes the factors into potential for worker exposure in the following order: inhalation and dermal exposure potential, numbers of potentially exposed workers, volumes associated with particular uses, exposure concentrations, and exposure mitigating factors.

1. If the IUR physical form as manufactured is liquid or gas or vapor only, the preliminary ranking is based on vapor pressure: high if > 1 mm Hg, medium if 0.001 to 1 mm Hg, or low if <

0.001 mm Hg. If not manufactured only as liquid or gas or vapor, the preliminary ranking is based on type of solid as manufactured: high if dry powder, medium if pellets or large crystals, or low if wet or other solid.

2. If an industrial or commercial/consumer use is indicated by IUR, HPV Challenge Submission, Hazardous Substances Data Bank (HSDB), or any source has aerosol/ mist potential (e.g., paints, coatings, and metal working), reset the ranking to high.

3. If an industrial or commercial/consumer use indicated by IUR, HPV, HSDB, or another source has significant potential for dermal exposures (e.g., automotive fluids, paints, or uses with immersion potential), reset the ranking to high.

4. If an IUR physical form or use from above is a 'minor' form or use (i.e., production volume for the use is relatively small), decrease the ranking by one level.

5. If the IUR aggregated maximum number of potentially exposed industrial workers is 1,000 or more, increase the ranking by one level.

6. If the IUR aggregated maximum number of potentially exposed industrial workers is less than 100, all submitters reported the number potentially exposed workers for all industrial uses, and there are no commercial/ consumer uses, decrease the ranking by one level.

7. If all commercial/ consumer uses have an aggregated volume of considerable quantity, increase the ranking by one level.

8. If the highest manufactured concentration is low (e.g. less than 1% concentration), reset the ranking to low.

9. If the chemical has an OSHA PEL, decrease the ranking by one level.

10. If the only use is as an intermediate (i.e., no commercial/ consumer use), decrease the ranking by one level.

11. If the chemical is used as a closed system intermediate or if potential exposure is mitigated by one of the following types of physical properties (e.g., rapid hydrolysis, corrosive, pyrophoric, etc.), reset the ranking to low.

12. If there are other factors not considered above, indicate the factor (or note 'confidential' if the factor is confidential business information) and the appropriate change in the ranking.

Potential Exposures to Consumers

The rankings for potential exposures to consumers relate specifically to possible exposures attributable to the consumer use of products containing the chemical. This is separate from the ranking for general population exposures, which is based on the potential presence of the chemical in the environment due to releases.

IUR reporting does not distinguish between commercial and consumer uses. Many products are used both in business and commercial contexts – for example, cleaning products used by janitorial services or construction contractors – and in consumer settings. Therefore, if an IUR report indicates that a chemical is used in commercial/consumer products, OPPT initially assumes that potential consumer exposure is likely. Additional information about consumer uses or, especially, concentration and bioavailability in consumer products would be very helpful. OPPT searches select (see Appendix C), additional, relevant databases to seek such information. Sometimes additional consumer uses are identified but rarely does the available information address the concentration or bioavailability of a chemical in a product.

The Agency may also conclude that there is potential for exposure to consumers due to uncertainty in the IUR reporting. For example, when IUR data from a manufacturer or importer indicate that a chemical's presence in consumer products is "not readily obtainable" (NRO) or that the chemical's commercial/consumer use category is reported only as "other," it is deemed prudent to assume there is a potential for consumer exposure.

When commercial/consumer uses for a chemical are not identified in IUR submissions but are identified in other public data sources, EPA generally assumes a high potential for consumer exposure to the chemical in the identified consumer uses.

Where information indicates specifically that chemicals are used in consumer products, the default assumption is that there is a high potential that consumers might be exposed. This exposure potential is also based on the assumption that consumers, unlike workers, generally do not use personal protective equipment or engineering controls to mitigate exposure. Where information indicates that there are no commercial/consumer uses, the default assumption is that there is a low potential that consumers might be exposed to the chemical through consumer use of products.

Potential Exposures to Children

The rankings for potential exposures to children relate specifically to products containing the chemical which are intended to be used by children. This is separate from the ranking for general population exposures, which is based on the potential presence of the chemical in the environment due to releases.

Factors affecting the potential for children's exposure include whether the IUR, or other relevant databases, indicate that a chemical is used in products intended for use by children (the IUR defines children as being 14 years of age and under); whether the chemical is in consumer products that could possibly result in exposures through household use, even if they are not specifically intended for use by children; and whether there is uncertainty (e.g., NRO reports) in the IUR. When no reporting exists, or when specific product information is unavailable, the search of other selected, relevant databases may provide further information on types of consumer products to which children might be exposed during household use, or may provide information on products intended for use by children. When there is uncertainty concerning the presence of a chemical in products intended for children's use – for example, because children's

product use was reported as NRO – OPPT may assume that potential exposure to children is likely, depending on the general uses reported for the chemical. For example, chemicals used in adhesives may be in craft glue that children could use.

If the chemical is identified in IUR submissions as being used in products intended for use by children under 14 years of age, OPPT assumes that there is a high potential that children might be exposed. If the chemical is used in consumer products but not in products specifically intended for use by children, OPPT's general assumption is that there is at least a medium potential that children might be exposed through the household use of the consumer product. These general assumptions may be revised either upward or downward depending on the nature of the product. For example, OPPT would assume that children are likely to be exposed routinely to household cleaning products, but are less likely to be exposed to automotive functional fluids (e.g., brake or transmission fluids).

Exposure Characterization Assumptions and Uncertainties

The following assumptions and uncertainties are generally applicable to Exposure Characterizations:

EPA assumes that the IUR production volumes and use information reported in 2006 are representative of current production volumes and uses, respectively.

EPA assumes that chemicals that have been evaluated by EPA to meet the requirements of a closed-system intermediate (CSI) under the HPV Program retain CSI status unless new information indicates otherwise.

There is inherent uncertainty in the data reported in IUR regarding the industrial processing and use information on the number of potentially exposed workers, the number of sites, and use information (including commercial and consumer uses and use in products intended for children). Submitters are required to only report this information to the extent that it is readily obtainable. This contributes to uncertainty in the potential exposure to workers, general population, consumers and children.

Screening-Level Risk Characterizations

A screening-level risk characterization is provided for the following five scenarios:

- Aquatic organisms from environmental releases
- General population from environmental releases
- Workers
- Consumers (adult)
- Children

For each of these scenarios, the hazard and exposure rankings (low, medium, high) are combined to provide the qualitative, screening-level risk characterization. The following simple matrix illustrates the typical risk rankings.

Decision Matrix for Risk Characterization

		EXPOSURE		
		Low	Medium	High
HAZARD	Low	L	L	L
	Moderate	L	M	M
	High	L	M	H

For aquatic organisms, the hazard rankings (low, moderate, high) for fish, aquatic invertebrates, and aquatic plants are each compared to the potential exposure ranking (low, medium, high) to provide the potential risk ranking (low, medium, high). The potential risks to adult human populations (general population, workers, consumers) are based upon consideration of each hazard ranking (i.e., repeated-dose, reproductive toxicity, prenatal developmental toxicity) with the exposure ranking. In situations where the hazard ranking is the same for the various health endpoints, a summary hazard and risk ranking for human health is provided. In situations where the hazard rankings differ (i.e., repeated-dose toxicity is medium, but all other endpoints are low) or specific populations have a different hazard ranking (i.e. prenatal developmental toxicity studies indicate a specific hazard to pregnant women), either an overall human health hazard ranking will be made that reflects the endpoint with the highest hazard ranking, or specific risk rankings will be made for each human health endpoint. In addition, specific statements are made for those human health endpoints that do not have specific hazard ranking criteria (i.e., irritation, carcinogenicity, neurotoxicity). For the risk rankings for children, consideration is given to the hazard information available for post-natal developmental toxicity, as well as the adult toxicity studies. All of this information is considered relevant since the exposure rankings for children are based on the IUR which defines children's products as those used by children up to 14 years of age; therefore both early life stage considerations are important as well as consideration of later life stages where some organs may have matured, and would be expected to respond in a similar manner as "adult" organs when exposed to a specific chemical.

For this prioritization exercise, chemicals with intrinsically low hazards will generally be considered to present low potential risk even where OPPT evaluates a high potential that humans or the environment may be exposed to them. Similarly, high hazard chemicals may be considered to present low potential risk where OPPT evaluates a low potential that humans or the environment may be exposed to them. Specific cases may deviate from the simplicity of the matrix and would be explained in the rationale for the risk characterization, but the matrix can serve as a guide.

In evaluating potential risk for this prioritization exercise, OPPT factors in additional relevant information that is directly related to risk. For example, in evaluating potential risk to workers, OPPT takes into account the existence of regulatory OSHA PELs and other authoritative and routinely applied industrial hygiene standards designed and intended to reduce risk by limiting worker exposures to specific chemicals. Accordingly, for chemicals that are clearly corrosive in nature (i.e., strong acids), OPPT would conclude that the potential for risk to workers would be

low because of the need to follow good industrial practice in order to work with them safely, and because any exposures that were to occur with corrosives in the workplace would be immediately recognized and dealt with, as opposed to subtle or delayed effects from non-corrosive chemicals. Similarly, in terms of potential risks of acid burns to consumers and children from corrosive chemicals in consumer products, OPPT would assume that, because of the safety restrictions and labeling requirements imposed by the Consumer Product Safety Act and the Federal Hazardous Substances Act, any potential exposures that may exist would be only to low concentrations and so the risk of acid-related burns would be correspondingly low.

Risk-Based Prioritizations

In determining whether a chemical or category is a high, medium, or low priority for further assessment or risk management activities, OPPT begins with the risk characterization and incorporates policy and regulatory considerations. Chemicals are prioritized in order to identify which chemicals present the greatest potential need for additional evaluation or other follow-up action.

The RBP begins with the information on a chemical provided in the hazard, exposure, and risk characterizations, and further takes into consideration the impact that existing regulations and other ongoing activities may have on its potential. For example, industrial chemicals that present potential risk for worker exposure but are already regulated by OSHA (i.e., with existing PELs), or are the subject of voluntary guideline limits set by authoritative bodies such as the American Conference of Governmental Industrial Hygienists (ACGIH) or information safety cards created by the National Institute of Occupational Safety and Health (NIOSH) or the United Nations' World Health Organization (WHO), would generally be considered to be a lower priority because their occupational risks are already known and being addressed. Similarly, chemicals of potential environmental risk that are already subject to regulatory limits or permitting for releases based on their toxicity and fate would generally be considered a lower priority than chemicals of similar potential risk not already subject to release or exposure limits. Chemicals for which additional information is needed might also be a lower priority for OPPT action if data gathering activities that would answer the perceived need are already underway in other organizations, such as other EPA Offices, the National Institutes of Health (NIH) or the Organization for Economic Cooperation and Development (OECD).

OPPT's screening-level evaluations, combined with additional relevant information, including existing regulations and ongoing activities, result in one of three possible risk-based priority decisions. Follow-up actions are commensurate with these priorities:

- *Low Priority, Follow-Up Action Not Suggested at this Time*: Information available to EPA on the chemicals or categories assigned to this priority suggests that they do not present significant risk issues that warrant further Agency consideration at this time. This prioritization category may include chemicals with known risks that are already being controlled or addressed by existing activities or regulations. EPA generally does not expect to follow up with voluntary or regulatory actions in the near future for low-priority chemicals. EPA would re-evaluate a low priority decision if new data or information became available that contraindicated a low-priority decision.

- *Medium Priority*: Information available to EPA on chemicals assigned to this priority suggests possible concerns, but with risk issues or uncertainties that might be resolved if additional data (e.g., on exposures, controls, and/or hazards) were available to provide a basis for evaluating the potential concerns. EPA will encourage voluntary actions to better understand or mitigate potential risks for medium priority chemicals and may identify the need to act directly via regulatory means.

- *High Priority*: Information available to EPA on chemicals assigned to this priority suggests that these chemicals appear to have more serious potential risk concerns. EPA will determine whether there is a need for risk management actions, regulations, and/or more comprehensive data. EPA will encourage prompt voluntary actions to better understand or mitigate potential risks for high-priority chemicals and will also identify the need to act directly via regulatory means.

As warranted, EPA may nominate some of these chemicals for inclusion in appropriate Federal research or assessment programs, such as the National Toxicology Program (NTP), the Integrated Risk Information System (IRIS), or the National Health and Nutrition Examination Survey (NHANES). EPA also intends to factor in non-domestic data development efforts that are likely to provide needed information (e.g., Canadian or European efforts). EPA regulatory actions to address high-priority chemicals might include, where appropriate, the initiation of proceedings for Section 4 test rules or Section 8 rules under the Toxic Substances Control Act (TSCA) to collect additional data for chemical assessment; TSCA Section 6 rules to mandate new labeling requirements or other risk controls; TSCA Section 5 (a)(2) significant new use rules (SNURs) to ensure notice and to limit future risks; or other actions.

APPENDIX A: PUBLIC SOURCES SEARCHED FOR MEASURED (EXPERIMENTALLY DERIVED) PHYSICAL/CHEMICAL PROPERTIES DATA

Data Source	Description
OECD HPV Programme SIDS (SIDS endpoint data for HPV chemicals)	http://cs3-hq.oecd.org/scripts/hpv/
U.S. HPV Challenge Program Data	http://www.epa.gov/hpv/ and http://www.epa.gov/chemrtk/hpvis/index.html
NIH Hazardous Substances Data Bank (HSDB)	http://toxnet.nlm.nih.gov/
Beilstein	See explanation of Beilstein database at: http://library.dialog.com/bluesheets/html/bl0390.html
CRC Handbook of Chemistry and Physics	D. R. Lide (ed.), 82nd Edition, CRC Press LLC, Boca Raton, 2001-2002
CRC Handbook on Organic Compounds	Weast, R. C. and Astle, M. J, Boca Raton, FL, CRC Press, 1985
Kirk Othmer Encyclopedia of Chemical Technology	Fifth Edition, John Wiley & Sons, Inc., (2004)
Lang's Handbook of Chemistry	Thirteenth Edition, McGraw-Hill Book Company, New York (1985)
The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals	Thirteenth Edition, Merck & Co., Inc., Whitehouse Station, NJ (2001)
Ullmann's Encyclopedia of Industrial Chemistry	Fifth Edition, Wiley VCH Weinheim publishing, (1990)
Environmental Fate Database (EFDB)	Syracuse Research Corporation, Syracuse, NY. Available from http://www.srcinc.com/what-we-do/efdb.aspx
Biodegradation and Bioaccumulation of the Existing Chemical Substances under the Chemical Substances Control Law	National Institute of Technology and Evaluation, Japan (2002) http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html
A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms.	Arnot, J.A. and F.A.P.C. Gobas, *Environmental Reviews* 14(4): 257-297 (2006)
USEPA - ECOTOX Database	http://cfpub.epa.gov/ecotox/ (For bioaccumulation/bioconcentration data)

APPENDIX B: PUBLIC DATABASES ROUTINELY SEARCHED FOR HAZARD INFORMATION

Providers/ Data Source	Description
National Library of Medicine Databases (Accessed through ChemID Plus)	**http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp Searching on a chemical name or ID produces results that are linked to the following databases:**
HSDB	Hazardous Substances Data Bank
IRIS	USEPA - Integrated Risk Information System (IRIS). Also directly accessible at: http://cfpub.epa.gov/ncea/iris/index.cfm
PubMed	Biomedical Citations From PubMed
PubMed Toxicology	Toxicology Citations From PubMed
RTECS	Registry of Toxic Effects of Chemical Substances
TOXLINE	NLM TOXLINE on TOXNET
ATSDR MMGs	Agency for Toxic Substances and Disease Registry (ATSDR) Medical Management Guidelines
ATSDR PHSs	ATSDR Public Health Statements
ATSDR Tox Profiles	ATSDR Toxicological Profiles Also directly accessible at: http://www.atsdr.cdc.gov/toxpro2.html#bookmark05
ATSDR ToxFAQs	ATSDR ToxFAQS
EPA SRS	EPA Substance Registry System with links to Agency regulations & documents. Also directly accessible at: http://www.epa.gov/srs/
NJ-HSFS	New Jersey Hazardous Substances Fact Sheets
NTP DBS	National Toxicology Program (NTP) Database Search. Also directly accessible at: http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm?fuseaction=ntpsearch.searchhome
NTPT	NTP Technical Reports
FIFRA	EPA Pesticide Active Ingredients
HPV	EPA High Production Volume Chemicals
IARC	International Agency for Research on Cancer Also directly accessible at: http://monographs.iarc.fr/ENG/Classification/index.php
NJ	New Jersey Right-to-know Substances
NTPA	NTP Report on Carcinogens
TRI	USEPA Toxics Release Inventory Also directly accessible at: http://www.epa.gov/enviro/html/tris/tris_query.html

TSCAINV	USEPA Chemical Substances Inventory
STN Databases	**Fee for Service Vendor** http://stnweb.cas.org/
REGISTRY	CAS REGISTRY (for locators to ID sources)
CA/CA Plus	Chemical Abstracts
MERCK	Merck Index Online
RTECS	Registry of Toxic Effects of Chemical Substances
Science Direct	http://www.sciencedirect.com/
TSCATS	**The Toxic Substance Control Act Test Submission Database** http://www.syrres.com/esc/tscats.htm
USEPA - Office of Pesticide Programs	http://www.epa.gov/pesticides/reregistration/status.htm http://www.epa.gov/opprd001/inerts/decisiondoc_a2k.html
USEPA - Ambient Water Quality Criteria Documents	http://www.epa.gov/waterscience/criteria/wqcriteria.html
USEPA - Drinking Water Standards Health Effects Support Documents	http://www.epa.gov/safewater/standards.html
USEPA - ECOTOX Database	http://www.epa.gov/ecotox
IPCS Concise International Chemical Assessment Documents (CICADs)	http://www.inchem.org/pages/cicads.html

APPENDIX C: PUBLIC DATABASES ROUTINELY SEARCHED FOR EXPOSURE/USE/RELEASE INFORMATION

As part of the Exposure Characterizations (ECs) prepared on HPV chemicals, the following databases are searched to determine whether they contain information concerning the specific HPV chemicals being evaluated. Individual ECs mention only those databases which included a reference to the chemical being evaluated.

Data Source	Description
Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) Study U.S. EPA	http://www.epa.gov/heasd/ctepp/index.htm
Contaminant Exposure and Effects-Terrestrial Vertebrates database (CEE-TV)	http://www.pwrc.usgs.gov/contaminants-online/pages/CEETV/CEETVintro.htm
Current National Recommended Water Quality Criteria U.S. EPA	http://www.epa.gov/waterscience/criteria/wqcriteria.html
EPA Environmental Monitoring and Assessment Program (EMAP)	http://www.epa.gov/emap/index.html
Everything Added to Food in the United States (EAFUS) U.S. FDA	http://vm.cfsan.fda.gov/~dms/eafus.html
Indoor Air Articles	Brown et al., *Indoor Air*, 4:123-134, 1994. Daisey et al., *Atmospheric Environment*, 28 (22): 3557-3562, 1994. Kelly et al., *Environmental Science & Technology*, 28(8): 378A-387A, 1994. NOPES Final Report, EPA/600/3-90/003 (NTIS PB90-152224), January 1990. Samfield, M.M. Indoor air quality data base for organic compounds. Govt. Reports Announcements & Index (GRA&I), Issue 12. EPA-600-R-92-025 (NTIS PB92-158468), 1992. Shah and Singh, *Environmental Science & Technology*, 2(12): 1381-1388, 1988. Sheldon et al., *Indoor Pollutant Concentrations and Exposures*, California Air Resources Board, Contract A833-156, Final Report, January 1992. Shields, et al., *Indoor Air*, 6:2-17, 1996.
Inventory Update Reporting (IUR) U.S. EPA	http://www.epa.gov/oppt/iur/

List of Drinking Water Contaminants and their Maximum Contaminant Levels (MCLs)	http://www.epa.gov/safewater/contaminants/index.html#mcls see also http://www.access.gpo.gov/nara/cfr/waisidx_02/40cfr141_02.html
National Air Quality System (AQS) U.S. EPA Office of Air and Radiation	http://www.epa.gov/aqspubl1/select.html
National Contaminant Occurrence Database (NCOD) U.S. EPA	http://www.epa.gov/safewater/data/ncod/index.html
National Emission Inventory (NEI) Database U.S. EPA	http://www.epa.gov/ttn/chief/eiinformation.html
National Fish Tissue Study U.S. EPA Office of Science and Technology	http://www.epa.gov/waterscience/fishstudy/overview.htm
National Health and Nutrition Examination Survey (NHANES) Center for Disease Control	http://www.cdc.gov/nchs/nhanes.htm
National Human Adipose Tissue Survey (NHATS) U.S. EPA Office of Pollution Prevention and Toxics	http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55204
National Human Exposure Assessment Survey (NHEXAS) U.S. EPA National Exposure Research Laboratory	http://www.epa.gov/heasd/edrb/nhexas.htm
National Institute of Health's (NIH) Household Products Database	http://hpd.nlm.nih.gov/products.htm
National Occupational Exposure Survey (NOES)	http://www.cdc.gov/noes/
National Sediment Inventory (NSI) Tissue Data U.S. EPA Office of Water	http://www.epa.gov/waterscience/cs/library/nsidbase.html
National Status and Trends Program (NSTP) National Oceanic and Atmospheric Administration	http://nsandt.noaa.gov/nsandt_overview.htm
National Stream Quality Accounting Network (NASQAN) Surface Water and Sediment Data U.S.G.S.	http://water.usgs.gov/nasqan/progdocs/wri014255/results/data.htm
National Water Quality Assessment (NAWQA) Program	http://infotrek.er.usgs.gov/servlet/page?_pageid=543&_dad=portal30&_schema=PORTAL30

Permit Compliance System (PCS) U.S. EPA	http://www.epa.gov/enviro/html/pcs/pcs_overview.html
Source Ranking Database (SRD)	http://www.epa.gov/opptintr/exposure/pubs/srd.htm
STORET U.S. EPA Office of Water	http://www.epa.gov/storet/
Total Exposure Assessment Methodology (TEAM) U.S. EPA	http://www.exposurescience.org/Wallace87
Toxic Release Inventory (TRI) U.S. EPA	http://www.epa.gov/tri/
Hazardous Substances Data Bank	http://toxnet.nlm.nih.gov/
High Production Volume (HPV) Challenge Submissions (contain Use and Exposure Information)	http://cfpub.epa.gov/hpv%2Ds/
Screening Information Data Sets (SIDS) Documents (contain Use and Exposure Information)	http://www.chem.unep.ch/irptc/sids/oecdsids/sidspub.html
eHPV Program Submissions	http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPPT-2006-1020
Premanufacture Notices (PMN)	EPA internal confidential system