United States Environmental Protection Agency | Office of Enforcement and Compliance Assurance (2201A) | EPA 325-F-08-002

Enforcement Alert

Volume 9, Number 4 | Office of Civil Enforcement | August 2008

Failure to Report Chemical Risks Can Result in Major Fines

Section 8(e) of the Toxic Substances Control Act

Those who manufacture, import, process or distribute chemical substances or chemical mixtures have a clear duty to notify the United States Environmental Protection Agency (EPA) when they obtain any information that their chemical substances or chemical mixtures present a substantial risk to public health or the environment.

Failure to timely report this critical information is a serious violation of the law because it prevents EPA from determining what actions may be necessary to understand and manage these potential risks. Penalties imposed for failing to report can be significant, up to $32,500 a day for each violation.

Effective management of potential risks to public health and the environment from chemical substances and chemical mixtures is tied to reporting requirements in the Toxic Substance Control Act (TSCA). Section 8(e) of TSCA is particularly important: essentially, it establishes an early warning system to immediately inform EPA and the public of possible risks associated with chemicals. Health concerns can include cancer, birth defects or serious impairment of normal activities.

Enforcement of Section 8(e)

EPA takes enforcement of Section 8(e) requirements seriously, as exemplified by the settlement between the Agency and E.I. DuPont de Nemours and Company (DuPont). The company paid a $10.25 million penalty, the largest administrative penalty in EPA's history, for failing to report risk information regarding the synthetic chemical substance perfluorooctanoic acid (PFOA) and related perfluorochemicals. The case underscores the importance of prompt reporting of Section 8(e) substantial risk information. PFOA has caused developmental and other adverse effects in laboratory animals.

Public health and environmental protections rely on timely reporting of substantial risk information.

The information withheld by DuPont demonstrated placental transfer of PFOA from human mothers to their babies during pregnancy, and the levels of PFOA found in a newborn and a two-year old. As a result of this and other information, EPA is investigating the effects of human exposure to PFOA and related perfluorochemicals. Although our investigation is on-going, EPA has sought voluntary commitments and taken regulatory chemical management activities intended to reduce release of, and exposure to, these chemicals while the Agency's assessment process is underway.

The E. I. du Pont de Nemours and Company Settlement

PFOA is used in the manufacture of fluoropolymers, which impart desirable properties such as oil, stain, grease and water repellency, and fire resistance. Fluoropolymers are used to provide non-stick surfaces on cookware, including some Teflon® products, and to create waterproof, breathable membranes for clothing. The chemicals are very persistent in the environment.

DuPont obtained information regarding substantial health risks posed by PFOA at its Washington Works Plant in Wood County, West Virginia, in connection with its use in the manufacture of fluoropolymers.

DuPont observed PFOA in blood samples taken from pregnant workers at the Washington Works facility and found at least one woman had transferred the chemical to her fetus.

DuPont also detected the chemical in drinking water supplies in West Virginia and Ohio communities near the facility, and knew that PFOA was in these water supplies at a greater level than the company's guidelines indicated would be without any effect on people. DuPont also had information regarding blood levels of PFOA in individuals living near the Washington Works Plant.

EPA discovered that the company had obtained substantial risk information showing three other perfluorinated chemical substances to be highly toxic when inhaled. The Agency learned of this information from a third party.

In its administrative complaint, EPA alleged that DuPont violated Section 8(e) for failing to report information it had obtained. In settlement, DuPont paid the record-setting penalty and agreed to come into compliance with the law. The company also agreed to undertake two Supplemental Environmental Projects, worth $6.25 million, aimed at protecting and enhancing public health and the environment.

Under one of the Supplemental Environmental Projects, DuPont is investigating the potential of nine of the company's fluorotelomer-based products to break down and form PFOA. The information developed should help industry, scientists, the public and EPA examine possible sources of PFOA in the environment and routes of human exposure to the chemical. In the second project, DuPont is fostering science laboratory curriculum changes in Wood County schools to reduce risk to children's health through exposure chemicals and enhance use of safer chemicals.

Fluoropolymers, created from PFOA, have thousands of important manufacturing and industrial uses. These products are not themselves PFOA. EPA has no information that routine use of household or other products using fluoropolymers, such as non-stick cookware or all weather clothing, poses a concern. For further information, see: http://www.epa.gov/opptintr/pfoa/ pubs/pfoainfo.htm

The Value of Voluntary Compliance

EPA also seeks to bring companies into compliance with Section 8(e) through self-audits of their reporting practices, immediate disclosure to EPA of any Section 8(e) violations found and correction of its violations. An audit agreement with EPA assists companies that either suspect or do not know whether they are in violation of federal law. In the context of Section 8(e), this tool helps ensure that EPA receives all substantial risk information obtained by a company, regardless of prior failures to timely submit it.

EPA's Audit Policy, formally titled "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations," safeguards human health and the environment by providing several major incentives for regulated entities to voluntarily come into compliance with federal environmental laws and regulations. The incentives include significant penalty reductions or penalty waivers.

The 3M Company Settlement

3M Company, another large chemical manufacturer, made use of a compliance incentive offered by EPA. In accordance with a corporate-wide audit agreement with the Agency, 3M reviewed its compliance with Section 8(e), as well as with other sections of TSCA, at 28 of its business units and facilities with respect to a variety of chemicals, including PFOA. As part of the agreement, 3M disclosed to EPA and corrected 234 violations of Section 8(e) and ten other TSCA violations it discovered. 3M also paid a civil administrative penalty of $1.52 million to resolve all 244 violations.

Information about EPA's various compliance incentives and self-disclosure programs can be found at http://www.epa.gov/compliance/incentives/index.html

Section 8(e) Information – Launching Global Protection

The Section 8(e) information EPA received from DuPont and 3M underlies the Agency's continuing efforts to identify and develop the scientific information needed to fully understand how people are being exposed to PFOA and what, if any, concerns the exposure may pose. It is now known that PFOA and related

chemicals are found worldwide in low levels and in the blood of the general United States population.

As part of EPA's efforts, in early 2006 the Agency initiated its 2010/15 PFOA Stewardship Program, inviting companies to reduce PFOA releases and its presence in products by 95 percent no later than 2010, and to work toward eliminating these sources of exposure five years after that, but no later than 2015. The commitments applicable to the companies' operations worldwide.

EPA's PFOA Stewardship Program is resulting in global change. All eight of the major companies using PFOA and related chemicals in their manufacturing processes signed up for the Program. As of 2008, all eight have reported significant drops in the release of these chemicals, putting the industry on target to meet both the 2010 and 2015 goals worldwide.

The change is measurable. In 2007, the Centers for Disease Control and Prevention reported that their analysis of human blood levels of PFOA collected in 2003-2004 showed a 25 percent reduction from levels found in samples collected in 1999-2000. CDC attributed this decline largely to EPA's efforts on PFOA. Additional reduction are expected as further progress is made by industry under EPA's PFOA Stewardship Program. EPA is continuing to investigate the risk to humans posed by PFOA and related chemicals. Voluntary activities by industry are also underway to help resolve the existing uncertainties and fill remaining data gaps.

Meeting Reporting Requirements

Section 8(e) requires immediate notification when any information is obtained that "reasonably supports the conclusion that [a chemical] substance or mixture presents a substantial risk of injury to health or the environment..."

EPA views "substantial risk of injury to health or the environment" to be a risk of considerable concern based on the seriousness of the effect and the probability of its occurrence. These two criteria are differentially weighted for different types of effects.

For example, some health effects are so serious that relatively little weight is given to the extent of exposure. In this situation, the mere fact that a particular chemical is in commerce constitutes sufficient evidence of exposure. In contrast, other types of health or environmental effects must involve, or be accompanied by, the potential for significant levels of exposure.

EPA interprets the term "immediately" to mean that a company or individual has 30 calendar days from the date it obtained substantial risk information in which to report to EPA.

The Section 8(e) 30-day reporting deadline does not apply to information on emergency incidents of environmental contamination, which should be reported to the EPA Administrator or by telephone to the National Response Center at **(800) 424-8802** as soon as a company has knowledge of the incident. This early notification of chemical emergencies is also required by the Comprehensive Environmental Response, Compensation and Liability Act (Superfund) and the Emergency Planning and Community Right-to-Know Act.

What should I do if I'm unsure whether I have information that should be reported under Section 8(e)?

Companies and others unsure whether information should be reported under Section 8(e) should promptly report the

information to EPA as a "For Your Information" (FYI) submission. EPA reviews both Section 8(e) and FYI submissions to determine whether the information submitted is Section 8(e) substantial risk information.

For more information and guidance about the Section 8(e) substantial risk reporting requirement, visit: http://www.epa.gov/opptintr/tsca8e/

How is Section 8(e) substantial risk information used?

Section 8(e) substantial risk information is extremely valuable in hazard identification, risk assessment and risk management activities, both within and outside of EPA. Within EPA, the Office of Pollution Prevention and Toxics screens all Section 8(e) submissions to identify chemicals for further assessment or testing, and refers pertinent information to other EPA offices. Section 8(e) information is also made available outside of the Agency to state and local governments, the public and other stakeholders, such as public interest groups and the chemical industry, subject to confidential business information considerations.

Where should I send Section 8(e) substantial risk information?

Information you wish to submit should be sent by certified mail or in any

other manner that provides you with verification of EPA's receipt. You should send Section 8(e) substantial risk information (and FYI information) to:

Document Processing Center (7407M)
Attn: Section 8(e)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

For courier service:
EPA East - Room 6428
1201 Constitution Avenue, N.W.
Washington, DC 20004-3302

Companies submitting substantial risk information containing Confidential Business Information must follow the Agency's procedures for submitting such information at 40 C.F.R. Part 2 and EPA's TSCA Section 8(e) website: http://www.epa.gov/opptintr/tsca8e/.

Is there an obligation to conduct risk assessments under Section 8(e)?

No. Preparation of a qualitative or quantitative risk assessment based on new toxicity or exposure data is not required under Section 8(e).

Do contractors, consultants and independent laboratories have a Section 8(e) reporting responsibility?

If an entity does not manufacture, process or distribute in commerce TSCA chemical substances or mixtures, it does not have a Section 8(e) reporting responsibility. Its client manufacturers, processors and distributors are responsible for reporting such information.

How should a company submit 8(e) information on different chemicals, as may happen as a result of a self-audit?

Separate submissions should be made for each chemical substance or mixture. For example, including more than one study report per submission relating to a particular chemical substance or mixture is acceptable; submitting studies on different chemical substances or mixtures in a single 8(e) submission is not. Similarly, FYI submissions should also be provided separately for each chemical substance or mixture.

For questions on TSCA Section 8(e) substantial risk reporting, contact the TSCA Hotline at (202) 554-1404. For more information regarding EPA's case against DuPont, and the 3M corporate-wide audit agreement, contact Tony Ellis (202) 564-4167, Office of Civil Enforcement.

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(2241A)
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Enforcement Alert

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Document Number: EPA 325-F-08-002

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www.epa.gov/compliance