



U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

EPA's Voluntary Chemical Evaluation Program Did Not Achieve Children's Health Protection Goals

Report No. 11-P-0379

July 21, 2011



Report Contributors:

Gabby Fekete
Jeffrey Harris
Jee W. Kim
Steve Weber

Abbreviations

BPA	Bisphenol A
ChemRTK	Chemical Right-to-Know
EO	Executive order
EPA	U.S. Environmental Protection Agency
OCHP	Office of Children's Health Protection
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OPPT	Office of Pollution Prevention and Toxics
TERA	Toxicology Excellence for Risk Assessment
TSCA	Toxic Substances Control Act
VCCEP	Voluntary Children's Chemical Evaluation Program

Cover photos: *From left:* An unborn child and two children in different stages of childhood.
(EPA's Office of Children's Health Protection)

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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We conducted this review to determine the outcomes of the U.S. Environmental Protection Agency's (EPA's) Voluntary Children's Chemical Evaluation Program (VCCEP) toward meeting its original goal and the goals outlined under the Chemical Right-to-Know Initiative (ChemRTK).

Background

Executive Order (EO) 13045 directed federal agencies to place a high priority on protecting children from environmental and safety risks. The goal of the 1998 ChemRTK was to give citizens information on the effects of chemicals to enable them to make informed choices in the home and marketplace. ChemRTK satisfied EO 13045 by directing EPA to undertake testing on chemicals to which children are disproportionately exposed. EPA accordingly established the VCCEP pilot.

For further information, contact our Office of Congressional, Public Affairs and Management at (202) 566-2391.

The full report is at:
www.epa.gov/oig/reports/2011/20110721-11-P-0379.pdf

EPA's Voluntary Chemical Evaluation Program Did Not Achieve Children's Health Protection Goals

What We Found

The VCCEP pilot did not achieve its goals to design a process to assess and report on the safety of chemicals to children. The pilot's design did not allow for desired outcomes to be produced. Specifically, the pilot had a flawed chemical selection process and lacked an effective communication strategy. Programmatic effectiveness was hampered by industry partners who chose not to voluntarily collect and submit information, and EPA's decision not to exercise its regulatory authorities under the Toxic Substances Control Act to compel data collection. EPA has not demonstrated that it can achieve children's health goals with a voluntary program. The VCCEP is no longer operational, and the Agency has no plans to revive, replace, or terminate the program. As a result, the Agency is not meeting the intent of EO 13045, ChemRTK, or the VCCEP pilot, and there remains no readily understandable source of chemical exposure information that the general public can access to determine potential risks to children.

What We Recommend

We recommend that EPA design and implement a new process to assess the safety of chemicals to children that (1) identifies the chemicals with highest potential risk to children, (2) applies the Toxic Substances Control Act regulatory authorities as appropriate for data collection, (3) interprets results and disseminates information to the public, and (4) includes outcome measures that assure valid and timely results.

The Agency concurred with our findings, indicating that work ongoing by the existing chemicals program addresses many of our concerns. EPA agreed with our recommendations related to improving its chemical selection process and developing performance measures for children's health protection. EPA did not explicitly agree to develop a workable data collection strategy for applying Toxic Substances Control Act regulatory authorities or a communications strategy for public information dissemination, but provided information on the program's current activities. Also, no target dates were provided by which to assess the completion of EPA's actions taken to address our recommendations.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

July 21, 2011

MEMORANDUM

SUBJECT: EPA's Voluntary Chemical Evaluation Program Did Not Achieve Children's Health Protection Goals
Report No. 11-P-0379

FROM: Arthur A. Elkins, Jr. 
Inspector General

TO: Steve Owens
Assistant Administrator for Chemical Safety and Pollution Prevention

This is a report on the evaluation of the U.S. Environmental Protection Agency's (EPA's) Voluntary Children's Chemical Evaluation Program, conducted by the EPA Office of Inspector General (OIG). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The estimated direct labor and travel costs for this report are \$337,310.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days. You should include a corrective actions plan for agreed-upon actions, including milestone dates. Your response will be posted on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal. We have no objections to the further release of this report to the public. We will post this report to our website at <http://www.epa.gov/oig>.

If you or your staff have any questions, please contact Wade Najjum at (202) 566-0832 or najjum.wade@epa.gov, Jeffrey Harris at (202) 566-0831 or harris.jeffrey@epa.gov, or Jee Kim at (202) 566-2912 or kim.jee@epa.gov.

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Chapter 1

Introduction

Purpose

The objective of this evaluation was to determine the outcomes of the U.S. Environmental Protection Agency's (EPA's) Voluntary Children's Chemical Evaluation Program (VCCEP). We specifically sought to determine:

- The results of the VCCEP pilot
- Whether the program achieved its intended goals
- If there are alternative mechanisms for achieving children's health protection goals from chemical exposures

Background

Children's health and chemical legislation reform are key issues for the current administration. EPA Administrator Lisa Jackson testified on October 26, 2010, before the Senate Subcommittee on Superfund, Toxics and Environmental Health that:

Ensuring that our children are protected from exposure to environmental threats is central to EPA's work...both EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities – particularly children.

Children face significant and unique threats from environmental hazards and industrial chemicals. Children encounter their environments differently than adults. Physically, their neurological, immunological, respiratory, digestive, and other physical systems are still developing and can be more easily harmed by exposure to environmental factors. Children eat more, drink more, and breathe more than adults in proportion to their body weight. Children's exposures to environmental pollutants are often different from those of adults because they engage in different activities, such as playing on floors and in soil and mouthing of their hands, toys, and other objects that can bring them into greater contact with environmental pollutants. EPA and academic research is addressing the potential for children's susceptibility to chemicals and on children's unique behavior and exposure patterns. EPA budget documents cite research concluding that children are getting steady infusions of industrial chemicals before they even are given solid food.

Toxic Substances Control Act Does Not Target Children's Health Concerns

EPA regulates chemicals under the Toxic Substances Control Act (TSCA), which was passed in 1976. TSCA's intent is to protect human health and the environment from risks associated with toxic chemicals.¹ TSCA includes no provisions that enable EPA to act specifically on children's health concerns.² In addition, TSCA limits EPA's authority to require industry to conduct health and safety studies. Unlike laws applicable to drugs and pesticides, TSCA does not have a mandatory program where EPA must conduct a review to determine the safety of existing chemicals. However, a variety of authorities exist under TSCA by which EPA can request information or require testing from the chemical industry.³ The VCCEP pilot Federal Register notice specifically cited EPA's TSCA Section 4 authority. Under TSCA Section 4, EPA can request additional information via a "test rule," if the following requirements are satisfied:

1. The chemical presents an unreasonable risk of injury to human health or the environment and/or the chemical is produced in substantial quantities that could result in substantial human exposure
2. Existing data is inadequate for risk assessment
3. Testing is needed to develop the data necessary to conduct the needed risk assessment

According to the Agency, since TSCA was passed in 1976, EPA has restricted or banned 5 and required testing for 200 existing chemicals. Currently there are approximately 84,000 chemicals on the market.

Children's Health Concerns Addressed by Executive Order 13045 and the Chemical Right-to-Know Initiative

Executive Order (EO) 13045 and the Chemical Right-to-Know Initiative (ChemRTK) were created to address concerns about children's health issues, and, in part, to address EPA's limitations in evaluating chemical risks. EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks," was signed by President Clinton on April 21, 1997. This Order directed federal agencies to place a high priority on identifying and assessing environmental

¹ The Act authorized EPA to collect information on, and to regulate the production and distribution of, chemicals. TSCA required EPA to (i) create an inventory of "existing chemicals" already in commerce, (ii) regulate unreasonable risk from "new chemicals" introduced into commerce subsequent to the Act, and (iii) make health and safety information available for examination while protecting manufacturers' confidential business information.

² The Food Quality Protection Act mandates that EPA apply an additional tenfold margin of safety to take into consideration children's particular susceptibility to pesticide exposures. The EPA Administrator is responsible for taking subgroups, including infants and children, into consideration when determining the potential effect of drinking water contaminants on public health under the Safe Drinking Water Act.

³ EPA authorities under TSCA Sections 8(a) and 8(d) are discussed in the report section entitled: EPA Lacks an Effective Children-Specific Chemicals Management Program.

health and safety risks that disproportionately affect children and ensure that their policies, programs, activities, and standards address these risks.

The ChemRTK was launched in April 1998 directing EPA to develop new programs to improve the public's knowledge about potentially harmful chemicals. Programs designed under this initiative were to ensure the public's right-to-know basic information about the hazards and risks of widely used chemicals that people, especially children, may be exposed to at home, at work, or in the environment. One component of the ChemRTK aimed to ensure that parents have the information they need to protect their children from harmful chemicals in their environment.⁴ The ChemRTK specifically directed EPA to undertake testing on chemicals to which children are disproportionately exposed. The VCCEP is this component of ChemRTK.

Voluntary Children's Chemical Evaluation Program

After consultation with stakeholders, EPA designed a voluntary pilot program to assess the possible risks from 23 chemicals. It was EPA's goal that the VCCEP provide the data needed to characterize health risks to children from chemical exposure. EPA asked the manufacturers and importers of 23 chemicals to volunteer to provide data sufficient for EPA to evaluate the risks of these chemicals to children's health. EPA selected chemicals found in human tissue or fluids; food and water children may eat and drink; and air children breathe. Thirty-five companies and 10 consortia⁵ volunteered to sponsor 20 of the 23 chemicals by June of 2001.

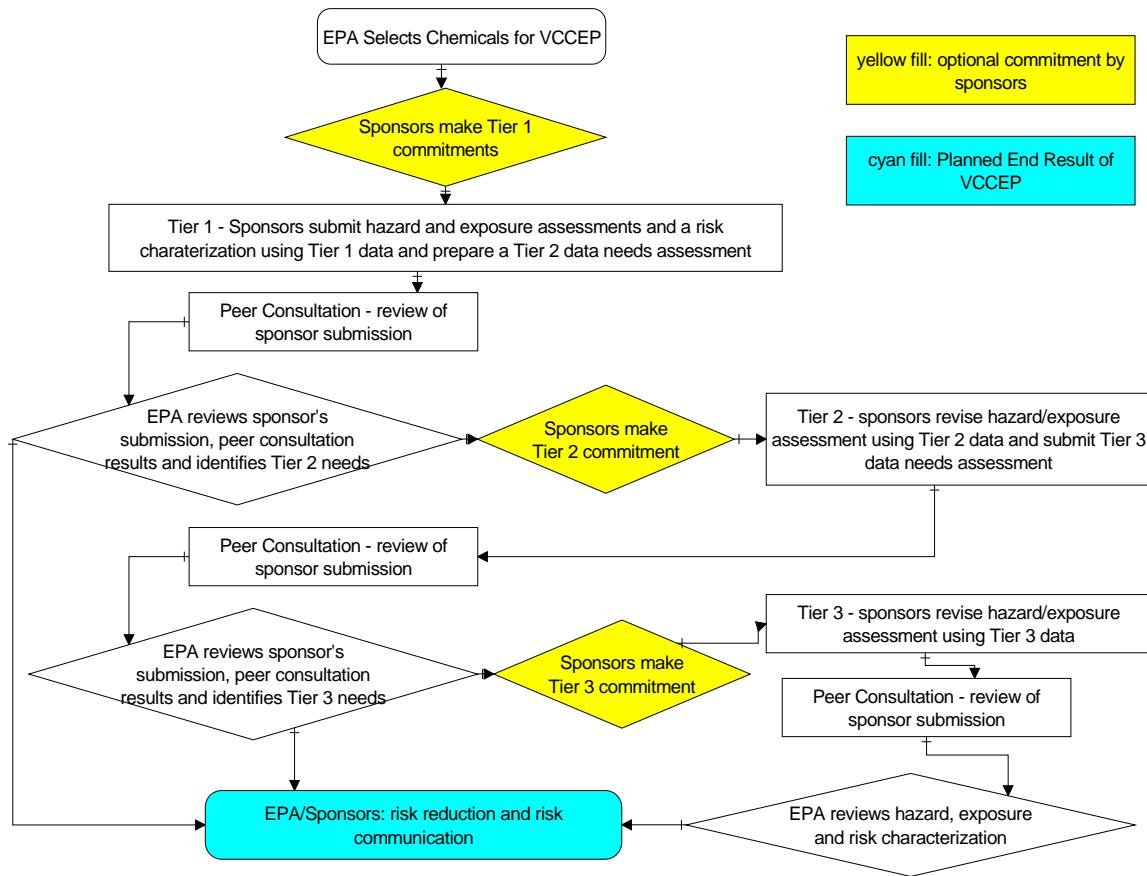
Under the pilot, if deemed necessary, EPA could request and collect up to three tiers of increasingly detailed information on a chemical from its sponsor, as shown in Figure 1.⁶ Each assessment within each of the three tiers includes: a summary of the toxicology information, a summary of the exposure information, and a risk characterization. A data needs assessment is required for tiers 1 and 2. The data needs assessment identifies the need for additional data to adequately characterize the risks the chemical may pose to children. The need for additional data was independently analyzed by a Peer Consultation Panel comprised of experts in toxicity testing and exposure evaluations. Ultimately, EPA was required to determine if more information and a higher tier of testing were needed to adequately characterize risks to children. Figure 1 illustrates each of the steps of the pilot and the respective contributions of EPA, sponsors, and peer reviewers.

⁴ The other two components of the ChemRTK are the High Production Volume Challenge and additions to the Toxic Releases Inventory.

⁵ Consortia are groups of manufacturers producing and representing the same chemical.

⁶ Information from all three tiers may not always be necessary to adequately characterize the risk to children. The toxicology studies included in the program are a subset of the test battery developed by the EPA to assess the effects of pesticides on children's health.

Figure 1: Voluntary Children's Chemical Evaluation Program Steps



Source: EPA OIG analysis of VCCEP announcement, Federal Register, December 26, 2000.

EPA's Office of Pollution Prevention and Toxics (OPPT), within the Office of Chemical Safety and Pollution Prevention (OCSPP), is the national program office and manager of the VCCEP.

Noteworthy Achievements

EPA attempted to specifically characterize chemical risks to children under the VCCEP, a novel effort by the Agency. OPPT staff considered the structure of the VCCEP pilot to be innovative for its time. EPA cites the use of the peer consultation panel process as one of the innovative aspects of the VCCEP pilot. The nature of the program created opportunities to highlight the voluntary provision of chemical data by industry. EPA and the American Chemistry Council sponsored an exposure workshop in December 2001 to assist industry in formulating and reporting exposure information on the VCCEP chemicals. In November 2006, EPA went through a detailed process to request comments from stakeholders on the VCCEP pilot to enable the Agency to evaluate how well it

was meeting the objectives and made modifications based on comments received.⁷

Scope and Methodology

We performed our evaluation from November 2010 to May 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. The evidence obtained provides a reasonable basis for our findings and conclusions based upon our objectives.

We conducted our evaluation in EPA headquarters and Research Triangle Park, North Carolina. At EPA headquarters, we interviewed program directors and staff from OPPT and the Office of Children's Health Protection (OCHP) regarding their roles and experiences with the VCCEP. In Research Triangle Park, we met with an EPA research scientist from the Office of Research and Development who participated in the review of chemical data as a core member of the peer consultation panel. We also interviewed a former EPA Assistant Administrator of OCSPP and representatives from the American Chemistry Council and Environmental Defense Fund to gain their insights on the VCCEP.

We reviewed VCCEP documents from EPA's VCCEP website, documents maintained in EPA's public VCCEP dockets, and documents prepared by various stakeholders. In addition, we reviewed applicable congressional testimony, proposed legislative changes, and scientific journals. We reviewed prior evaluation reports from the U.S. Government Accountability Office and EPA OIG on chemical management and children issues. We also reviewed international policies and programs that regulate chemicals.

⁷ At this time, no chemicals have gone through the revised VCCEP process.

Chapter 2

VCCEP Did Not Achieve Children's Health Protection Goals

The VCCEP pilot did not achieve its goals to design a process to assess and report on the safety of chemicals to children. The pilot's design did not allow for desired outcomes to be produced. Specifically, the pilot had a flawed chemical selection process and lacked an effective communication strategy. Children's behavior, children's tendencies, and chemicals commonly found in children's products were not factored in the chemical selection. Also, some industry partners chose not to voluntarily collect and submit information, and EPA's decided not to exercise its regulatory authorities under TSCA to compel data collection. This decision, along with a lack of timely program execution, led to only a fraction of the chemical assessments for the pilot being completed. Finally, the Agency failed to develop a means to promote its results and explain its findings to the general public. The VCCEP is no longer operational, and the Agency has no plans to revive, replace, or terminate the program. As a result, the Agency is not meeting the intent of EO 13045, ChemRTK, or the pilot, and there remains no readily understandable source of chemical exposure information that the general public can access to determine potential risks to children.

VCCEP Did Not Address the Chemicals Posing the Greatest Potential Risk to Children

One of the central issues in the development of the pilot was chemical selection. The impetus for the program, the ChemRTK Program, called for EPA to "assure extensive testing on chemicals to which children are disproportionately exposed." The chemicals in the pilot were not selected based on children's behavior, tendencies, or a focus on those chemicals commonly found in children's products. EPA selected chemicals that were found as contaminants in human tissue or fluids, food and water children may eat and drink, and air children breathe. The identification of these chemicals in monitoring systems indicated the existence of data on these chemicals. Therefore, these were all data-rich chemicals that EPA assumed would allow for rapid movement through the tiered system without long delays for data acquisition. Both environmental and industry advocacy stakeholder groups questioned EPA's selection of chemicals because the 23 chemicals selected for the VCCEP pilot were not the chemicals posing the greatest potential risks to children.

VCCEP Missed Opportunity to Assess Chemicals of High Concern

An OPPT director told us that given the state of the science, it was too challenging to develop a program with a specific children's chemical focus at the

pilot's inception.⁸ However, there were specific chemicals not included in the pilot that were known by EPA and the children's health community to pose greater risks to children. For example, the pilot development process gave substantial consideration to including phthalates. Phthalates, ultimately excluded from the pilot, are of concern to children's health and are found in a wide range of products, including children's toys. Since 1999, six phthalates have been restricted for use in toys in the European Union and at least 14 other countries have banned these phthalates in children's toys. Three of the five phthalates included in the early materials developed for the VCCEP program but excluded from the actual pilot were identified in scientific and regulatory materials as a reproductive or developmental toxicant or a carcinogen. EPA's reasoning for exclusion was that other government agencies were examining phthalates at that time. EPA planned to obtain and post publicly all information gathered for other agencies within a year. This information was received 4 years later.

EPA, after excluding phthalates from the pilot, ultimately published an action plan for phthalates in 2009. This Phthalates Action Plan focused on their toxicity⁹ and the evidence of pervasive human and environmental exposure to phthalates.⁹ EPA noted that, given the well-characterized health effects of phthalate exposure in animals in conjunction with the demonstrated widespread phthalate exposure in children, it believes that the cumulative health risks of phthalates should be assessed to determine what actions are warranted to ensure protection of children's health from this group of chemicals. By excluding the chemical class from the pilot program, EPA had a significant missed opportunity to make these determinations early on and speak to public concerns regarding phthalates and children.

Stakeholders cited that Bisphenol A (BPA) would have posed a natural fit for the pilot but was not considered for sponsorship or included in the draft list of chemicals for the VCCEP. EPA did not include BPA because, at the time, BPA was not found in the biomonitoring data used to select VCCEP chemicals. BPA is a plasticizer commonly used in baby bottles and sippy cups. Scientific research in the late 1990s indicated concern regarding the potential toxicity of BPA.¹⁰ Scientists with the Centers for Disease Control found BPA in the urine of nearly all of the people tested, indicating widespread exposure to BPA in the U.S. population. In March 2010, almost 10 years after the advent of the pilot, EPA

⁸ According to EPA, it became apparent during the stakeholder process used to gather input for the design of VCCEP that there were no readily available data sources at that time that could be used to identify chemicals that were affecting children more than the general population. EPA also noted that this information, if available, was not provided by the affected industry stakeholders.

⁹ In addition, The Consumer Product Safety Improvement Act of 2008 (CPSIA) banned the use of six phthalates in toys and child care articles at concentrations greater than 0.1 percent: DEHP, DBP, BBP, DINP, DIDP, and DnOP.

¹⁰ Two studies in particular pointed to the reproductive effects of BPA. vom Saal FS, Timms BG, Montano MM, Palanza P, Thayer KA, Nagel SC, Dhar MD, Ganjam VK, Parmigiani S, Welshons WV. 1997 March 4. Prostate enlargement in mice due to fetal exposure to low doses of estradiol or diethylstilbestrol and opposite effects at high doses. Proc Natl Acad Sci USA 94(5): 2056–2061.; Howdeshell KL, Hotchkiss AK, Thayer KA, Vandenberg JG, vom Saal FS. 1999. Exposure to bisphenol A advances puberty. Nature 401(6755): 763-4.

created an action plan for BPA. As was the case with phthalates, EPA had a missed opportunity to communicate risk to the public and serve as an authoritative voice on children's health and chemical risk.¹¹

EPA Failed to Adequately Explain Chemical Information to the General Public

One of the goals of the pilot was to evaluate methods for public dissemination of information received from industry on the pilot chemicals. The ChemRTK, the impetus for the VCCEP, directed the Agency to "ensure the public's right to basic information about the hazards and risks of widely used chemicals that people, especially children, may be exposed to at home, at work or in the environment." EPA's intent with VCCEP was, in part, to help parents have the information necessary to protect their children from harmful chemicals in their environment.

In implementing the VCCEP pilot, EPA did not effectively establish a communications strategy to achieve public understanding of the information produced from the pilot. The communication mechanism outlined in the Federal Register notice called for EPA to post VCCEP data and peer consultation documents on the Agency's website and for stakeholders to be involved in contributing to followup communication of risk information developed by VCCEP. While EPA did post data and peer consultation documents on the VCCEP website, according to EPA, stakeholders were rarely involved in sharing risk information. OPPT staff did not work with EPA's OCHP¹² to develop a communications strategy or outreach materials for the VCCEP pilot. No actions were taken to interpret the data. EPA conducted no risk communication or risk reduction activities to educate the public, consumers, or parents regarding data from the pilot. EPA did not translate or synthesize any of the information obtained in the pilot to make it understandable for the public, particularly parents. EPA took no action to evaluate any methods beyond web posting for public dissemination of information received from sponsors. Stakeholders noted that simply posting scientific data on the internet does not achieve the goal or intent of EPA's ChemRTK program or the pilot.

As a consequence of the lack of attention to program communication and coordination with internal offices, EPA provided no recommendations to the public regarding health risks from exposure to the pilot chemicals. Additionally, the lack of an effective communications strategy also created challenges for EPA in promoting industry's contributions to the pilot to the public. Industry

¹¹ In the absence of EPA statements on and data collection for chemicals such as BPA, states, municipalities, and other countries have taken the lead role in establishing protective regulation measures. For example, BPA bans are in place in New York, Vermont, Maryland, Minnesota, Connecticut, Massachusetts, Wisconsin, Washington, Chicago, Illinois, Canada, and Europe.

¹² EPA established OCHP in May 1997 to make the protection of children's health a fundamental goal of public health and environmental protection in the United States. OCHP supports and facilitates Agency efforts to protect children's health from environmental threats.

voluntarily entered into the VCCEP pilot, working with EPA to develop the necessary data. However, EPA did little to publicize industry's voluntary commitment, their findings, nor the effort undertaken to participate and conduct the pilot.

VCCEP Pilot Did Not Produce Complete or Timely Results or Employ EPA's Regulatory Authorities

Only a fraction of the chemical assessments for the VCCEP pilot were completed due to the lack of pre-established deadlines for actual submissions of and review of assessments. The Federal Register notice did provide allowable timeframes for sponsors to conduct toxicology tests and prepare final reports. However, these allowable timeframes were merely guidelines and did not serve as actual deadlines, which hampered the results of the VCCEP pilot. There was no information provided as to timeframes allotted for EPA's review of VCCEP reports in the Federal Register notice. In addition, EPA chose not to invoke its TSCA regulatory authority under Section 4. The constraints resulted in lengthy data collection and review processes for both sponsors and EPA. This is evidenced by the fact that over the course of the past 10 years, only 15 of the 23 chemicals went through the peer consultation process and EPA received sufficient data to assess chemical risk for only 6 of the 15.

The safety to children of all pilot chemicals remains in question; EPA still needs additional data to characterize health risks to children for the 17 chemicals indicated in the yellow rows in Table 1. In addition, EPA has not assessed the health risks to children for the 6 chemicals that have been identified by EPA as "no further data needs" even though they have collected sufficient data from sponsors.

Table 1: VCCEP Pilot Results

Results	Reason	# of VCCEP Chemicals	Name of Chemicals
Safety of chemicals remain in question	No sponsors	3	<ul style="list-style-type: none"> • Ethylene dibromide, • Chlorobenzene, • m-Dichlorobenzene
	Sponsors never provided Tier 1 information	5	<ul style="list-style-type: none"> • p-Dichlorobenzene • Ethylene Dichloride • Trichloroethylene • Tetrachloroethylene • a-Pinene
	Sponsors received data needs decision (EPA requesting Tier 2 or 3 studies) and declined further sponsorship	6	<ul style="list-style-type: none"> • Benzene • o-Xylene • m-Xylene • Toluene • Pentabromodiphenyl ether • Octabromodiphenyl ether
	EPA attempted to enter into an Enforceable Consent Decree to require the sponsor to provide the requested test data but sponsor committed to withdraw the chemical from commerce before a test rule could be promulgated	1	<ul style="list-style-type: none"> • Decabromodiphenyl ether
	Sponsors never received a data needs decision from EPA	2	<ul style="list-style-type: none"> • p-Dioxane • Ethylbenzene
No further data needs identified by EPA	EPA received all necessary information to make a determination regarding data needs from the sponsor and through the peer consultation process.	6	<ul style="list-style-type: none"> • Acetone • Vinylidenechloride • Methyl ethyl ketone • n-Dodecane • Decane • Undecane

Source: OIG analysis of EPA materials.

From the outset of the pilot, 3 of the 23 chemicals proposed for the pilot never received sponsors.¹³ The remaining 20 sponsored chemicals entered into Tier 1 of the pilot. For the 20 sponsored chemicals, EPA received no information from 5 chemical sponsors.¹⁴ Despite going through the peer consultation process, 2 of

¹³ According to the Agency, 3 of the original 23 chemicals were not sponsored because one was a pesticide (not subject to TSCA) and the other two were no longer produced.

¹⁴ According to the Agency, the five sponsors did not submit Tier1 information because of EPA's decision to suspend funding for peer consultations. When it became necessary for sponsors to pay for the cost of peer consultation, they chose not to submit the remaining Tier 1 assessments.

the 20 sponsored chemicals never received a “data needs decision” from EPA. Sponsors opted not to provide EPA with requested higher tier studies for 7 of the 20 chemicals,¹⁵ including 1 for which EPA ultimately attempted to take regulatory action. EPA’s request for higher tier studies indicates that there was a lack of data on tests and endpoints of concern to children. The lack of commitment by sponsors effectively ended EPA’s data collection for these chemicals.

We found that the lack of timeliness and efficiency was due to the pilot’s lack of pre-established deadlines for data submissions from sponsors, or for EPA’s issuance of data needs decisions to industry. With no pre-established deadlines for either the sponsors or the Agency, EPA could not ensure timely completion of chemical evaluations conducted as part of the pilot. For example, sponsors of Benzene and Toluene took over 4 years to collect and submit their Tier 1 data to EPA, 3 years past when EPA expected to receive the data. EPA was also not timely in its review of submitted Tier 1 data. It took EPA almost 3 years to issue a data needs decision for Decabromodiphenyl ether, and EPA has yet to issue data needs decisions for two chemicals that participated in the peer consultation process.

Although some sponsors failed to volunteer data, EPA chose not to invoke its TSCA regulatory authority under Section 4.¹⁶ EPA stated in the past that the Section 4 ‘test rule’ process is time-consuming and burdensome for the Agency to administer. The test rule process was the initial construct of the pilot. This process provides EPA with limited authority to request health and environmental effects testing from chemical manufacturers and processors. EPA opted to use a voluntary structure for the VCCEP based on input from stakeholder meetings to avoid the TSCA process for data collection under a test rule. However, per the VCCEP Federal Register Notice, EPA did retain the authority to use a test rule if necessary for the pilot: “If some chemicals are not sponsored in the VCCEP, EPA will consider whether a test rule under section 4 of TSCA is appropriate.” EPA never employed the test rule to require data provision.

EPA’s failure to utilize available regulatory mechanisms to compel data collection from sponsors unwilling to commit to higher tiers of the VCCEP pilot left EPA unable to make necessary determinations regarding the safety of a majority of VCCEP chemicals to children. EPA was therefore constrained by both the design of the pilot, under which sponsors committed to providing data on a tier-by-tier basis instead of to the program as a whole, and by their failure to use existing regulatory authorities to compel data collection.

¹⁵ According to the Agency, sponsors of two of these chemicals (pentaBDE and octaBDE) declined to do further testing because they were ceasing the manufacture and import of those chemicals.

¹⁶ According to EPA, OCSPP currently plans to issue a proposed test rule under Section 4 that will propose that the tests requested, but not provided, under VCCEP for pentaBDE, octaBDE, and decaBDE be required if the chemicals continue in commerce.

EPA Lacks an Effective Children-Specific Chemicals Management Program

According to EPA Administrator Jackson, ensuring the protection of children from exposure to environmental threats is central to the Agency's work. EPA, however, lacks an active children-specific chemical management program or framework. Despite the failure of the VCCEP pilot to provide the Agency with an effective mechanism to identify and evaluate chemicals that might pose a particular risk to children, EPA has not developed an alternative program to fill this critical void.

An OPPT director stated that there is not currently a children-specific existing chemical evaluation program in EPA and no such program in development. EPA's alternative to a specific program is to assume that children are "always a consideration" in EPA's chemical evaluation of new chemicals because of the inclusion of children's age groups in required testing. The pilot, however, collected data on existing chemicals which are grandfathered under TSCA and excluded from the review required for new chemicals by the Agency. The Director of OCHP also stated in a separate interview that the Agency's plan for filling the void left by the pilot is to engage other EPA offices to ensure that children's health is addressed in their decisions and programs. He was not aware of any plans within the Agency to create a program to evaluate chemicals and their risks to children.

EPA recently made a commitment to prioritize chemicals in the Agency's Cross-cutting Strategy for Environmental Justice and Children's Health. This commitment is: "Using children's health indicators and the latest children's health research findings, EPA will identify 5 to 10 priority chemical hazards for children's health for EPA to target through all Agency mechanisms, including regulations, enforcement, research, and voluntary programs (by April 2011)."¹⁷ Following through on this commitment is an important first step in meeting the intent of EO 13045, the ChemRTK, the underpinnings of the VCCEP, and creating a child-specific focus for chemical evaluation in the Agency. However, EPA still lacks a program or framework that provides the public with data that assess children's health risks from exposure to potentially toxic chemicals. EPA supports the reauthorization and modernization of TSCA. EPA's 2011-2015 Strategic Plan states the following:

As we look to the future, it is important to work together with Congress and stakeholders to modernize and strengthen the tools available under TSCA to prevent harmful chemicals from entering the marketplace and to increase confidence that those chemicals that remain are safe and do not endanger the environment or

¹⁷ This information is not in the fiscal year 2011-2015 Strategic Plan, nor is it openly available to the public on EPA's website. In conversations with the Agency, this measure was not cited.

human health, especially for consumers, workers, and sensitive subpopulations like children.

The Agency's principles for TSCA reform (Appendix A) include specific provisions for the protection of children's health, and focus on EPA's ability to collect necessary chemical data, one of the concerns predicated the VCCEP pilot. EPA notes that a reformed TSCA should require that exposure and hazard assessments from manufacturers include a thorough review of the chemical's risks to sensitive subpopulations such as children.

Under the Agency's principles for TSCA reform, EPA states that it should have clear authority to take risk management actions when chemicals do not meet established safety standards. The principles further state that this authority should include the flexibility to take into account a range of considerations, including children's health. OCSPP Assistant Administrator Steve Owens testified that in reforming TSCA both EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities, particularly children. Proposed legislation in both houses of Congress have provisions to improve EPA's authority to reduce risk from exposure to toxic chemicals, require the chemical industry to submit to EPA the data it needs, and improve EPA's authority to compel testing by the chemical industry. The improvement to the Agency's ability to obtain necessary data under statutory means would afford EPA the capacity to construct a new, effective children's chemical program.

In lieu of TSCA reform, EPA recently proposed several modifications to its existing chemicals program. The Agency states that it is "initiating a comprehensive approach to enhance the Agency's current chemicals management program within the limits of existing authorities." The activities under this approach include the Action Plans for specific chemicals of concern, the proposal to require additional reporting on existing chemicals, and increased transparency in EPA's chemical management actions. Of particular note to our evaluation, EPA stated that it plans to do the following:

- Require that companies submit information to fill the remaining gaps in basic health and safety data on high production volume chemicals¹⁸
- Make the reporting of chemical use information more transparent, more current, more useful, and more useable by the public
- Prioritize chemicals for future risk management

Prioritizing chemicals includes a first attempt at developing a "Chemicals of Concern" list under TSCA Section 5, highlighting chemicals that "may present an unreasonable risk of injury to health and the environment." EPA states that inclusion on the list publicly signals EPA's strong concern about the risks that those chemicals pose and the Agency's intention to manage those risks. EPA's

¹⁸ The chemicals included in the VCCEP pilot were all High Production Volume chemicals.

successful execution of the action items listed above should aid the Agency in considering children's health in its existing chemicals program.

EPA can also utilize tools under TSCA Section 8 to strengthen its existing chemicals program. TSCA Section 8 focuses on data gathering activities to provide data that EPA can utilize to identify, assess, manage, and reduce actual or potential risks posed by exposure to existing chemical substances. TSCA Section 8(a) gives EPA the authority to require, by rulemaking, manufacturers and processors of chemical substances to maintain records and report such data as EPA may reasonably require to carry out the TSCA mandates.¹⁹ In addition, under TSCA Section 8(d), EPA has the authority to promulgate rules to require producers, importers, and processors to submit lists and/or copies of ongoing and completed unpublished health and safety studies. In completing the VCCEP pilot, EPA chose not to invoke either of these tools.

Conclusions

Poor program design and the Agency's failure to use its TSCA regulatory authorities to compel data collection resulted in the failure of the VCCEP as an effective children-specific chemical management program. EPA demonstrated that it could not achieve children's health goals with a voluntary program. The VCCEP is no longer operational, and the Agency has no plans to revive, replace or terminate the program. As a result, the Agency is not meeting the intent of EO 13045, ChemRTK, or the pilot, and there is still no readily understandable source of chemical exposure information that the general public can access to determine potential risks to children.

Recommendation

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention

1. Design and implement a process to assess the safety of chemicals to children. Specifically, we recommend a new design that includes:
 - a. A chemical selection process that identifies and includes the chemicals with the highest risk potential to children.
 - b. A workable data collection strategy for applying the TSCA regulatory authorities as appropriate.
 - c. A communications strategy that interprets results and disseminates information to the public.
 - d. Specific outcome measures that provide assurance the process will provide valid and timely results.

¹⁹ Examples of information that can be required to be reported include: chemical or mixture identity, categories of use, quantity manufactured or processed, by-product description, health and environmental effects information, number of individuals exposed, and method(s) of disposal.

Agency Comments and OIG Evaluation

The Agency agreed that as a voluntary program with no strong integrated regulatory component to ensure results, VCCEP was not a successful model. The Agency also provided technical corrections. We made appropriate corrections based on our analysis of the Agency's comments. The Agency agreed in part with our recommendation, concurring with recommendation 1 parts a. and d., but neither concurring nor disagreeing with parts b. and c. The Agency did not provide concrete milestone dates for the planned achievement of the actions taken to address the recommendation. Those dates are required for each part of the recommendation.

The Agency agreed with recommendation 1 part a. EPA stated that, since 2009, it continues to identify priority chemicals of concern for children's health for children's health for priority action under TSCA. While the Agency did not explicitly agree with recommendation 1 parts b. and c., we found the Agency to be responsive. In reference to part b., EPA stated that the regulatory tools for collecting information related to chemical hazards, exposures, and risks have long been regarded as unwieldy, time consuming, and overly deliberative, but committed to use the available TSCA Section 4, 5, and 8 regulatory tools as expeditiously as possible to gather information necessary to manage potential chemical risks. The OIG recognizes the challenges of working within the TSCA regulatory framework in the report.

For recommendation 1 part c., EPA stated that it has taken a series of significant actions to increase the public's access to critical information about chemicals. EPA drafted a proposed rule, currently in interagency review, that will establish a TSCA Section 5(b)(4) chemicals of concern list. EPA plans to publish the data resulting from improved Inventory Update Rule reporting, which will highlight information on chemicals used in products intended for children. The OIG agrees that the amendments to Inventory Update Rule reporting and additional actions taken by EPA are important steps in determining information on chemicals in children's products. However, because the changes to Inventory Update Rule reporting are not yet final, the effectiveness of this work remains to be determined.

The Agency agreed with recommendation 1 part d. The Agency stated that goals and measures developed for EPA's enhanced existing chemicals program should address this issue.

Status of Recommendations and Potential Monetary Benefits

Rec. No.	Page No.	RECOMMENDATIONS			POTENTIAL MONETARY BENEFITS (in \$000s)		
		Subject	Status ¹	Action Official	Planned Completion Date	Claimed Amount	Agreed-To Amount
1	14	Design and implement a process to assess the safety of chemicals to children. Specifically, we recommend a new design that includes: <ul style="list-style-type: none"> a. A chemical selection process that identifies and includes the chemicals with the highest risk potential to children. b. A workable data collection strategy for applying the TSCA regulatory authorities as appropriate. c. A communications strategy that interprets results and disseminates information to the public. d. Specific outcome measures that provide assurance the process will provide valid and timely results. 	U	Assistant Administrator for Chemical Safety and Pollution Prevention			

¹ O = recommendation is open with agreed-to corrective actions pending
 C = recommendation is closed with all agreed-to actions completed
 U = recommendation is undecided with resolution efforts in progress

Agency Response

MEMORANDUM

SUBJECT: Draft Evaluation Report: EPA's Voluntary Chemical Evaluation Program Failed to Achieve Children's Health Protection Goals

FROM: Stephen A. Owens
Assistant Administrator

TO: Jeffrey Harris
Director for Programs, Cross Media Issues
Office of Inspector General

Thank you for providing my Office with the opportunity to review the draft evaluation report: EPA's Voluntary Chemical Evaluation Program Failed to Achieve Children's Health Protection Goals. OIG's recommendations are appreciated and clearly identify some actions that will be important to pursue as the Agency proceeds in its efforts to address the potential health impacts of chemicals on children. This memorandum provides responses to OIG's evaluation of the Voluntary Children's Chemical Evaluation Program (VCCEP), comments on OIG's recommendations, and identifies the actions the Agency will be taking in response to the recommendations.

Response to VCCEP Pilot Evaluation

- **The draft report states the VCCEP pilot did not achieve its goals to design a process to assess and report on the safety of chemicals to children.**

EPA concurs with this overall evaluation and is currently actively addressing this concern in the context of enhancing the Existing Chemicals Program authorized by the Toxic Substances Control Act (TSCA). Our responses to additional OIG evaluation comments below provide more detail on our enhanced chemical program.

OIG Response: The OIG appreciates EPA's concurrence with the overall conclusion of this evaluation.

- **The draft report states EPA lacks an effective children-specific management program.**

There are many ongoing initiatives across the Agency addressing the potential health impacts of chemicals on children, including OCSPP's comprehensive effort to enhance the TSCA Existing Chemicals Program with a particular emphasis on taking regulatory action to address chemicals of concern, especially to children. Our enhanced chemicals management effort, announced in September 2009, by Administrator Lisa Jackson, has included the

development of chemical specific action plans to identify OCSPP's planned risk management efforts on priority chemicals of concern. This comprehensive effort to enhance the Agency's chemicals management program also includes requiring the development and reporting and of information needed to understand chemical risks, creating a chemicals of concern list under section 5(b)(4) of TSCA, undertaking a host of new regulatory risk management actions (several of which focus directly on children's potential health risks), and increasing public access to information about chemical hazards, exposures and risks. OCSPP intends to utilize the full array of regulatory tools under TSCA to address identified risks, including the authority to label, restrict, or ban chemicals under Section 6 of TSCA.

Addressing chemicals of concern for children's health is a priority in our enhanced chemical management program enhancement effort. The September 2009 announcement made clear that children's health is a key focus of this effort and, the OCSPP website listed a number of criteria the Agency had used (and is using) to identify chemicals for action which included "chemicals potentially of concern for children's health because of reproductive or developmental effects." The Action Plans include chemicals in consumer products that are of concern to children, such as benzidine dyes and pigments; bisphenol A (BPA); penta, octa, and decabromodiphenyl ethers (PBDEs) in products; and phthalates. Children's health will continue to be one of the important factors we consider as we identify additional high priority chemicals for review and action under TSCA.

OCSPP will move quickly to ensure that the Agency has the hazard, use, and exposure data critical to prioritizing chemicals for review and making risk management decisions. EPA will soon issue a final rule that modifies the Inventory Update Rule (IUR) to ensure the reporting of chemical use information is more transparent, more current, more useful, and more useable by the public. IUR requires chemical manufacturers and importers to report production volume, processing, and use information on chemicals, including chemicals included in consumer products intended for use by children. The final rule implementing these improvements to IUR will provide the Agency and the public a unique and essential set of data which allows for better understanding of the chemicals that children may be disproportionately exposed to. In addition, OCSPP intends to require that companies submit information to fill the remaining gaps in basic health and safety data on High Production Volume (HPV) chemicals so that their hazards are understood. OCSPP has promulgated or is in the process of promulgating three regulations that address 93 chemicals to accomplish this.

Among the new regulatory risk management actions that the Agency is taking in its enhanced program that deal specifically with chemicals of concern to children are rulemakings under section 6 of TSCA to phase out or ban the use of mercury in a range of switches, relays, measuring devices, and other products (many of which can be found in the home or in consumer products) and to ban the use of lead in wheel weights, and a rulemaking under section 5(a)(2) of TSCA to require prior notification to the Agency of any new consumer use of monoglyme and diglyme because of their potential developmental health effects.

OIG Response: As our report described, EPA has recently initiated several action items in its existing chemicals program designed to aid the consideration of children's health. However, these actions have not yet been fully implemented or evaluated, and their effectiveness remains to be determined.

- **The draft report states VCCEP did not address the chemicals posing the greatest potential risk to children due to its flawed chemical selection process which did not select chemicals to which children are disproportionately exposed due to the unique behavior and tendencies of children, and did not focus on chemicals commonly found in children's products.**

It was the intention of the designers of VCCEP to select chemicals to which children were disproportionately exposed. However, during the stakeholder process used to gather input for the design of VCCEP, in 2000, it became apparent that there were no readily available data sources at that time that could be used to identify chemicals that were affecting children more than the general population. This information was also not provided by the affected industry stakeholders.

The chemical selection process which OCSPP decided to use for VCCEP focused on chemicals which have been found to be present in human tissues or fluids (e.g., adipose tissue, blood, breast milk, breath), food or water children may eat or drink, and air children may breathe at home or at school. There were biomonitoring and environmental data in nine databases that OCSPP used to identify chemical candidates for the VCCEP program. This chemicals selection process was presented at the public stakeholder meetings and received support from the stakeholders.

As a result of the lack of data on use of chemicals in children's products, in 2003 EPA amended the IUR to require submission of this information for a subset of chemicals subject to IUR, beginning with reporting in 2006. EPA is using these data in its current program to identify priority chemicals with concerns for children's health. As noted above, EPA also soon will issue a final rule making additional modifications to the IUR that will increase the number of chemicals subject to reporting requirements on use in children's products and will further improve the Agency's ability to identify chemicals to which children may be disproportionately exposed.

OIG Response: The amendments to the Inventory Update Rule are an important step in determining information on chemicals in children's products. However, because the changes to the Inventory Update Rule are not yet final, their effectiveness remains to be determined. We concur that the intent of the designers of VCCEP was to select chemicals to which children were disproportionately exposed and added language to the report that details the challenge to find readily available data sources.

- **The draft report states the VCCEP pilot did not produce complete results.**

EPA agrees. As a voluntary program with no strongly integrated regulatory component to ensure results, VCCEP was not a successful model. For instance, EPA funded the peer consultation process for some of the initial chemicals as part of its commitment to the pilot program. When it became necessary for sponsors to pay for the cost of peer consultation, they chose not to submit the remaining Tier 1 assessments.

- **The draft report states the VCCEP pilot did not produce timely results because it had no established timelines.**

The Federal Register notice which announced VCCEP and solicited participation (65 FR 81699, Dec 26, 2000) states (Unit III.V., Unit IV.B.5., and Unit VII.) that the sponsor was expected to complete its work within the time period specified. Unit III.V., in particular, specifies the time EPA considers to be sufficient for the completion and report preparation of each test listed in Table 4 (65 FR 81769 at 81714). Because VCCEP was a completely voluntary program, however, there was no way to ensure that work would be completed on the expected timeline. In addition, the voluntary nature of VCCEP required Peer Consultations to verify that assessments provided by manufacturers were accurate, but peer consultations were shown to be cumbersome and not a particularly expedient aspect of the pilot process.

OIG Response: Although there were timeframes in the VCCEP Federal Register notice for completion of particular tests, there were no deadlines for the necessary consultations and decision milestones among the industry sponsors, EPA, and the peer consultation panel. The lack of pre-established deadlines for these discussions and determinations hampered the results of the VCCEP pilot. We amended the language in the report to better reflect the existence of timeframes for test execution.

The draft report states the VCCEP pilot had no communication strategy to promote its results and make recommendations to the public on health risks of the pilot chemicals to children.

A communication strategy was included in the FR notice launching the program (65 FR 81699 at 81715) in Unit III.X., but in retrospect was not sufficient. It was also anticipated that stakeholders would be involved in follow-up communication of risk information developed by VCCEP but this rarely occurred.

EPA is committed to transparency, to making as much information available as possible, and to making information available in ways that are as useful as possible to the public. OCSPP has been working to provide the public with improved information on its Existing Chemicals program, including information on chemicals of concern for children's health. Over the past two years, EPA has taken a range of aggressive steps to increase the public's access to critical information on the chemicals manufactured and used in this country, including making more health and safety data available on the Web along with an improved search tool for navigating the data, and a program to evaluate and challenge, as appropriate, claims of confidential business information for information submitted under TSCA. For example, on June 8, 2011, EPA declassified and made public the identities of more than 150 chemicals contained in 104 health and safety studies that had been claimed confidential by industry. This is just one specific example of EPA's commitment to take significant action to provide the public with greater access to information on the chemicals that are manufactured and used in the United States.

OIG Response: We amended the language in the report to acknowledge the planned and anticipated communications of pilot results as detailed in the Federal Register notice. Nevertheless, as EPA's response acknowledges, the communications outlined in the Federal Register notice were insufficient.

- **The draft report states that some industry partners chose not to voluntarily collect and submit information.**

Sponsors did volunteer to complete the Tier 1 assessments which were a substantial effort on their part. Tier 2 commitments, however, were disappointing and revealed that relying on a voluntary process is not a viable strategy. The enhanced Existing Chemicals Program has a greater emphasis on regulatory actions and will address OIG's VCCEP concern associated with the inadequacy of the voluntary approach.

OIG Response: We agree that that the Tier 2 commitments were disappointing and evidenced the lack of viability of the VCCEP strategy. However, we disagree that sponsors provided all necessary Tier 1 assessments. Our report details the instances when Tier 1 assessments were not completed.

Response to OIG Conclusions

The draft report concludes that poor program design and the Agency's failure to use its TSCA enforcement authorities (this should probably be described as regulatory authorities) to compel data collection resulted in the failure of the VCCEP as an effective children-specific chemical management program.

EPA agrees that, as a voluntary program with no strongly integrated regulatory component to ensure results, VCCEP was not a successful model. The enhanced Existing Chemicals Program emphasizes a more assertive application of TSCA's regulatory tools and, we believe, addresses OIG's recommendation.

Responses to Specific OIG Recommendations

OIG Overall Response: EPA needs to provide concrete dates and plans for achieving all recommendations outlined below.

- **The draft report recommends that a chemical selection process be used that identifies and includes the chemicals with the highest risk potential to children.**

EPA agrees and, beginning in 2009, has been identifying priority chemicals of concern for children's health. We are committed to continuing our work to identify chemicals of concern for children's health for priority action under TSCA.

OIG Response: EPA needs to provide milestone dates for the planned achievement of the development of a list of chemicals with the highest potential risk to children, as well as each for the successive recommendation responses below.

- **The draft report recommends the development of workable data collection strategy for applying the TSCA enforcement authorities as appropriate.**

The regulatory tools for collecting information related to chemical hazards, exposures and risks have long been regarded as unwieldy, time consuming and overly deliberative. Almost all stakeholders involved in TSCA legislative reform discussions have recognized this. Until meaningful reform has been enacted, EPA's enhanced Existing Chemicals Program will use the available TSCA Section 4, 5 and 8 regulatory tools as expeditiously as possible to gather information necessary to manage potential chemical risks. Key to this effort will be to focus on priority chemicals so that resources are effectively deployed on the chemicals of greatest concern.

- **The draft report recommends a communications strategy that interprets results and disseminates information to the public.**

OCSPP has been working to provide the public with improved information on its Existing Chemicals program, including information on chemicals of concern for children's health. As indicated earlier, EPA has taken a series of significant actions to increase the public's access to critical information on chemicals manufactured and used in this country and will continue to enhance the information disseminated through our Existing Chemicals website by making even more health and safety studies publicly available, and by continuing to examine and challenge, where appropriate, claims of confidential business information in those studies. In addition, EPA has drafted a proposed rule, currently in interagency review, that will establish a TSCA section 5(b)(4) chemicals of concern list. This list will highlight chemicals that may be a concern to children's health. EPA will also publish the data resulting from improved IUR reporting, which will highlight information on chemicals used in products intended for children.

OIG Response: The OIG agrees that the amendments to the Inventory Update Rule are an important step in determining information on chemicals in children's products. However, because the changes to the Inventory Update Rule are not yet final, their effectiveness remains to be determined.

The draft report recommends development of specific outcome measures that provide assurance the process will provide valid and timely result.

EPA agrees with this goal. We believe that the goals and measures developed for our enhanced Existing Chemicals program should address this need.

Again, we appreciate the opportunity to review and comment on this draft report. Some minor comments on some factual errors included in the draft report are listed in Attachment 1. Should you have any questions or concerns regarding this response, please contact Ward Penberthy, Deputy Director, Chemical Control Division, at (202) 564-8171, or Janet Weiner, Audit Follow-up Coordinator for OCSPP at (202) 564-2309.

EPA's Essential Principles for Reform of Chemicals Management Legislation

Source: EPA's Existing Chemicals Webpage:
<http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html>

The U.S. Environmental Protection Agency (EPA) is committed to working with the Congress, members of the public, the environmental community, and the chemical industry to reauthorize the Toxic Substances Control Act (TSCA). The Administration believes it is important to work together to quickly modernize and strengthen the tools available in TSCA to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive subpopulations such as children, or the environment.

The following Essential Principles for Reform of Chemicals Management Legislation (Principles) are provided to help inform efforts underway in this Congress to reauthorize and significantly strengthen the effectiveness of TSCA. These Principles present Administration goals for updated legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Principle No. 1: Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

Principle No. 2: Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect safety, such as increased production volume, new uses or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

Principle No. 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations

EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

Principle No. 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner

EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations

Principle No. 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

Principle No. 6: EPA Should Be Given a Sustained Source of Funding for Implementation

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

Appendix C

Distribution

Office of the Administrator

Assistant Administrator for Chemical Safety and Pollution Prevention

Agency Followup Coordinator

Agency Followup Official (the CFO)

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Associate Administrator for Congressional and Intergovernmental Relations

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