U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities

Report No. 10-P-0066

February 17, 2010





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Abbreviations

CBI	Confidential Business Information
EPA	U.S. Environmental Protection Agency
FY	Fiscal Year
NOC	Notice of Commencement
OECA	Office of Enforcement and Compliance Assurance
OECD	Organisation for Economic Cooperation and Development
OIG	Office of Inspector General
OPPT	Office of Pollution Prevention and Toxics
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PMN	Premanufacture Notice
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act

Cover: From left to right: Toxic chemicals (photo courtesy New York State Department of Environmental Conservation); chemical testing (photo courtesy EPA); storage tanks at a chemical facility (photo courtesy U.S. Department of Homeland Security).

U.S. Environmental Protection Agency
Office of Inspector General

10-P-0066
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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We conducted this evaluation to review the U.S. Environmental Protection Agency's (EPA's) implementation of the Toxic Substances Control Act (TSCA) by determining how well EPA's processes for oversight and regulation meet the objectives of TSCA, and whether the performance measures accurately reflect EPA's assurance that the objectives of TSCA are met.

Background

EPA is responsible for ensuring that new chemicals entering commerce do not pose unreasonable risk to human health and the environment. The Office of Pollution Prevention and Toxics (OPPT) is responsible for reviewing industry submissions and managing risks from new chemicals. The Office of Enforcement and Compliance Assurance (OECA) provides assistance and monitors compliance.

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

To view the full report, click on the following link:
www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf

EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities

What We Found

EPA does not have integrated procedures and measures in place to ensure that new chemicals entering commerce do not pose an unreasonable risk to human health and the environment. We found that EPA's New Chemicals Program had limitations in three processes intended to identify and mitigate new risks – assessment, oversight, and transparency. The program is limited by an absence of test data and a reliance on modeling because TSCA does not require upfront testing as part of a Premanufacture Notice (PMN) submission. PMN submitters are required to submit health and safety data in their possession and a description of data known to or reasonably ascertainable by the submitter at the time of its submission. Nonetheless, the majority of PMN submissions do not include chemical toxicity or environmental fate data. Oversight of regulatory actions designed to reduce known risks is a low priority, and the resources allocated by EPA are not commensurate with the scope of monitoring and oversight work. In addition, EPA's procedures for handling confidential business information requests are predisposed to protect industry information rather than to provide public access to health and safety studies.

OPPT's and OECA's respective performance measures for managing risks from new chemicals do not accurately reflect program performance in preventing risk, nor do they assure compliance. In cases where full information does not exist or analyses are limited, OPPT reports the new chemicals as not having risk, while the limitations in the measure are not disclosed. OECA's performance measure is not outcome based; rather, the measure tracks program activities.

What We Recommend

We recommend that EPA better coordinate risk assessment and oversight activities by establishing a management plan that contains new goals and measures that demonstrate the results of OPPT and OECA actions. We recommend that the Office of Prevention, Pesticides, and Toxic Substances establish criteria for selecting chemicals or classes of chemicals for low-level exposure and cumulative risk assessments, and develop confidential business information classification criteria to improve EPA's transparency and information sharing. Finally, we recommend that OECA develop a management plan for Core TSCA enforcement that includes training, consistent enforcement strategies across regions for monitoring and inspection protocols, and a list of manufacturers and importers of chemicals for strategic targeting. The Agency agreed with our recommendations.

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

OFFICE OF
INSPECTOR GENERAL

February 17, 2010

MEMORANDUM

SUBJECT: EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities
Report No. 10-P-0066

FROM: Wade T. Najjum
Assistant Inspector General
Office of Program Evaluation

TO: Bob Perciasepe
Deputy Administrator

Steve Owens
Assistant Administrator for Prevention, Pesticides, and Toxic Substances

Cynthia Giles
Assistant Administrator for Enforcement and Compliance Assurance

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). 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 resolution procedures.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $786,181.

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. We have no objections to the further release of this report to the public. This report will be available at: http:www.epa.gov/oig.

If you or your staff have any questions regarding this report, please contact me at 202-566-0827 or najjum.wade@epa.gov, Jeffrey Harris at 202-566-0831 or harris.jeffrey@epa.gov, or Jill Ferguson at 202-566-2718 or ferguson.jill@epa.gov.

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Chapter 1
Introduction

Purpose

The objective of this evaluation was to assess the U.S. Environmental Protection Agency's (EPA's) implementation of the Toxic Substances Control Act (TSCA), with a focus on EPA's policies, procedures, and authority for managing risks to human health and the environment posed by new chemicals. Specifically, we sought to answer the following questions:

(1) How well do EPA processes for new chemical oversight and regulation meet the objectives of TSCA?
(2) Do the performance measures accurately reflect EPA's assurance that the objectives of TSCA are being achieved?

Background

In 1976, Congress passed the Toxic Substances Control Act to protect human health and the environment from risks associated with toxic chemicals.[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 (CBI).

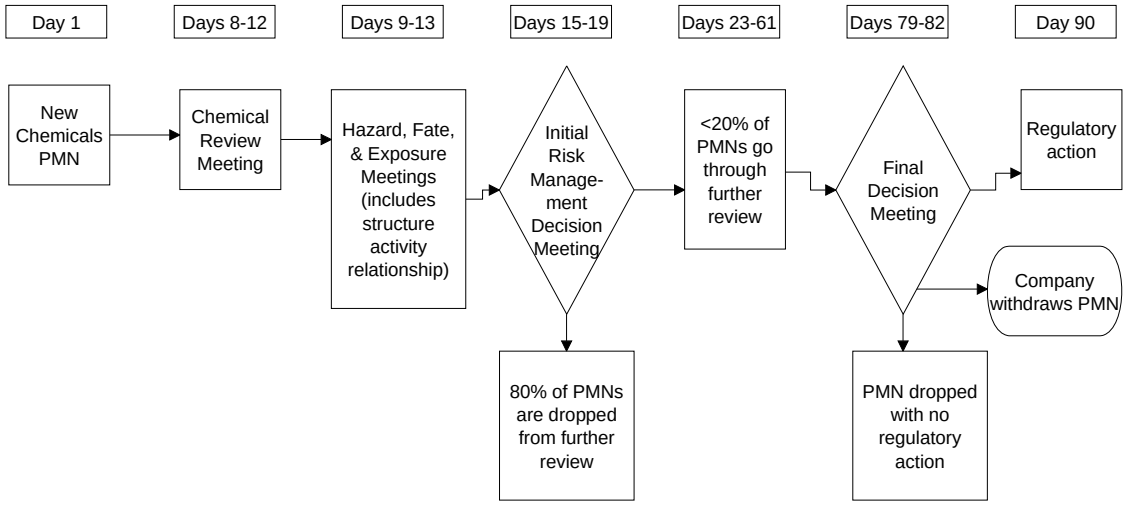
TSCA authorized EPA to identify and regulate unreasonable risks from new chemicals prior to manufacture or import. However, TSCA limits EPA's authority to require industry to conduct health and safety studies. Therefore, EPA's oversight is largely dependent on available data on comparable chemicals and any information provided by manufacturers and importers. To request additional information on chemical safety from industry, EPA must first make a determination that the chemical presents an unreasonable risk. In addition, EPA must ensure that the burden of EPA's request is commensurate with the potential harm from exposure to the new chemical. Although TSCA does not specifically authorize EPA to continually review the safety of a chemical once it enters commerce, Section 8(e) of TSCA requires producers and importers to maintain records and report to EPA any newly identified risks or harm from their chemicals – whether existing or new.

[1] TSCA excludes chemicals in pesticides, food, pharmaceuticals, tobacco, and firearms that are regulated by other statutes.

The New Chemicals Program

Manufacturers and importers must submit a Premanufacture Notice (PMN) to EPA at least 90 days prior to introducing a new chemical into commerce. EPA's multistep review process and tools to review PMNs are illustrated in Figure 1-1. Teams of EPA technical experts, including scientists, engineers, and toxicologists, use computer models to predict the potential toxic effects of a chemical based on available data. A PMN remains valid indefinitely once it has gone through the 90-day review period regardless of when (or whether) the chemical is manufactured or imported. Within 30 days of manufacture or import, a Notice of Commencement (NOC) must be submitted to EPA, at which time EPA adds the substance to the TSCA inventory.

Figure 1-1: New Chemicals Review Process

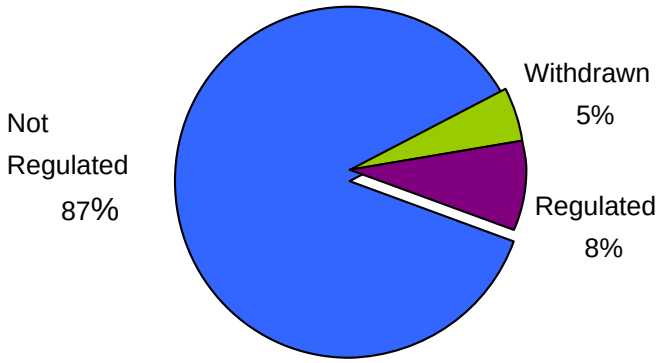


Source: EPA.

EPA can manage potential unreasonable risks found during the PMN review process through Consent Orders[2] and Significant New Use Rules (SNURs).[3] Between 1996 and 2008, EPA received approximately 1,500 PMNs annually, on average. As illustrated in Figure 1-2, on average, less than 10 percent were regulated.

[2] Through a Consent Order, EPA places certain conditions on the manufacture/import of the chemical, often including a requirement for more testing to be done on the chemical.
[3] A SNUR extends the requirements of a Consent Order to other manufacturers/importers, or puts restrictions on uses of the chemical other than those identified in the PMN. If EPA makes a determination that a chemical will cause harm to human health or environment, TSCA gives EPA authority to ban the chemical from manufacture or import.

Figure 1-2: Average Fate of PMNs Submitted to EPA



Source: EPA.

TSCA also implements the intent of Congress that health and safety studies for chemicals introduced into commerce be made available to the public. However, manufacturers and importers can request protection of CBI in health and safety studies submitted pursuant to PMN and Section 8(e) notice requirements.

Finally, TSCA directs that EPA collect a fee to defray the costs of assessing risks from new chemicals. The PMN fee is capped at $2,500 and $100 for large and small businesses, respectively. This fee cap has remained the same since TSCA was enacted in 1976. EPA began charging the fee in 1988.

EPA's Implementation and Oversight of TSCA

Two offices at EPA are primarily responsible for implementing TSCA: the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) and the Office of Enforcement and Compliance Assurance (OECA). Within OPPTS, the Office of Pollution Prevention and Toxics (OPPT) is responsible for reviewing submitter information and managing risks from new chemicals. As EPA's compliance and enforcement arm, OECA is responsible for providing assistance, monitoring, and enforcing compliance with TSCA by inspecting manufacturers and importers.

OPPT activities related to managing risk from new chemicals include:

- Developing guidance and tools for PMN submission review
- Reviewing PMNs and NOCs
- Maintaining the TSCA and CBI inventories, with periodic updates from information received under the Inventory Update Rule
- Restricting the manufacture of certain chemicals (based on results of PMN review) with Consent Orders and SNURs
- Reviewing risk information identified on Section 8(e) notices
- Making health and safety data available to the public

OECA activities related to Core TSCA[4] include providing compliance assistance and incentives as well as conducting inspections to ensure manufacturers and importers:

- submit required notices to EPA such as PMNs and NOCs,
- comply with terms of Consent Orders and SNURs,
- report any newly identified risk or harm as Section 8(e) notices,
- maintain all records of manufacturing, and adverse reactions to health or the environment by a chemical, as required by TSCA.

Noteworthy Achievements

EPA established an inventory of 62,000 existing chemicals when TSCA was enacted. Since then, EPA has added 23,000 new chemicals to the inventory. Through September 2008, EPA had regulated 1,432 chemicals by means of Consent Orders and issued a total of 1,415 SNURs. In addition, OPPT's New Chemicals Program developed and shared risk assessment models with industry.

Scope and Methodology

Our evaluation focused on EPA's strategy and processes for preventing risk from new chemicals under its Core TSCA responsibilities. Specifically, we evaluated how OPPT assesses and regulates risk from new chemicals through the PMN review process (TSCA Sections 5 and 8) and how OECA ensures compliance with Core TSCA submissions and manufacturing and importing restrictions (TSCA Sections 4, 5, 8, 12, and 13). We did not review EPA's management of risk from "existing chemicals"; however, incidental references to existing chemicals are included when relevant to the current discussion. We also reviewed EPA's policies and processes for making significant risk information from chemicals available to the public (TSCA Section 14). In addition, we reviewed the amount and history of the PMN submission fee (TSCA Section 26). We performed our evaluation between December 2008 and December 2009.

We conducted literature reviews, interviewed EPA staff and external experts, and analyzed EPA processes, measures, and data. We evaluated OPPT goals, measures, and data related to the prevention of unreasonable risk from new chemicals, as well as OECA goals, measures, and data for compliance assistance, inspections, and enforcement for regions and Headquarters. Appendix A includes a logic model we developed to identify shared or overlapping responsibilities of OPPT and OECA for managing risk from new chemicals. The logic model also shows how their activities, outputs, and outcomes contribute to the meeting of

[4] Core TSCA is the generic name for Title I that includes the major provisions of Sections 4, 5, 8, 12, and 13. TSCA consists of Title I: Control of Toxic Substance (also known as Core TSCA), and the subsequent amendments: Title II: Asbestos Hazard Emergency Response, Title III: Indoor Radon Abatement, and Title IV: Lead Exposure Reduction.

EPA's long-term goal of protecting human health and the environment from new chemical risks.

We conducted this review in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the review to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based upon our objectives.

Chapter 2
EPA Lacks a Coordinated Process for Ensuring Risk Mitigation

EPA is responsible for meeting TSCA's objective that new chemicals entering commerce do not pose an unreasonable risk to human health and the environment. However, EPA does not have integrated procedures and measures in place to ensure that it is achieving this objective. We found limitations in the three processes intended to identify and mitigate new risks – assessment, oversight, and transparency. EPA's New Chemicals Program is limited by the absence of test data and a reliance on modeling, because TSCA does not require upfront testing as part of a PMN submission. PMN submitters are required to submit health and safety data in their possession and a description of data known to or reasonably ascertainable by the submitter at the time of their submission. Nonetheless, the majority of PMN submissions do not include chemical toxicity or environmental fate data. Oversight of regulatory actions designed to reduce known risks is a low priority, and the resources allocated by EPA are not commensurate with the scope of monitoring and oversight work. Finally, EPA's procedures for handling CBI requests are predisposed to protect industry information rather than to provide public access to health and safety studies.

Limitations of Risk Assessment of New Chemicals

EPA's New Chemicals Program is limited by an absence of test data and the resulting reliance on existing information and models to overcome data gaps. To perform new chemical reviews, OPPT uses the information manufacturers submit on PMNs. According to OPPT managers, approximately 50 percent of the PMN submissions contain no test data, and close to 85 percent contain no toxicity data. In addition, only a few submissions contain environmental effects and fate data for the chemical. In the absence of test data, OPPT must rely upon expert analyses, comparisons with structurally similar chemicals, and models in order to perform its risk assessments. Specifically, reviewers utilize analog data on other PMN chemicals, Section 8(e) data, modeling tools, and/or regulatory options to support screening-level risk assessments.

External reviewers, including nongovernmental organizations, academics, and peers, have repeatedly expressed concerns that EPA's New Chemicals Review Process is limited because of its dependence on risk assessment models. As far back as 1994, a review by the Organisation for Economic Cooperation and Development (OECD) found that due to a paucity of experimental data, EPA has to rely on predictive methods that estimate the properties of a chemical.[5]

[5] Organisation for Economic Co-operation and Development, *US EPA/EC Joint Project on The Evaluation of (Quantitative) Structure Activity Relationships*, OCDE/GD(94)28, Environment Monograph No. 88, 1994.

According to the OECD report, the models in use by OPPT at the time of its review had good predictive capabilities for ecotoxicity, but had limited predictive capabilities for general systemic health effects.

More recently, Environmental Defense Fund scientists expressed concern that the models are not accurate in predicting risks from prolonged low-level exposure to chemicals. Currently, OPPT analyzes each new chemical in isolation without factoring in potential risks from multiple exposure pathways or from exposure to multiple chemicals. The National Research Council recently recommended that EPA revise its risk assessment process to assess cumulative exposure risks from multiple chemicals, because human health and environment are not exposed to one chemical at a time.[6] Additionally, pervasive CBI redactions inhibit independent peer reviews and oversight by independent and external knowledgeable parties.[7]

In order to complete PMN risk assessments, OPPT also refers to information on similar existing chemicals found in EPA's Integrated Risk Information System database. The database currently contains only 553 of the more than 80,000 chemicals in the TSCA inventory. At present, just 67 of those 553 substances have complete toxicological information.

The incomplete information available on existing chemicals further limits the amount of information upon which OPPT can assess the risk of new chemicals. Because OPPT depends on information reported by industry, it might miss chemical risks not self-disclosed by manufacturers. The models OPPT has developed are useful tools for estimating the risk of new chemicals, but are not as reliable as actual test data, particularly for some health threats.

If no potential risks are identified within the 90-day review period, the chemical may be manufactured after submitting a NOC. However, given the limitations of the review process, EPA's assurance that new chemicals or organisms introduced into commerce do not pose unreasonable risks to workers, consumers, or the environment is not supported by data or actual testing.

Limited Oversight of New and Existing Chemicals

Oversight of regulatory actions designed to reduce known chemical risks is a low priority. The resources allocated by EPA are not commensurate with the scope of monitoring and oversight work. One of OECA's responsibilities is to develop strategies, tools, and priorities to ensure compliance with Core TSCA regulations. We found that OECA's oversight of Core TSCA-regulated entities is inconsistent and presents a minimal presence. Further, OECA does not provide feedback to

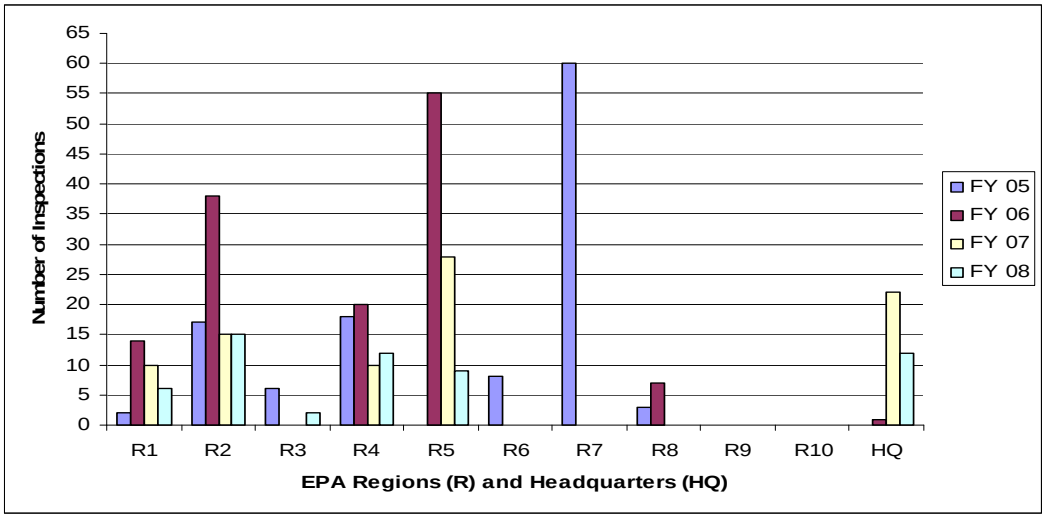
[6] Committee on the Health Risks of Phthalates, *Phthalates and Cumulative Risk Assessment: The Tasks Ahead,* National Research Council, 2008.
[7] Denison, Richard A., "Ten Essential Elements in TSCA Reform," *Environmental Law Review*, 2009.

OPPT regarding the results of its oversight activities, preventing an Agency assessment of how effectively EPA's New Chemicals Program is implemented.

Enforcement resources are not commensurate with the scope of work. The number of inspectors is declining and their allocation is not determined by potential risks. Over the course of the Core TSCA program, OECA has shifted responsibility for conducting inspections among regions; OECA headquarters; the Core TSCA Enforcement Center in Denver, Colorado; and combinations thereof. During the last resource shift in 2001, regions were offered the responsibility for ensuring compliance. Only Regions 2, 4, and 5 assumed responsibility for Core TSCA enforcement, while OECA Headquarters and the Core TSCA Enforcement Center assumed responsibility for the remaining seven regions. This dispersed responsibility has led to an inconsistent approach and process that hinders effective oversight.

EPA claims that deterrence is an essential element in its environmental compliance monitoring and enforcement program. However, only 56 Core TSCA inspections were conducted in Fiscal Year (FY) 2008 in a universe that is estimated to include hundreds of thousands of regulated entities. We found that there was minimal or no oversight in some regions (i.e., 3, 6, 8, 9, and 10). Figure 2-1 illustrates the trends in inspections from FY 2005 through FY 2008. According to Region 6 and 9 personnel, these two regions have a high concentration of chemical manufacturers and importers. Despite the large ports in Region 9 and numerous chemical manufacturers in Region 6, there are no TSCA inspectors to monitor compliance or coordinate with U.S. Customs and Border Protection inspections. Moreover, these regions are not informed of OECA inspections within their jurisdiction because OECA Headquarters staff does not coordinate inspections with these regions.

Figure 2-1: Number of Core TSCA Inspections by EPA Region and Headquarters, Fiscal Years 2005- 2008

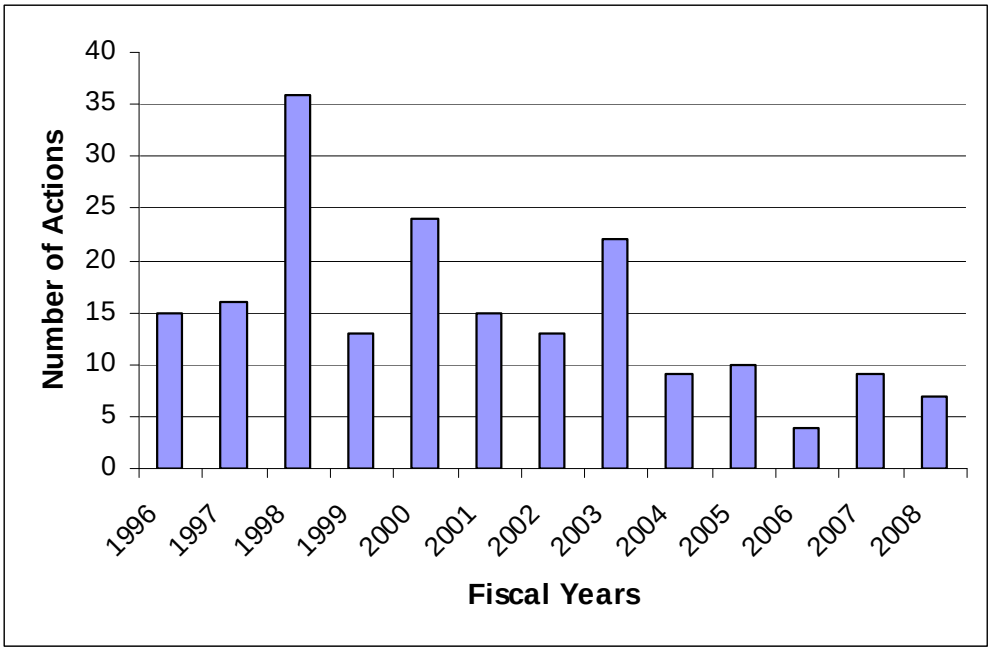


Source: OECA data.

OECA's allocation of inspection resources to Core TSCA enforcement reflects Core TSCA's low priority. Regions 2, 4, and 5 each have only one full-time equivalent employee conducting inspections. Until recently, OECA had tasked the oversight for the remaining regions to two inspectors in the Core TSCA Enforcement Center in Denver.[8] The Acting Branch Chief of OECA's Chemical Risk and Reporting Enforcement Branch explained that it is difficult to compete for EPA enforcement resources when other programs assess $10 million fines. OECA prioritizes EPA enforcement actions by outputs that will result in the highest fines rather than those that will reduce the most risk or exposure. Core TSCA's low fines make TSCA a low priority among the statutes EPA enforces. Additionally, Core TSCA enforcement actions have decreased in the past 5 years (FY 2004 to 2008), and the total number of Core TSCA inspections conducted declined from FY 2005 to 2008 nationwide, from 114 inspections to 56.

Figure 2-2 illustrates the variation and decline in Core TSCA enforcement actions. Between 1996 and 2008, a total of 193 Administrative Actions were completed for the Core TSCA violations identified. Regions 2, 4, and 5 (the three regions maintaining a Core TSCA enforcement presence) were responsible for over 50 percent of the penalties administered.

Figure 2-2: Core TSCA Enforcement Actions, Fiscal Years 1996-2008



Source: OECA data.

Finally, OECA's oversight of TSCA is hindered by an incomplete knowledge of the universe of manufactures and importers. With a lack of knowledge of the Core TSCA universe and low-level, geographically limited monitoring, OECA

[8] Core TSCA oversight responsibilities are being centralized in Headquarters and the inspections previously conducted by OECA staff in Denver will be conducted by OECA contractors out of Washington, DC.

cannot measure the impacts of its activities. OECA personnel we interviewed stated that the number of manufacturers and importers subject to Core TSCA regulations is large, but a complete list has not been identified as required.[9] Neither OECA nor the regional inspectors were able to provide us with the size of their regulated universe. However, both stated that the mix of the universe has changed and continues to change every year. They stated that the number of chemical manufacturers within the United States has decreased, while the number of importers has been increasing. This trend is a concern because inspectors believe that importers are at a higher risk of noncompliance.

Lack of Systematic Collaboration between OECA and OPPT

EPA implements TSCA through OPPT regulating risk from new chemicals entering commerce, and OECA monitoring industry for compliance with Core TSCA requirements and EPA regulatory actions. Although these activities are interconnected, EPA does not have an effective system in place requiring information sharing between the two activities. In addition, TSCA is not a shared priority between these two EPA programs. As a result, the two offices operate independently, each focusing its efforts only on the scope of work for which it is directly accountable.

OECA depends on timely and current information from OPPT to effectively execute its monitoring and oversight activities. Specifically, OECA needs information from OPPT databases on PMNs, NOCs, and Section 8(e) notices. In return, OPPT needs OECA to ascertain that manufacturers and importers submit PMNs and NOCs for each new chemical that enters commerce. In addition, OPPT depends on OECA inspections to (1) ensure that the manufacturers and importers submit all studies and information that identify new risks from chemicals, and (2) provide assurance that industry complies with Consent Orders and SNURs. However, in examining the TSCA implementation process in its entirety, we found a lack of systematic and timely communication between OPPT and OECA. Some examples include:

- According to EPA's regional inspectors, as of May 2009, their scheduled monthly conference calls with OPPT and OECA had not been held in 5 months.
- As of May 2009, OPPT had not provided regional inspectors with the current data that industry periodically submits to EPA in accordance with the 2006 TSCA Inventory Update.
- Inspectors reported that poor information sharing between OPPT, OECA, and regions was inhibiting the ability of inspectors to know their universe and select targets.
- Because of the minimal presence of OECA's Core TSCA activities, OPPT does not receive convincing feedback on industry's level of

[9] *OECA's Operations Manual for the Core TSCA Compliance and Enforcement Program*, February 2003.

compliance with their regulated actions, nor on whether industry is providing all required studies and risk information to OPPT.

The lack of collaboration between OECA and OPPT results in an uneven emphasis placed on the screening and regulation of new chemicals, with minimal follow-up and compliance assurance. The success of the New Chemicals Program depends on comprehensive screening, regulating when there is potential risk through regulatory actions (Consent Orders, SNURs, and/or bans), and support by vigilant and frequent monitoring of the regulated entities. However, EPA does not have effective guidance or a plan for shared priorities and accountabilities between OPPT and OECA.

Public Access to Health and Safety Data Not Assured

Another objective of TSCA is for chemical health and safety data to be made available to the public. However, we found that EPA's current process for handling CBI requests is weighted toward the protection of industry information rather than public access. Current CBI procedures, based on the TSCA statute, also do not allow EPA to discuss CBI with other countries such as Canada or the European Union unless companies provide permission to do so. TSCA provides protection for data that reveal the manufacturing processes of a chemical or mixture, and data that reveal the composition of a mixture. According to OPPT's Chief of TSCA Security Staff, companies are required to address a series of substantiation questions when requesting confidentiality for information submitted under TSCA. The CBI requests granted by EPA apply to information including the chemical manufacturer, chemical name, facility location, and quantity of chemical produced. When such basic information is assigned permanent CBI protection, the public cannot be fully informed about the health and safety data. The health and safety data are of limited value, for example, if the chemical the data pertain to is unknown. An increased disclosure of health and safety data would also provide academia and researchers information on risk data that could be used for further independent studies and external oversight.

The OPPT Chief of TSCA Security Staff estimated manufacturers and importers are sending a large percentage of submissions with requests for CBI protection (as high as 90 percent of PMNs and 50 percent of Section 8(e) notices). Despite the intention of TSCA to provide access to health and safety data, OPPT does not conduct any systematic verification or validation of the requests, instead deferring to the submitter's determination. EPA administratively tracks the presence or absence of CBI requests but does not comprehensively assess the merit of the claims. In some cases, the information claimed as CBI is publicly available through the manufacturer's advertising materials or even other EPA databases.

Furthermore, the current procedures for submitting PMNs and Section 8(e) notices allow manufacturers and importers to make the determination with regard to the length of time they would like CBI protection. Commonly, CBI

designations have no expiration date. Since there is no systematic verification or validation done for CBI requests, CBI protection on information in health and safety studies can potentially remain in effect indefinitely and, in some cases, incorrectly. For example, after a recent review of TSCA Inventory Update submissions (some dating back to 1998), EPA announced it will release information on 530 chemicals after finding that, without requests from submitters, it had needlessly provided confidential treatment for the chemical's health and safety data.

In addition to limiting public access, information sharing across EPA offices is often constrained by the TSCA CBI protections. Hard copies of CBI documents are housed at the CBI Center at EPA Headquarters. Some CBI information is available on OPPT's CBI Local Area Network, but it is only accessible to staff that deal directly with the PMN and Section 8(e) notice reviews. Sharing CBI with other EPA staff is a time- and labor-intensive process, because CBI must be handled in a secured manner in accordance with the TSCA CBI Protection Manual. Despite other national security clearance procedures, only individuals who have undergone CBI security training and have been granted clearance from OPPT may access CBI.

PMN Fees Do Not Defray EPA's Costs

TSCA authorizes EPA to charge a fee to businesses submitting a PMN application. The fee is intended to defray the cost of EPA's review under the New Chemicals Program. Currently, the fees collected from manufacturers and importers do not reflect actual costs. In 1988, the fee rule went into effect at $2,500 maximum, and it remains unchanged. For the past 5 years, fees collected by EPA for PMN reviews have amounted to approximately 11 percent of its costs (Table 2-1). Moreover, the monies collected are not directly used to fund EPA's review. Collected fees are deposited into the general Treasury and are not directed to the review program or even EPA.

Table 2-1: PMN Program Budget and Fees, Fiscal Years 2004-2008

	FY2004	FY2005	FY2006	FY2007	FY2008
PMN Budget	$12,166,700	$12,435,700	12,879,200	12,416,400	12,654,300
Fees Collected	$1,300,000	$1,390,000	$1,360,000	$1,290,000	$1,320,000
Percent Defrayed	10.7	11.2	10.6	10.4	10.4

Source: EPA.

Every year since FY 2001, EPA has sought permission to lift the maximum fee amount, but Congress has not approved an increase. The 2010 President's Budget proposes to eliminate the $2,500 cap on the fee, which EPA estimates would bring in an additional $4 million. An elimination of the fee cap would defray about 40 percent of the review cost. This proposal is consistent with government-

wide efforts to appropriately align program costs to those who benefit directly from such services. Of note is that EPA initially drafted a proposal to raise the cap to $12,500, not eliminate it completely. Also not mentioned in the published budget is the EPA proposal to establish a separate account within the Treasury for the PMN fees collected. This account would be accessible to the review program to defray review costs, and would be in line with the statute's intent.

Measures Do Not Reflect Performance

TSCA performance measures for prevention and compliance are deficient. OPPT's and OECA's respective performance measures for managing risks from new chemicals do not accurately reflect program performance in preventing risk or in assuring compliance. In cases where full information does not exist or analyses are limited, OPPT reports the new chemicals as not having risk, while the limitations in the measure are not disclosed. OECA's performance measure is not outcome based; rather, the measure tracks program activities.

Assurance of Protection from New Chemicals Overstated

Performance Measure: ***Percentage of new chemicals or organisms introduced into commerce that do not pose unreasonable risks to workers, consumers, or the environment.*** Target: 100 percent

EPA's New Chemicals Program seeks to prevent any new chemical from entering into commerce that poses an unreasonable risk. EPA's assessment of whether this objective has been met is based on self-disclosures from chemical manufactures and importers. OPPT's performance measure is calculated by comparing the risks identified on Section 8(e) notices received in the fiscal year to previously reviewed PMNs. The intent of the comparison is to measure present-day performance of the PMN review process. The question answered during the calculation of the measure is "what would the program conclude if it received the same chemical information [submitted and reviewed as a PMN] today?" If the risk identified in a Section 8(e) notice would not be correctly identified and mitigated by the review, then according to OPPT, it has failed to meet its target percentage. For FY 2005 and FY 2006, OPPT reported to Congress and the public that 100 percent of chemicals introduced into commerce did not pose any unreasonable risks. In FY 2007, it identified one failure resulting in a report of 96 percent success.

EPA receives approximately 300 Section 8(e) notices annually. Of those 300, approximately 30 are applicable to chemicals that had undergone the PMN review process. The applicable Section 8(e) notices may relate to chemicals that underwent PMN review as many as 20 years ago. Therefore, the notices do not necessarily relate to chemicals being introduced into commerce in the current year. While industry is required to submit these notices for any potentially unreasonable risks identified, industry is not required to conduct any regular

testing. Moreover, the measure does not include risks identified in scientific studies conducted by other organizations or through EPA's own data collection efforts; information from these sources is not required to be submitted through Section 8(e) notices.

Due to the allocation of limited resources to oversight activities, as discussed in the oversight limitations section of this report, EPA does not have assurance that industry submits all Section 8(e) notices for identified risks. One such example is the Agency's settlement with E. I. du Pont Nemours in 2005 resulting in a $10.5 million penalty – the largest EPA settlement under the TSCA statute. EPA's monitoring did not uncover the industry failure to inform EPA of newly identified risk. Rather, an attorney working on a class action suit on behalf of the citizens of Ohio and West Virginia brought this information to EPA in 2001. EPA issued a press release on July 8, 2004, and announced that OECA filed an administrative action against the company for two violations of TSCA Section 8(e). The press release stated, "The violations consist of multiple failures to report information to EPA about substantial risk of injury to human health or the environment from a chemical during a period beginning in June 1981 through March of 2001."

OECA inspectors emphasize assistance and oversight of smaller establishments, unlike DuPont, with the assumption that the larger companies are more likely to be cognizant of the regulations and more capable and inclined to comply.

Core TSCA OECA Performance Measures

In EPA's annual reports, OECA reported the number of inspections conducted, violations found, and fines issued for Core TSCA as results of performance rather than the amount of risk prevented or compliance assured. OECA does not report any other performance measure for Core TSCA.

OECA reports the number of inspections conducted as a measure of compliance success. This measurement method is insufficient for several reasons. First, it does not demonstrate that OECA's monitoring and enforcement activities are helping EPA prevent risk from toxic chemicals. Second, TSCA inspections are few in number compared with the estimated size of the universe of manufacturers and importers. Third, inspections are not strategically selected to cover a meaningful cross-section of the universe, and OECA has not provided a consistent targeting scheme to be used across regions.

Conclusions

EPA lacks a coordinated process for ensuring risk mitigation from new chemicals. OPPT and OECA need a coordinated, consistent, and strategically designed approach to Core TSCA implementation and enforcement. EPA cannot provide assurance that that all risks from new chemicals are regulated and that

the restrictions are followed by industry. While OPPT invests many resources in the review and regulation of new chemicals, OECA views TSCA as a low enforcement priority. Lack of consistency in procedures for information and priority sharing between OPPT, OECA, and regions has reduced effectiveness and efficiency by limiting access to necessary shared information. OECA has not instituted a nationwide strategy to maximize compliance assurance in a way that effectively uses its limited resources. Further, the lack of a collective EPA strategy for Core TSCA oversight and regulation can result in less effective risk mitigation and reduced public confidence.

Recommendations

We recommend that the Deputy Administrator:

2-1 Link the execution of OPPT's New Chemicals Program with OECA's Core TSCA program, establishing areas of mutual responsibility for managing new chemical risks.

2-2 Link the TSCA goals of OPPT and OECA and devise performance measures that ensure accountability of each office, while demonstrating EPA's overall assurance of meeting the objectives of TSCA.

2-3 Request statutory authority to increase PMN fees to recover PMN review costs with justification for lifting the fee cap without a new fee limit, or to establish a new fee limit to defray the review costs.

We recommend that the Assistant Administrator for Prevention, Pesticides, and Toxic Substances:

2-4 Establish criteria and procedures outlining what chemicals or classes of chemicals will undergo risk assessments for low-level and cumulative exposure. Periodically update and revise risk assessment tools and models with latest research and technology developments.

2-5 Develop a more detailed TSCA CBI classification guide that provides criteria for approving CBI coverage and establishes a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals.

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance:

2-6 Develop a management plan for Core TSCA enforcement and compliance processes, including:
   a. Regularly scheduled Core TSCA education and training of OECA and OPPT personnel.

b. Consistent enforcement strategies across regions for monitoring and inspection protocols.
c. Periodic assessment and evaluations of techniques and strategies employed.

2-7 Ensure the planned enforcement strategies meet the objectives of TSCA while maximizing resources across regions and leveraging input from OPPT technical experts.

2-8 Develop a methodology to create and periodically update a list of known regulated entities. For unknown regulated entities or nonfilers, develop a profile of entities of interest for use by inspectors, as well as OPPT personnel.

Agency Comments and OIG Evaluation

The Agency concurred with our recommendations and agreed to implement them. It stated that TSCA authority is outdated and does not provide EPA with the tools to adequately protect human health and the environment. In September 2009, the Administrator announced a set of core principles to strengthen U.S. chemical management laws and in January 2010, listed, "assuring the safety of chemicals" as one of seven EPA priorities. The Agency commented that legislative reform of TSCA may take time and it will utilize its current authority to the fullest extent in the meantime.

Our recommendations are intended to result in more effective coordination of risk assessment, oversight, and enforcement activities for TSCA-regulated chemicals. In addition, the Agency's overall assurance of meeting the objective and intent of TSCA should be more accurately reflected in performance measures and public reports. The Agency has already started to take actions that will address our recommendations and there is potential to integrate new tools and authorities as they become available. The recommendations are open pending completion of corrective actions.

The Agency's complete response is included in Appendix B.

Status of Recommendations and Potential Monetary Benefits

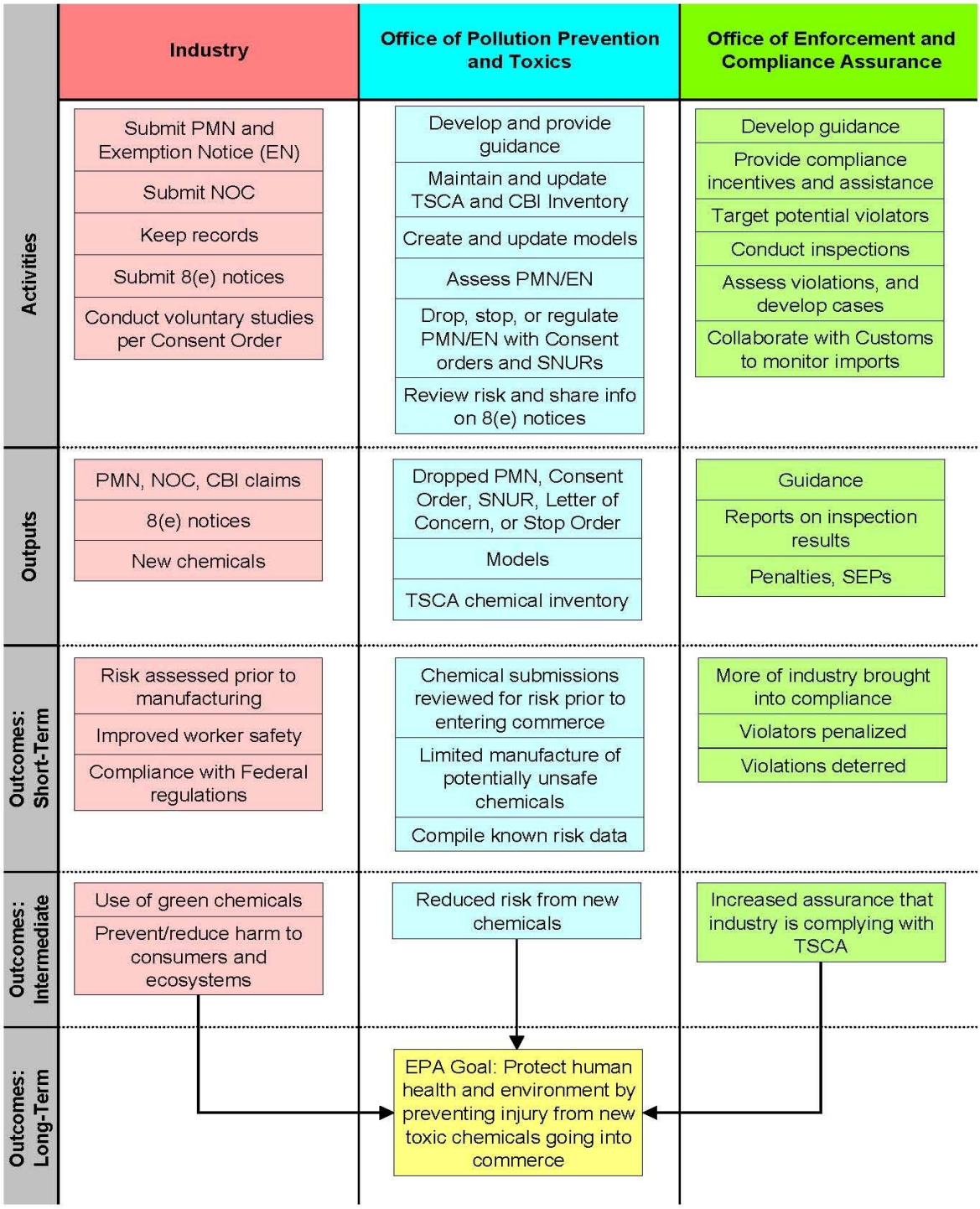
RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
2-1	15	Link the execution of OPPT's New Chemicals Program with OECA's Core TSCA program, establishing areas of mutual responsibility for managing new chemical risks.	O	Deputy Administrator			
2-2	15	Link the TSCA goals of OPPT and OECA and devise performance measures that ensure accountability of each office, while demonstrating EPA's overall assurance of meeting the objectives of TSCA.	O	Deputy Administrator			
2-3	15	Request statutory authority to increase PMN fees to recover PMN review costs with justification for lifting the fee cap without a new fee limit, or to establish a new fee limit to defray the review costs.	O	Deputy Administrator			
2-4	15	Establish criteria and procedures outlining what chemicals or classes of chemicals will undergo risk assessments for low-level and cumulative exposure. Periodically update and revise risk assessment tools and models with latest research and technology developments.	O	Assistant Administrator for Prevention, Pesticides, and Toxic Substances			
2-5	15	Develop a more detailed TSCA CBI classification guide that provides criteria for approving CBI coverage and establishes a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals.	O	Assistant Administrator for Prevention, Pesticides, and Toxic Substances			
2-6	15	Develop a management plan for Core TSCA enforcement and compliance processes, including: a. Regularly scheduled Core TSCA education and training of OECA and OPPT personnel. b. Consistent enforcement strategies across regions for monitoring and inspection protocols. c. Periodic assessment and evaluations of techniques and strategies employed.	O	Assistant Administrator for Enforcement and Compliance Assurance			
2-7	16	Ensure the planned enforcement strategies meet the objectives of TSCA while maximizing resources across regions and leveraging input from OPPT technical experts.	O	Assistant Administrator for Enforcement and Compliance Assurance			
2-8	16	Develop a methodology to create and periodically update a list of known regulated entities. For unknown regulated entities or nonfilers, develop a profile of entities of interest for use by inspectors, as well as OPPT personnel.	O	Assistant Administrator for Enforcement and Compliance Assurance			

[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

Appendix A

New Chemicals Program Logic Model

This conceptual logic model for the New Chemicals Program illustrates the interrelated responsibilities among industry, OPPT, and OECA in meeting TSCA objectives. The logic model shows how the coordinated long-term outcomes of the three can contribute to the meeting of EPA's long-term goal.



Source: OIG analysis.

Appendix B

Agency Comments on Draft Report

(Received on January 15, 2010)

MEMORANDUM

SUBJECT: Draft Evaluation Report: EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities

FROM: Bob Perciaseppe
Deputy Administrator

TO: Jeffrey Harris
Director for Program Evaluation, Cross-Media Issues

Thank you for providing the opportunity to review the draft evaluation report: EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities. We appreciate and concur with OIG's recommendations. This memorandum includes the corrective actions the Agency commits to take in response to the recommendations, as well as planned completion dates for each action.

We note that OIG acknowledged in their report the limitations regarding the Agency's authority to regulate chemicals under the Toxic Substances Control Act (TSCA). It is true that TSCA authority is outdated and does not provide the tools to adequately protect human health and the environment as the American people expect, demand and deserve. As stated by Administrator Lisa Jackson in her testimony before the U.S. Senate Committee on Environment and Public Works about chemical management reform, the time has come to bring TSCA into the 21st century.

TSCA was signed into law in 1976 and was intended to provide protection of health and the environment against risks posed by chemicals in commerce. However, when TSCA was enacted, it authorized manufacture and use, without any evaluation, of all chemicals that were produced for commercial purposes in 1976 or earlier years. Thus, manufacturers of these "grandfathered" chemicals were not required to develop and produce data on toxicity and exposure that are needed to properly and fully assess potential risks. Further compounding this problem, the statute never provided adequate authority for EPA to evaluate existing chemicals as new concerns arose or as new scientific information became available.

TSCA does provide some authority to EPA to mandate industry to conduct testing, but even in these cases it has taken years to obtain data and information. As a result, there are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. As OIG's report acknowledges, TSCA also does not place any legal obligation on producers to conduct testing on new chemicals being introduced into commerce. They are required only to supply existing data to EPA and are not required to provide all the data

necessary to fully assess a chemical's risks. The Agency should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that is relevant to determining the safety of chemicals, without delays and obstacles currently in place, or excessive claims of confidential business information. All of this must happen with transparency and concern for the public's right to know.

In addition, we believe it is also important to evaluate TSCA enforcement with a clear understanding of the statutory and regulatory framework. Enforcement of Core TSCA is critical to ensuring environmental protection, but TSCA lacks the broad information-gathering and enforcement provisions equivalent to other major environmental protection statutes. For example, TSCA lacks the administrative authority to seek injunctive relief, issue administrative orders, collect samples, and quarantine and release chemical stocks, among other key authorities.

For these reasons and others, there is a compelling case that TSCA must be updated and strengthened. The following are the Administration's core principles to strengthen U.S. chemical management laws as announced by Administrator Jackson on September 29, 2009:

- 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.
- 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.
- Risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations.
- Manufacturers and EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
- Green chemistry should be encouraged and provisions assuring transparency and public access to information should be strengthened.
- EPA should be given a sustained source of funding for implementation.

Because legislative reform may take time, the Agency will utilize the current authority under TSCA to the fullest extent to protect the American people and the environment from dangerous chemicals. The recommendations contained in your report are consistent with the Agency's approach to effectively manage chemicals and we accept them. In accordance with EPA Manual 2750, below are responses for each recommendation contained in the OIG report.

Response to Specific Recommendations

The report recommends that the Deputy Administrator:

2-1 Link the execution of OPPT's New Chemicals Program with OECA's Core TSCA program, establishing areas of mutual responsibility for managing new chemical risks.

The Agency accepts this recommendation. OPPTS and OECA share responsibility for managing chemical risks and have already implemented several activities to ensure better communication and coordination. Specifically, senior managers of OPPT and OECA began discussions in the summer of 2009 regarding fostering better coordination across all TSCA enforcement and programmatic activities (including the New Chemicals Program). At the senior leader level, the two offices agreed to conduct formal quarterly meetings between the Assistant Administrators for OPPTS and OECA; the first two such meetings occurred in October and December 2009. The Assistant Administrators for OPPTS and OECA have continued to meet on several occasions to discuss TSCA enforcement matters.

Additionally, OPPTS and OECA conducted a national meeting in October with the Regions to discuss how to better coordinate our mutual responsibilities and to help identify priorities for 2011. Finally, OPPTS and OECA have also begun development of a document that enhances collaboration between the two offices and establishes clear areas of responsibility. The document is intended to provide structure for collaboration between the two offices to maximize the efforts to achieve the shared strategic goals of protecting public health and the environment by reducing risks. The target date for finalizing the document is June 30, 2010. Finally, at the staff level, greater collaboration between the offices is already taking place in the area of sharing information and developing focus areas. One example of this collaboration is an agreement to initiate a joint project in the 2nd quarter of FY 2010 to develop the criteria and supporting data needed to target for compliance inspection certain regulated facilities subject to New Chemical Significant New Use Rules (SNURs) and Low Volume Exemptions.

2-2 Link the TSCA goals of OPPT and OECA and devise performance measures that ensure accountability of each office, while demonstrating EPA's overall assurance of meeting the objectives of TSCA.

The Agency accepts this recommendation to devise related measures that ensure accountability yet reflect the separate functions of each office. As a first step, OPPTS and OECA will coordinate in the development of their respective National Program Managers (NPM) guidance. The NPM guidance establishes programmatic priorities and implementation strategies for the respective offices. An integral part of the NPM process is the development of the Annual Commitment System (ACS) accomplishments. The ACS is the central repository of Agency performance measurements. OPPTS and OECA will work to coordinate performance measures in the 2011 NPM and ACS processes. The draft NPM guidance is due to OCFO by February 12, 2010, the final guidance will be issued by OCFO on April 23, 2010 and full implementation will begin on October 1, 2010.

2-3 Request statutory authority to increase PMN fees to recover PMN review costs with justification for lifting the fee cap without a fee limit, or to establish a new fee limit to defray the review costs.

The Agency accepts this recommendation and has already taken steps to address the issue. In fact, the Agency has included in its President's Budget submissions since 1999 language to increase the PMN fees. Note that the U.S. Department of the Treasury collects the fees for the PMN program; they are not received by the Office of Prevention, Pesticides and Toxic Substances to recover PMN review costs. Moreover, as discussion of TSCA reform continues, we would like to highlight Administrator Jackson's core principal of giving EPA a sustained source of funding for implementation.

We recommend that the Assistant Administrator for Prevention, Pesticides and Toxic Substances (OPPTS):

2-4 Establish criteria and procedures outlining what chemicals or classes of chemicals will undergo risk assessments for low-level and cumulative exposure. Periodically update and revise risk assessment tools and models with latest research and technology developments.

OPPTS agrees with this recommendation, and recognizes the need to conduct cumulative risk assessments where appropriate. Such an assessment requires an understanding of the mode of action of the chemical or class of chemicals, and an understanding of common exposure pathways. Developing a better understanding of cumulative risk is a high priority of the Agency's science agenda. Under the authorities currently granted by TSCA, this level of understanding is not generally available for most PMNs in the New Chemicals Program. However, this information is available for some classes of chemicals in the Existing Chemicals Program; assessments of these chemical classes can inform the New Chemicals program when PMNs for similar chemicals are submitted. As stated in Administrator Jackson's principles for TSCA Reform, 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.

To this end, OPPT is initiating cumulative assessments of eight phthalates as outlined in the Action Plan release on December 30, 2009. EPA intends to lay the groundwork to consider initiating rulemaking under TSCA Section 6(a) to regulate the eight phthalates in 2012. In preparation for the rulemaking, EPA intends, in cooperation with the U.S. Consumer Product Safety Commission (CPSC) and the U.S. Food and Drug Administration (FDA), to continue to work to fully assess the use, exposure and substitutes for these chemicals. In its further review, EPA plans to consider the future results of the cumulative assessment that will be developed by the CPSC. The cumulative assessment approach under development by CPSC, which may be completed in 2012, as well as the ongoing review of phthalates at the FDA and the assessment for EPA's IRIS program, are due to be completed in 2012.

In addition, with regard to the recommendation that the Office periodically update and revise risk assessment tools and models with latest research and technology developments, OPPTS agrees with this recommendation, and, in fact, does this on a routine basis. OPPT will report on progress on November 1, 2010.

2-5 Develop a more detailed CBI classification guide that provides criteria for approving CBI coverage and establishes a time limit for all CBI requests to allow for eventual public access to health and safety data for chemicals.

OPPTS accepts this recommendation. As stated in one of the Administration's core principles for TSCA reform, public access to information should be strengthened. The Agency is committed to transparency and believes that the public right to know about the hazards of chemicals is integral to sound chemical management practices. Since the summer of 2009, OPPTS has been making important strides in this area. In July 2009, OPPTS published notice that the Agency was shifting 530 chemicals from the non-public to the public portion of the TSCA Inventory. Another example is the new initiative to addess CBI claims in TSCA Notices of Substantial Risk (TSCA Section 8(e) filings). In early 2010 OPPTS will publish a Federal Register Notice that will inform chemical companies that they may not claim chemical identify as CBI in an 8(e) submission when the substance is listed on the public portion of the TSCA inventory. These efforts and others will be part of a multi-faceted approach, which will include periodic but systematic review of CBI claims made in TSCA filings classified as containing health and safety data.

It should be noted, the criteria for making CBI claims for TSCA are located generally at 40 CFR 2.208 and 2.306 but there are also TSCA rule specific regulations that provide criteria as well.

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance (OECA):

2-6 Develop a management plan for Core TSCA enforcement and compliance processes including:

- **a. Regularly scheduled Core TSCA education and training of OECA and OPPT personnel.**
- **b. Consistent enforcement strategies across regions for monitoring and inspection protocols.**
- **c. Periodic assessment and evaluation of techniques and strategies employed.**

The Agency concurs with the recommendation that a plan be developed that includes training and education as well as the development of consistent national enforcement strategies and periodic assessment. We have made significant progress to address this recommendation. Specifically, OECA is working with OPPTS and the Regions to develop a TSCA Compliance Monitoring Strategy (CMS). The CMS is a plan to maximize available resources and develop consistent enforcement strategies across all of TSCA. A draft CMS document has been developed and is currently being reviewed by a Headquarters and Regional workgroup. Because the CMS covers all of TSCA and not

just the sections reviewed by the OIG, it is anticipated that drafting of the CMS will continue through the spring of 2010.

OECA is also currently revising the February 2003 Core TSCA Operations Manual and Inspection Manual to ensure the most current techniques and approaches are used to meet the objectives of TSCA. A regional workgroup is currently reviewing the first draft of both the operations and inspection manuals and comments are due to OECA by January 29, 2010.

Also, OECA will work with OPPTS to explore the development of a Core TSCA national meeting beginning in FY2011. The purpose of this meeting will be to provide training on current inspection and enforcement techniques as well as highlight best practices.

2-7 Ensure the planned enforcement strategies meet the objectives of TSCA while maximizing resources across regions and leveraging input from OPPT technical experts.

The Agency concurs with the recommendation that enforcement strategies align with the objectives of TSCA, that we maximize resources and leverage input from OPPT. OECA and OPPTS believe that quarterly meetings at the Assistant Administrator level, a coordinated NPM and ACS process, a CMS and revised operations and inspection manuals will address the concerns identified in this recommendation. Specific actions and dates are included in other responses to recommendations found in this document.

2-8 Develop a methodology to create and periodically update a list of known regulated entities. For unknown regulated entities or nonfilers, develop a profile of entities of interest for use by inspectors, as well as OPPT personnel.

The Agency concurs with the recommendation and agrees that enforcement could be enhanced with a targeted list of facilities. It is important to note that neither the TSCA statute nor the regulations require companies to notify EPA they are in the business of manufacturing, importing, or using chemicals. By introducing a new chemical into commerce, any facility could become newly regulated. As a consequence, OECA and OPPTS do not have complete and accurate information on the universe of regulated entities. However, OPPTS has recently made significant progress in integrating regulatory data systems and by early 2010 will integrate over 6,300 TSCA facility records with EPA's facility registry system (FRS). As more of the Agency's data systems become integrated, EPA's ability to define the universe will steadily improve. Finally, OPPTS and OECA will work together to identify a profile of potential targets within the universe of regulated entities in the revision to the Core TSCA Operations Manual.

Again, we appreciate the opportunity to review and comment on this draft report. Should you have any questions or concerns regarding this response, please contact Megan Carroll in OPPTS at 202-564-2814 or Rosemarie Kelley in OECA at 202-564-4014.

Appendix C

Distribution

Office of the Administrator
Deputy Administrator
Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances
Assistant Administrator, Office of Enforcement and Compliance Assurance
Agency Follow-up Official (the CFO)
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General Counsel
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Audit Follow-up Coordinator, Office of Enforcement and Compliance Assurance
Acting Inspector General