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REPORTING SUBSTANTIAL RISKS UNDER SECTION 8(e) OF THE TOXIC SUBSTANCES CONTROL ACT

JONATHAN S. KAHAN*

The Toxic Substances Control Act¹ (hereinafter TSCA or the Act) was signed by President Ford on October 11, 1976. The Act was passed by Congress in response to the growing concern over the pervasive spread and enduring nature of chemicals in our environment.² About two million chemical compounds are presently known³ and over 9,000 of these compounds are in commercial use in amounts exceeding 1,000 pounds annually.⁴ TSCA is designed to regulate those chemical substances and mixtures that present a hazard to health or the environment. The Act is not intended to make our society free of all risks presented by chemicals; rather, it seeks to control only those chemicals presenting unreasonable risks or imminent hazards.⁵

The primary methods chosen by Congress to regulate and control toxic substances are the requirement for premarket notification of new chemicals,⁶ testing requirements,⁷ the authority to regulate unreasonable risks and imminent hazards,⁸ and the requirement for recordkeeping and

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¹ 15 U.S.C. §§ 2601-2629 (1976).

² *Id.* at § 2601.

³ COUNCIL ON ENVIRONMENTAL QUALITY, TOXIC SUBSTANCES 3 (1971). This report is reprinted in LEGISLATIVE HISTORY OF THE TOXIC SUBSTANCES CONTROL ACT, 757 (1976) [hereinafter cited as LEGISLATIVE HISTORY].

⁴ *Id.* In 1973, production of the top 50 chemicals alone totalled 410 billion pounds. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ACTIVITIES OF FEDERAL AGENCIES CONCERNING SELECTED HIGH VOLUME CHEMICALS (1975), H.R. REP. NO. 1341, 94th Cong., 2d Sess. 3 (1975), reprinted in LEGISLATIVE HISTORY, *supra* note 3, at 411 n.3.

⁵ TSCA § 2(b)(2), 15 U.S.C. § 2601(b)(2) (1976), states that one of the major purposes behind the Act is to provide that

adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards.

⁶ TSCA § 5(a), 15 U.S.C. § 2604(a) (1976), provides that any person planning to manufacture, process or import a new chemical substance for commercial purposes or apply an existing chemical substance to a significant new use must notify the Environmental Protection Agency (EPA) Administrator at least 90 days in advance.

⁷ TSCA § 4, 15 U.S.C. § 2603 (1976). Under § 4, the EPA Administrator must require the testing of a chemical substance if he finds that: (1) the chemical may present an unreasonable risk of injury to health or the environment; (2) there is insufficient information to assess the effects of use of the chemical; and (3) testing is required to develop such data. *Id.* § 4(a), 15 U.S.C. § 2603(a). Testing is also required when, *inter alia*, a substance is to be produced in substantial quantities and it reasonably may be anticipated that there will be extensive environmental exposure. *Id.* § 4(a)(1)(B)(i), 15 U.S.C. § 2603(a)(1)(B)(i).

⁸ *Id.* § 6, 15 U.S.C. § 2605. Section 6 provides that if the EPA Administrator "finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment," he must regulate the substance to the extent necessary. *Id.* § 6(a), 15 U.S.C. § 2605(a). The Administrator is directed to impose the least burdensome requirement to adequately protect against the risk, including the options of

reporting of information that a chemical product presents a substantial risk of injury to health or the environment.⁹ It is this last requirement, concerning substantial risk notification, upon which this article will focus.¹⁰

The substantial risk notification requirement is contained in section 8(e) of TSCA. Section 8(e) provides that:

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.¹¹

This provision is modeled after similar notification requirements in the Consumer Product Safety Act (CPSA)¹² and the National Traffic and Motor Vehicle Safety Act of 1966.¹³ Accordingly, the TSCA notification re-

halting manufacture, processing and distribution of the substance, or limiting the amount which may be manufactured, processed or distributed in commerce. *Id.* § 6(a)(2)(A), (B), 15 U.S.C. § 2605(a)(2)(A), (B). The regulation of a chemical under § 6 must be by rule in a rulemaking proceeding. *Id.* § 6(a), 15 U.S.C. § 2605(a).

Imminent hazards are regulated under § 7, which authorizes the Administrator to initiate a civil action in an appropriate United States district court for seizure of an imminently hazardous chemical or for relief against a manufacturer or distributor of the chemical. *Id.* § 7(a)(1)(A), (B), 15 U.S.C. § 2606(a)(1)(A), (B). If the Administrator has not yet made an immediately effective rule as provided by § 6(d)(2)(A)(i), § 7(a)(2), requires the Administrator to initiate such a suit. 15 U.S.C. § 2606(a)(2). Section 7(d), provides that, where appropriate, the Administrator shall initiate a rulemaking procedure pursuant to § 6. 15 U.S.C. § 2606(d). A risk associated with a chemical substance or mixture is an imminent hazard if it is likely to result in serious or widespread injury to health or the environment before a final rule protecting against an unreasonable risk can be promulgated under § 6. TSCA § 7(f), 15 U.S.C. § 2606(f).

⁹ TSCA § 8, 15 U.S.C. § 2607 (1976). Under § 8(a), EPA may promulgate rules requiring reports on all chemicals produced in the United States including information on use, exposure, and environmental and health effects. *Id.* § 8(a)(2), 15 U.S.C. § 2607(a)(2).

¹⁰ For a more general review of TSCA, its origins and its purposes, see Druley and Ordway, *The Toxic Substances Control Act*, (BNA 1977); Symposium, *Hazardous Substances in the Environment: Law and Policy*, 7 *ECOLOGY L. Q.* 207-677 (1978); Gaynor, *The Toxic Substances Control Act: A Regulatory Morass*, 30 *VAND. L. REV.* 1149 (1977); Olpin, *Policing Toxic Chemicals*, 1976 *UTAH L. REV.* 85; Zener, *The Toxic Substances Control Act: Federal Regulation of Commercial Chemicals*, 32 *BUS. LAW.* 1685 (1977); Note, *Risk-Benefit Analysis and Technology-Forcing Under The Toxic Substances Control Act*, 62 *IOWA L. REV.* 942 (1977).

¹¹ 15 U.S.C. § 2607(e) (1976).

¹² 15 U.S.C. §§ 2051-2081 (1976). Section 15(b) of the CPSA provides:

Every manufacturer of a consumer product distributed in commerce, and every distributor and retailer of such product, who obtains information which reasonably supports the conclusion that such product—

(1) fails to comply with an applicable consumer product safety rule;

or

(2) contains a defect which could create a substantial product hazard described in subsection (a)(2) of this section,

shall immediately inform the Commission of such failure to comply or of such defect, unless such manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

Id. § 2064(b) (1976). There are also similar defect notification provisions in the Radiation Control for Health and Safety Act of 1968, 42 U.S.C. § 263(g) (1970).

¹³ Pub. L. No. 89-563, § 113, 80 Stat. 725 (1966) (now codified at 15 U.S.C. § 1411 (1976)). Section 113 of the 1966 Act provided that:

quirement raises many of the same questions of interpretation faced by persons subject to those acts.

The primary questions of interpretation raised by section 8(e) are: (1) who is required to report under this provision; (2) when will a person be regarded as having obtained information triggering the reporting requirement; (3) what constitutes a substantial risk; (4) what kinds of information reasonably support the existence of a substantial risk; and (5) what are the requirements to report in connection with information received prior to the effective date of the Act. This article will first consider and attempt to answer each of these questions of interpretation, drawing primarily upon recent interpretative statements by the Environmental Protection Agency. In this light, the article will then turn to the actual mechanics of reporting substantial risks under section 8(e), as well as the various civil and criminal penalties for failing to so report. Finally, this article will conclude with a discussion of the consequences to a TSCA-regulated business of complying with the notification requirement of section 8(e).

I. INTERPRETING SECTION 8(e)

As it has done with many other statutory provisions which are broadly and vaguely drafted, Congress has left the specifics and details of section 8(e) to be fleshed out by an administrative body. That body is the Environmental Protection Agency, and it has responded to section 8(e)'s lack of substance by issuing its Section 8(e) Proposed Guidance in September of 1977,¹⁴ and finalizing that guidance in its Section 8(e) Statement of Interpretation in March of 1978.¹⁵ This final Statement of Interpretation, which will be discussed in some detail in the following pages, is of great help in interpreting the statute but still leaves partially unanswered the questions of interpretation noted above. These questions will now be considered in turn.

A. *Who Is Subject to the Reporting Requirement*

Section 8(e) specifically provides that "[a]ny person who manufactures, processes, or distributes . . . a chemical substance or mixture" is subject to the reporting requirement.¹⁶ EPA originally interpreted this language to mean that any employee capable of recognizing substantial risks

Every manufacturer of motor vehicles or tires shall furnish notification of any defect in any motor vehicle or motor vehicle equipment produced by such manufacturer which he determines . . . relates to motor vehicle safety, to the purchaser . . . within a reasonable time after such manufacturer has discovered such defect.

¹⁴ 42 Fed. Reg. 45,362 (1977) [hereinafter cited as Section 8(e) Proposed Guidance].

¹⁵ 43 Fed. Reg. 11,110 (1978) [hereinafter cited as Section 8(e) Statement of Interpretation]. EPA reissued its guidance under the rubric "Statement of Interpretation and Enforcement Policy" to avoid any suggestion that the guidelines were subject to the public comment and delayed effectiveness provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-559 (1976). EPA never even considered issuing its notification guidelines as substantive rather than interpretive rules, in contrast to the Consumer Product Safety Commission. See 43 Fed. Reg. 17,972, 17,973 (1977) (CPSC notice asking for comment on whether it should issue its substantial product hazard guides as a substantive rather than an interpretive rule).

¹⁶ 15 U.S.C. § 2607(e) (1976).

has the responsibility to report.¹⁷ Partly due to the extremely adverse comment prompted by this proposal, EPA has softened this strict rule in its final Section 8(e) Statement of Interpretation.¹⁸ EPA now takes the position that individual officers and employees can be relieved of their *individual* duty to report to EPA if the employing organization establishes, internally publicizes, and affirmatively implements procedures for employee submission and corporate processing of pertinent substantial risk data.¹⁹ Such procedures must, at a minimum:

- (1) Specify the information that officers and employees must submit; (2) indicate how such submissions are to be prepared and the company official to whom they are to be submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly advising officers and employees in writing of the company's disposition of the report, including whether or not the report was submitted to EPA (and if not, informing employees of their right to report to EPA, as protected by TSCA, section 23).²⁰

Any employee of a company that has established and publicized the procedures just described shall be considered to have discharged his obligation under section 8(e) once he files his substantial risk report with the company. Nevertheless, all company officers who are responsible for implementing such employee reporting procedures shall retain personal liability for ensuring that any substantial risk information received from employees is relayed to EPA.²¹

If a business organization does not establish the requisite employee reporting procedures, EPA maintains that individual employees and officers must report substantial risk information directly to EPA itself.²² Although the employee or officer may also report such information to his superior rather than to EPA, such action will not satisfy his section 8(e) obligation.²³

EPA apparently feels that procedures which allow commercial establishments to assume exclusive responsibility for reporting will be in conformity with the agency's goal of ensuring that pertinent information obtained by employees is promptly and appropriately considered, while minimizing duplicative or ill-considered submissions. Such procedures also appear to be in the best interest of any company affected by TSCA. Not only will adoption of the suggested procedures lessen the friction between employers and employees which could result from an employee directly notifying EPA, but also the procedures assure that a company is fully aware

¹⁷ Section 8(e) Proposed Guidance, 42 Fed. Reg. at 45,364.

¹⁸ 43 Fed. Reg. 11,110, 11,111 (1978).

¹⁹ *Id.*

²⁰ *Id.* Section 23 of TSCA provides that no employer may discharge any employee or discriminate against him with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee commenced, caused to be commenced, or is about to commence a proceeding under the Act. TSCA § 23(a)(1), 15 U.S.C. § 2622(a)(1) (1976). If an employee notifies EPA under § 8(e) and feels that his employer has taken retaliatory action, EPA has taken the position that he can file a complaint with the Secretary of Labor. *Id.* § 23(b)-(d), 15 U.S.C. § 2622(b)-(d).

²¹ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,111.

²² *Id.*

²³ *Id.*

of a possible substantial risk before an EPA investigation is underway. However, it is still unclear whether there will be widespread adoption of the procedures suggested by EPA.

While providing general guidelines, EPA has not attempted to detail the specifics of an intracompany reporting procedure. Many companies which manufacture consumer products, however, have already established their own hazard documentation, evaluation and reporting procedures²⁴ in response to their obligations under section 15 of the Consumer Product Safety Act.²⁵ Chemical manufacturers, distributors, and processors should consider adopting similar procedures for evaluating and documenting potential substantial risks under section 8(e). For example, a company should draft guidelines classifying different types of hazards and outlining specific steps which should be taken to evaluate each type of hazard. If there are many different divisions within a company, procedures should be developed for distribution of information to every division which could provide valuable advice regarding the seriousness of the risk presented by a chemical or chemical mixture. The company should also consider delegating all reporting responsibility to a special committee consisting of technical and legal personnel, or alternatively, delegating that authority to one person who can consult others as needed.²⁶ The chief executive officer of a TSCA-regulated company should formally delegate the reporting responsibility with a proviso that he be informed of all significant matters relating to substantial risk.²⁷ In addition, each company should draft substantial risk notification forms which are available to all employees. Procedures should be developed so that these forms, containing all relevant information, are immediately sent to the responsible committee or officer who has been delegated the reporting responsibility by the chief executive officer.

B. *When Is Substantial Risk Information Obtained*

The reporting requirement of section 8(e) arises when a person "obtains information which *reasonably supports* [the existence of] . . . a substantial risk."²⁸ Originally, EPA proposed that a person would be considered to have "obtained" information within the meaning of section 8(e) as soon as

²⁴ See WASHINGTON BUSINESS INFORMATION, INC., COMPLAINT, EVALUATION, DOCUMENTATION AND COR-ACTION PROCEDURES FOR DOW CORNING CORPORATION (1975).

²⁵ See text and note 12 *supra*.

²⁶ Under the CPSC regulations, the chief executive officer must certify the authenticity of information submitted to CPSC or delegate that authority. If the chief executive officer decides to delegate the authority, he must submit a "Delegation of Authority" form to the CPSC. 16 C.F.R. § 1115.9 (1978).

²⁷ EPA has noted that even if a business organization establishes and publicizes the required procedures, the organization is still responsible for becoming cognizant of any substantial risk information obtained by its officers or employees. Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,111.

Contractors and independent laboratories are not responsible for reporting information directly to EPA; rather, their client manufacturers, processors, and distributors have that responsibility. Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,114. EPA has also apparently taken the position that submission of a § 8(e) notice by a trade association is inappropriate. See EPA, STATUS REPORT, 8E-0178-0030 (March 17, 1978) (indicating that a notice from the American Petroleum Institute on mutagenesis in crude shale oils may be inappropriate).

²⁸ 15 U.S.C. § 2607(e) (1976).

he received information *suggesting* substantial risk.²⁹ However, since there is nothing in either the language or the legislative history of the Act supporting a reporting requirement merely because a substantial risk is suggested, EPA has revised its interpretation.³⁰ The Section 8(e) Statement of Interpretation now provides that a person "obtains" information within the meaning of section 8(e) at the time he first *comes into possession of or knows* of substantial risk information.³¹

Section 8(e) is not intended to compel searches for information or require extraordinary efforts to acquire substantial risk data. However, if a prudent person could reasonably be expected to be aware of the information, EPA will consider that person to have "obtained" the information.³² EPA maintains that negligent or intentional avoidance of information will not absolve a person of his section 8(e) obligation.³³ Individual determinations will necessarily have to be made in each case as to whether a person actually "obtained" the information.

Although EPA has recently adopted a more lenient interpretation of the term "obtains," the agency has maintained a stricter stance on the accompanying statutory phrase "reasonably supports . . . a substantial risk."³⁴ EPA has emphasized in its interpretation of that phrase that the term "reasonably supports" is not identical to a conclusive demonstration of substantial risk.³⁵ Rather, EPA has indicated that the former "typically occurs, and must be reported at an earlier stage."³⁶ The question arises whether an incomplete study with only preliminary results pointing to a substantial risk "reasonably supports" the existence of a substantial risk within the meaning of section 8(e). EPA answers this question affirmatively, in situations "where appropriate,"³⁷ but this answer does not really assist a company in deciding whether to report. The final decision as to whether information reasonably supports the existence of a substantial risk must be made by technical personnel evaluating the information in conjunction with legal personnel who are familiar with section 8(e).

C. *What Constitutes a Substantial Risk*

In its Section 8(e) Statement of Interpretation, EPA attempts to give some guidance concerning the definition of substantial risk:

A "substantial risk of injury to health or the environment" is a risk of considerable concern because of (a) the seriousness of

²⁹ Section 8(e) Proposed Guidance, 42 Fed. Reg. at 45,364.

³⁰ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,111.

³¹ *Id.* Persons regulated under § 15 of CPSA, on the other hand, are required to report as soon as they receive information which would lead a reasonable man to conclude that a product defect *could create* a substantial product hazard. 15 U.S.C. § 2064(b) (1976). See note 12 *supra* for the text of § 15. Determining the scope of the term "could create" has led to many problems for those in the consumer product distribution chain, and the deletion of the "may suggest" language by EPA will hopefully avoid some of the same problems for industries regulated under TSCA. See Kahan, *The Reporting of Substantial Product Hazards Under Section 15 of The Consumer Product Act*, 30 AD. L. REV. 289 (1978) [hereinafter cited as Kahan].

³² Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,114.

³³ *Id.*

³⁴ *Id.* at 11,110.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 11,112.

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the effect . . . and (b) the fact or probability of its occurrence, (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".)³⁸

Thus, in EPA's view, seriousness of effect and probability of occurrence are the key factors in determining the existence of a substantial risk.

EPA has attempted to list the kinds of effects which are of sufficient seriousness to constitute a substantial risk.³⁹ The main problem with EPA's list is the pervasive use of broad and vague terminology such as "relatively serious impairment of normal activities," "strongly implicated," "serious or prolonged incapacitation," "widespread and previously unsuspected distribution," "pronounced bioaccumulation," "non-trivial adverse effect," and

³⁸ *Id.* at 11,111.

³⁹ *Id.* at 11,112. The factors listed were:

(a) *Human health effects*—(1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.

(b) *Environmental effects*—(1) Widespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities).

(2) Pronounced bioaccumulation. Measurements and indicators of pronounced bioaccumulation heretofore unknown to the Administrator (including bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 25,000) should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

(3) Any non-trivial adverse effect, heretofore unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media.

(4) Ecologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth or survival.

Examples include: (i) Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems.

(ii) Interference with critical biogeochemical cycles, such as the nitrogen cycle.

(5) Facile transformation or degradation to a chemical having an unacceptable risk as defined above.

Id. The agency has taken the position that the listed human health effects will trigger the reporting requirement even if there is little exposure. *Id.* at 11,111. This position is grounded on the presumption that the mere fact that the implicated chemical is in commerce constitutes sufficient evidence of exposure. *Id.* Environmental effects, on the other hand, must involve or be accompanied by the potential for significant levels of exposure because of general production levels, persistence, typical uses, common means of disposal, or other factors. *Id.*

EPA also takes the view that emergency incidents of environmental contamination are effects which must be reported. *Id.* 11,112. Any environmental contamination by a chemical substance to which any of the above human or environmental effects have been ascribed must be reported if, because of pattern, extent, or amount of contamination, the chemical (1) seriously threatens humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation, or (2) seriously threatens non-human organisms with large scale or ecologically significant population destruction. *Id.*

"ecologically significant changes in species' interrelationships." Unfortunately, what is ecologically significant or non-trivial to one scientist is not so to another. Thus, while EPA has made a fairly good attempt to develop objective criteria for a decision that must necessarily relate to the facts of each individual case, these criteria should provide only a starting point. The party responsible for reporting at each company also should consult with company legal personnel who should be able to give some advice as to whether the risk is reportable under EPA criteria and under the case law that may have developed up to that point.

If technical people believe that a chemical creates a substantial risk to human health or the environment based on the EPA criteria, management should evaluate the problem very carefully before determining not to make a section 8(e) report. Unlike the reporting of potential substantial product hazards under CPSA,⁴⁰ reporting under section 8(e) is essentially a scientific and technical decision where the views of toxicologists and scientists must be given the utmost consideration. When EPA investigates to determine whether a report should have been made earlier, any documents or testimony revealing internal company scientific opinion of the existence of a substantial risk could be used to support a civil penalty. This does not mean that management must make a section 8(e) report whenever one scientist says a report should be made. If that opinion is based upon questionable data, a second opinion may be sought from another source without violating either the letter or spirit of section 8(e). For example, a single occurrence of cancer or other serious effect should probably not be reported unless there is other evidence strongly implicating the chemical.⁴¹ Nevertheless, where there appears to be a valid basis for opinion that a substantial risk exists, the safest course to follow is to immediately file a report with EPA while still continuing testing to verify the original opinion. As noted earlier, a company does not necessarily have to have conclusive information of risk before reporting.⁴²

D. *Information Which Reasonably Supports the Existence of a Substantial Risk*

EPA has stated that there are two primary sources of information which "often 'reasonably support' the existence of substantial risk": (1) Designed and controlled studies including in vivo experiments and tests, in vitro experiments and tests, epidemiological studies, and environmental monitoring studies; and (2) Undesigned and uncontrolled studies.⁴³ This

⁴⁰ See note 12 *supra*.

⁴¹ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,114.

⁴² See text at notes 34-36 *supra*. In its original proposed guidance, EPA took the position that human health effects and environmental effects need not be conclusively demonstrated to be caused by a chemical substance or mixture as long as evidence links the chemical substance or mixture to the effects. Section 8(e) Proposed Guidance, 42 Fed. Reg. at 45,365. This provision was dropped because of the vagueness of the term "links." Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,112. Again, the safest course for a company to follow is to consult with as many experts as it can to determine if the suspected effects result from the suspect chemical. If there is some opinion that there is a cause and effect relationship, and that opinion appears based on valid, albeit controvertible, data, the company probably should report.

⁴³ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,112.

latter category includes medical and health surveys, clinical studies, and reports concerning effects on consumers, workers, or the environment.⁴⁴ A company is not required under section 8(e) to conduct studies to determine whether a chemical presents a substantial risk, but should it become aware of studies pointing to such a risk, that study should be carefully evaluated.⁴⁵ In general, any source of information could point to a substantial risk although the basis for most reports will probably be controlled or uncontrolled studies and employee exposure data.

Even if certain information reasonably supports the existence of substantial risk, it need not be reported to EPA if it has been: (1) published by EPA in a report; (2) submitted in writing to EPA pursuant to any mandatory reporting requirement under TSCA or some other law administered by EPA as long as that report contains all the information that EPA requires in a section 8(e) report and is identified from that point on as a section 8(e) notice; or (3) published in the scientific literature and referenced by one of six abstract services.⁴⁶

E. Information Received Prior to the Effective Date of the Act

EPA has taken the position that any substantial risk information possessed by a person prior to January 1, 1977, the effective date of TSCA, must be reported to EPA by May 16, 1978 if the person was *aware* of the information after January 1, 1977.⁴⁷ EPA considers a person aware of information after January 1, 1977 if he reviewed memoranda, written reports, and other documents after that date or participated in conferences or discussions after January 1, 1977 which referred to the information.⁴⁸ Additionally, a person will be considered aware of information if he has been "alerted" to it after January 1, 1977, including any information concerning a chemical for which the person is presently assessing health and environmental effects.⁴⁹ Finally, in a catchall paragraph, EPA has stated

⁴⁴ *Id.* Any information received through product liability suits or customer complaints can also point to a substantial risk. *Id.* Consumer complaints should be kept and evaluated; it is possible that consumer complaints could be sufficient to trigger the reporting requirement if there are numerous complaints of serious effects even if no specific study points to substantial risk. For example, on November 7, 1977, Velsicol Chemical Corporation filed a § 8(e) notice concerning the allergenic effect of DCPD acrylate on one employee. Section 8(e) Notice 8E-1177-0017P. Since the employee had worked with numerous other chemicals and there was only a minor health effect identified, EPA concluded no action should be taken. This is just an example of how cautious, and possibly overcautious, some companies are being in reporting under § 8(e).

⁴⁵ EPA can require a company to test a specific chemical or mixture under certain circumstances. TSCA § 4, 15 U.S.C. § 2603 (1976). See note 7 *supra*.

⁴⁶ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,112. The six abstract services are (1) Agricola, (2) Biological Abstracts, (3) Chemical Abstracts, (4) Dissertation Abstracts, (5) Index Medicus, and (6) National Technical Information Service. *Id.*

Information also need not be reported if it is simply corroborative of well-established adverse effects already documented in the scientific literature and referenced in one of the six services listed above, unless the information concerns an emergency incident of environmental contamination. *Id.* If the information is contained in a notification of spills under § 311(b)(5) of the Federal Water Pollution Control Act, 33 U.S.C.A. § 1321(b)(5) (Supp. 1978), it also need not be reported. Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,112.

⁴⁷ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,112.

⁴⁸ *Id.*

⁴⁹ *Id.*

that a person will be considered aware of information of which he has actual knowledge.⁵⁰

There is nothing in either the legislative history or the specific language of section 8(e) requiring that information received prior to the effective date of TSCA be reported. Indeed, many commenters on EPA's Section 8(e) Proposed Guidance argued that section 8(e) applies only to information obtained after January 1, 1977.⁵¹ Notwithstanding the lack of support in the legislative history for the retroactive application of section 8(e), EPA would likely prevail in a court test on this issue. The courts have had no problem applying the defect notification provisions of the National Traffic and Motor Vehicle Safety Act of 1966⁵² to automobiles manufactured prior to the effective date of that law.⁵³ Similarly, the Consumer Product Safety Commission has taken the position that anyone obtaining information that a product defect could create a substantial product hazard must report regardless of when that information was obtained.⁵⁴ One commentator has examined the constitutional aspects of the CPSC position and concluded that neither the prohibition against *ex post facto* legislation nor the due process requirements of the fifth amendment would forbid such an interpretation of CPSA.⁵⁵

As under CPSA, any constitutional challenge to the retroactive application of section 8(e) would in all likelihood fail. The question thus becomes one of statutory construction: Did Congress intend section 8(e) to be applied retroactively? In light of the broad purpose of TSCA to prevent unreasonable risks of injury to health or the environment,⁵⁶ it is unlikely that a court would limit substantial risk reporting only to information "obtained" after the effective date of the Act. Section 8(e) was passed to prevent risks such as those associated with the Kepone disaster in Virginia;⁵⁷ a court is not likely to hold that a person has no obligation to report such a risk simply because he obtained information relating to the danger before January 1, 1977.

Thus, under section 8(e) a person must report if he was *aware* of the danger after January 1, 1977 even if he obtained the information prior to that date. As noted above,⁵⁸ EPA has taken a rather broad view as to the meaning of the term "aware." However, if a company scientist or officer has read about a substantial risk associated with a chemical but only has a

⁵⁰ *Id.* at 11,112-13.

⁵¹ *Id.* at 11,110-11.

⁵² 15 U.S.C. § 1411 (1976).

⁵³ See, e.g., *United States v. General Motors Corp.*, 518 F.2d 420, 425-27 (D.C. Cir. 1975) (applying notification provisions to wheels on 1960-65 pickup trucks); *United States v. General Motors Corp.*, 65 F.R.D. 115, 116, 120 (D.D.C. 1974) (applying notification provisions to pitman arm failures on 1959-60 model year Cadillacs), *rev'd on other grounds*, 561 F.2d 923 (D.C. Cir. 1977), *cert. denied*, 98 S. Ct. 765 (1977).

⁵⁴ Although the applicable regulation, 16 C.F.R. § 1115.4 (1977), does not state explicitly that information received prior to the effective date of the law must be reported, CPSC maintains that information must be reported regardless of when it is received.

⁵⁵ Note, *Federal Regulation of "Substantial Product Hazards": An Analysis of Section 15 of the Consumer Product Safety Act*, 25 AM. U. L. REV. 717, 720-30 (1976).

⁵⁶ S. REP. NO. 698, 94th Cong., 2d Sess. 1 (1976), reprinted in LEGISLATIVE HISTORY, *supra* note 3, at 157.

⁵⁷ S. REP. NO. 698, 94th Cong., 2d Sess. 22 (1976), reprinted in LEGISLATIVE HISTORY, *supra* note 3, at 178.

⁵⁸ See text at note 50 *supra*.

vague recollection of the specifics, that person is not obligated to go back through the records and search out the information; he is not "aware" of the information.⁵⁹ On the other hand, if that person has seen a report or discussed substantial risk information with others so that the information is fairly clear in his mind after January 1, 1977, he should report that information even if he read the report or had the discussion prior to January 1, 1977.⁶⁰

II. MECHANICS OF REPORTING UNDER SECTION 8(e)

Once a business organization, through either its section 8(e) review committee or through the person delegated section 8(e) responsibility by the chief executive officer, determines that it is in the possession of substantial risk information, it must then decide whether to report. The organization could decide, of course, that it would rather risk the penalties for not reporting⁶¹ rather than take the consequences that can result from a report. Such consequences could be adverse publicity,⁶² a possible EPA ordered halt in manufacture or recall under section 6 or 7,⁶³ and possible product liability suits.⁶⁴ However, if an organization does decide to report, it should be aware of the procedures involved.

Section 8(e) requires any person who obtains substantial risk information to "immediately inform" EPA of such information.⁶⁵ EPA has interpreted the term "immediately inform" to mean that EPA must receive a section 8(e) report not later than the 15th working day after the date the person obtained such information.⁶⁶ Written notices are directed to be delivered to the EPA Office of Toxic Substances and should:

- (a) Be sent by certified mail . . . ,
- (b) State that it is being submitted in accordance with section 8(e),
- (c) Contain the job title, name, address, telephone number, and signature of the person reporting and the name and address of the manufacturing, processing, or distributing establishment with which he is associated,
- (d) Identify the chemical substance or mixture (including, if known, the CAS Registry Number),
- (e) Summarize the adverse effects being reported, describing the nature and the extent of the risk involved, and
- (f) Contain the specific source of the information together with a summary and the source of any available supporting technical data.⁶⁷

⁵⁹ See Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,114.

⁶⁰ See *id.*

⁶¹ See text and notes 69-71 *infra*.

⁶² See text at notes 109-24 *infra*.

⁶³ See text at notes 77-84 *infra*.

⁶⁴ See text at notes 103-108 *infra*.

⁶⁵ 15 U.S.C. § 2607(e) (1976).

⁶⁶ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,113. Supplementary information generated after a § 8(e) notification must also be immediately reported, if appropriate. *Id.* For emergency incidents of environmental contamination, a person must report the incident to EPA by telephone as soon as he has knowledge of the information. *Id.*

⁶⁷ *Id.*

Many companies that have reported under section 8(e) to date have attached copies of studies which the companies nevertheless assert may not constitute section 8(e) data.⁶⁸ Even if a company is not absolutely convinced that the data rises to the level of substantial risk information, however, it is still prudent to report the information with the disclaimer that the notice is not an admission that the data or studies demonstrate substantial risk.

It is important that all persons with any responsibility under section 8(e) be as completely informed as possible since noncompliance can result in a civil penalty of \$25,000.⁶⁹ Each day which passes without reporting constitutes a separate violation and subjects the violator to another \$25,000 penalty.⁷⁰ Violation of section 8(e) could also give rise to criminal penalties in those cases involving a knowing or willful failure to notify EPA of a substantial risk.⁷¹

III. THE CONSEQUENCES OF REPORTING UNDER SECTION 8(e)

There are five primary consequences of reporting under section 8(e) that should be of concern to every reporting business organization. First, EPA could use the section 8(e) information to institute imminent hazard proceedings under section 7 of Act,⁷² or to seek a rule under section 6 of the Act.⁷³ A section 6 rule could require, *inter alia*: the cessation of manufacturing, processing, or distribution; the limitation of the amount of the chemical which may be manufactured, processed, or distributed in commerce; notice of an unreasonable risk of injury; or, the replacement or repurchase of the substance as elected by the person to which the requirement is directed.⁷⁴ Second, EPA could determine that the reporter has not filed its notice in a timely fashion under section 8(e) and could seek penal-

⁶⁸ The author obtained numerous § 8(e) notices from EPA pursuant to a Freedom of Information Act request. Velsicol Chemical Corporation, which has submitted numerous notices, uniformly stated that the company makes no judgment that studies submitted contain substantial risk information. See, for example, Velsicol Section 8(e) Notices: 8EHQ-0578-0142 (May 1, 1978); 8EHQ-0178-0031PS (January 13, 1978); 8EHQ-1177-0018PS (November 7, 1977); 8EHQ-1077-0007 (September 26, 1977); 8EHQ-1077-0008 (September 26, 1977); 8EHQ-0977-0005 (September 7, 1977); 8EHQ-0777-0001 (July 21, 1977).

⁶⁹ TSCA §§ 15, 16, 15 U.S.C. §§ 2614, 2615 (1976). Under § 15(3), it is a violation of the Act to fail to give the requisite notice under § 8(e). 15 U.S.C. § 2614(3) (1976). An alleged violator has the right to a full adjudicatory hearing pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. § 554 (1976), before the Administrator can assess the civil penalty. TSCA § 16(a)(2)(A), 15 U.S.C. § 2615(a)(2)(A) (1976). On August 4, 1978, EPA published interim rules of practice setting forth the procedures to be followed by parties litigating administratively assessed penalties under § 16 of the TSCA. 43 Fed. Reg. 34,729 (1978).

⁷⁰ TSCA § 16(a)(1), 15 U.S.C. § 2615(a)(1) (1976).

⁷¹ *Id.* § 16(b), 15 U.S.C. § 2615(b). Section 16(b) provides:

Any person who knowingly or willfully violates any provision of section [15] of this title shall, in addition to or in lieu of any civil penalty which may be imposed under subsection (a) of this section for such violation, be subject, upon conviction, to a fine of not more than \$25,000 for each day of violation, or to imprisonment for not more than one year, or both.

In addition, EPA can seek to enjoin a violation of § 8(e) under § 17, which provides that the district courts shall have jurisdiction over civil actions to restrain any violation of § 15 (failure to notify under § 8(e) is a violation of § 15) and to compel the taking of action required by TSCA. *Id.* § 17(a)(1)(A), (C), 15 U.S.C. § 2616(a)(1)(A), (C).

⁷² See note 8 *supra*.

⁷³ *Id.*

⁷⁴ *Id.*

ties for noncompliance pursuant to section 15 and 16 of TSCA.⁷⁵ Third, EPA could issue an order requiring the testing of the chemical substance pursuant to section 4 of the Act.⁷⁶ Fourth, potential plaintiffs could use the section 8(e) information, and the fact that a notice was filed against a company in a product liability suit. Finally, adverse publicity and the possible public release of confidential and sensitive information could result from a report. These potential consequences will now be considered in turn.

A. Proceedings Under Sections 6 and 7

Section 6 of TSCA provides that the EPA Administrator can, by rule, take rather drastic action against a chemical that presents or will present an unreasonable risk of injury to health or the environment. EPA can order, among other things, a halt to manufacturing and distribution, and replacement or repurchase.⁷⁷ In order for EPA to seek a section 6 rule there must be evidence that the suspect chemical or mixture presents an "unreasonable risk of injury to health or the environment . . ."⁷⁸ By comparison, a section 8(e) report, although it relates only to "substantial risk" rather than to "unreasonable risk," may well provide just the information which EPA needs to institute a section 6 rulemaking proceeding.⁷⁹ Unreasonable risk is nowhere defined in TSCA, but since it involves elements of "probability of harm, the potential severity of that harm, and similar considerations," the elements of unreasonable risk and substantial risk are very similar.⁸⁰ If a company reports substantial risk information under section 8(e), it is also providing exactly the kind of information which EPA needs to justify the initiation of a section 6 rulemaking.

Upon receipt of a section 8(e) notification, EPA will evaluate the risk and thereafter draft a complete status report on the suspect chemical. That report will describe the contents of the notice, and the current use of the suspect chemical. It will also include a toxicological evaluation and a recommendation as to what action should be taken in connection with the chemical. There are numerous options open to the agency in deciding what action to take. It could recommend that no action be taken due to the low

⁷⁵ See text at notes 69-71 *supra*.

⁷⁶ See note 7 *supra*.

⁷⁷ TSCA § 6, 15 U.S.C. § 2605 (1976); see note 8 *supra*.

⁷⁸ TSCA § 6(a), 15 U.S.C. § 2605(a) (1976).

⁷⁹ A § 6 rulemaking proceeding is conducted in accordance with the Administrative Procedure Act, 5 U.S.C. § 553 (1976). In addition, EPA must:

(A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule; (B) allow interested persons to submit written data, views, and arguments, . . . ; (C) provide an opportunity for an informal hearing in accordance with [§ 6(c)(3)]; (D) promulgate, if appropriate, a final rule based on the matter in the rulemaking record . . . ; and (E) make and publish with the rule the finding described in [§ 6(a)].

TSCA § 6(c)(2), 15 U.S.C. § 2605(c)(2) (1976). Section 6(a) empowers the EPA Administrator to act upon a finding that there is "a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to the health or the environment . . ." *Id.* § 6(a), 15 U.S.C. § 2605(a) (1976).

⁸⁰ Compare Gaynor, *The Toxic Substances Control Act*, 30 VAND. L. REV. 1149, 1153 (1977) (definition of "unreasonable risk") with Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,111 (defining "substantial risk").

production volume of the chemical.⁸¹ EPA could also recommend referral to the National Institute for Occupational Safety and Health (NIOSH) and to the Occupational Safety and Health Administration (OSHA) if the chemical is basically an occupational hazard.⁸² However, should EPA conclude that the section 8(e) data demonstrates that the product presents an unreasonable risk, a section 6 proceeding could be recommended.⁸³

Of course, the possibility of a section 6 proceeding is not a valid reason not to report if a company concludes it has section 8(e) information. If the chemical actually presents either a substantial or an unreasonable risk, EPA may well learn of the risk through published studies or some other source.⁸⁴ When EPA does become aware of the risk, it is quite possible that those manufacturing, processing or distributing the chemical could be subject to penalties for failure to report if EPA concludes that the company concealed substantial risk information.⁸⁵

Section 7 of TSCA authorizes EPA to control "imminent hazards."⁸⁶ An imminent hazard is defined as one which is likely to result in serious or widespread injury to health or the environment before a final rule protecting against unreasonable risk can be promulgated under section 6.⁸⁷ A section 8(e) report could very well lead EPA to conclude that the chemical presents an imminent hazard within the purview of section 7. If so, EPA could seek a court order for seizure of the chemical or other relief to protect health and the environment.⁸⁸ However, just as with section 6, if the chemical does in fact present an imminent hazard, EPA will likely learn of it sooner or later. Accordingly, the safest course for a company to follow is to report the risk. In addition, the company might consider taking some voluntary recall action, in order to lessen its product liability exposure by minimizing the chance of further injury or environmental harm.

B. Civil Penalties

It is too early in the development of the EPA's section 8(e) procedures to judge whether the agency will examine the timeliness of section 8(e) reports. At this time, EPA is primarily concerned with the completion of the

⁸¹ Under § 8(a), EPA can require companies to submit the total amount of each substance and mixture manufactured as well as "reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use." 15 U.S.C. § 2607(a)(2)(C) (1976). For examples of an EPA recommendation that no action be taken due to low production volume, see EPA, STATUS REPORT 8E-0278-0042 (March 17, 1978), and EPA, STATUS REPORT 8E-0777-0001 (August 10, 1977).

⁸² See, e.g., EPA, STATUS REPORT 8E-378-0086 (March 28, 1978); EPA, STATUS REPORT 8E-0278-0052P (March 17, 1978); EPA, STATUS REPORT 8E-0278-0044 (March 17, 1978).

⁸³ See text and notes 79-80 *supra*.

⁸⁴ The TSCA Interagency Testing Committee has been given the task of identifying and recommending to the Administrator chemical substances which should be tested to determine their hazard to human health or to the environment. TSCA § 4(e), 15 U.S.C. § 2603(e) (1976). This committee will inform EPA of those chemicals which are already in the suspect category. For examples of Interagency Testing Committee reports, see 42 Fed. Reg. 55,025-26 (1977); 43 Fed. Reg. 16,683-88 (1978).

⁸⁵ See text and notes 69-71 *supra*.

⁸⁶ 15 U.S.C. § 2606 (1976). See note 8 *supra*.

⁸⁷ TSCA § 7(f), 15 U.S.C. § 2606(f) (1976).

⁸⁸ *Id.* § 7(a), 15 U.S.C. § 2606(a).

chemical inventory and getting TSCA enforcement underway. The agency is therefore not likely to immediately divert personnel to examine the timeliness of section 8(e) reports. However, if the Consumer Product Safety Commission experience with the defect notification provisions of CPSA is any example, EPA at some point will develop an enforcement policy regarding the timeliness of section 8(e) reports. Until that policy is developed, however, companies should be aware that a section 8(e) report can trigger an investigation into whether the company has obtained substantial risk information and illegally delayed its reporting.

A section 8(e) timeliness investigation would be much more likely in a Kepone-type situation where a section 8(e) report could be a significant factor in EPA taking action to avoid danger to health and the environment. If EPA should become aware that the company knew of the serious risk presented by a chemical and did not "immediately" report the substantial risk, the agency would much more likely seek penalties for late reporting. As noted previously, sections 15 and 16 of TSCA provide that any failure or delay in reporting can result in a fine of up to \$25,000. EPA could seek \$25,000 a day in penalties since each day which passes without reporting constitutes a separate violation.⁸⁹

Developments in the CPSC area are helpful in judging just what could happen in section 8(e) timeliness cases. CPSC has brought several actions against consumer product manufacturers for failure to immediately notify the Commission of a defect that could create a substantial product hazard.⁹⁰ The cases have resulted in settlements in the amount of \$325,000 (out of a possible \$500,000 maximum),⁹¹ \$40,000,⁹² and \$25,000.⁹³ No company to date has fought a Commission complaint which alleged that the company failed to file a substantial product hazard report under section 15 of CPSA. The CPSC has used the timeliness weapon very sparingly and it is quite possible that EPA will do the same.

Nonetheless, a TSCA-regulated company should not risk continuing daily fines of up to \$25,000 without careful consideration. If the company has obtained substantial risk information, it has 15 days to report to EPA⁹⁴ and every day of delay, as noted, can be costly. All a company can do is use its best judgment in determining whether it has "obtained" section 8(e) information, basing that judgment upon expert technical and legal advice. If the company concludes that the information could well be section 8(e) information, it may be safer to report and take the consequences rather than risk a \$25,000 continuing daily fine. Experience seems to indicate that many companies are taking this position since as of June 6, 1978, there have been over 200 substantial risk notices to EPA.⁹⁵

⁸⁹ See text and notes 69-71 *supra*.

⁹⁰ For a more in-depth discussion of these cases see Kahan, *supra* note 31.

⁹¹ In re Corning Glass Works, CPSC Docket No. 77-4 (July 14, 1977).

⁹² In re Wham-O Mfg., CPSC Docket No. 77-2 (Oct. 27, 1977).

⁹³ In re North Am. Systems, CPSC Docket No. 77-3 (June 16, 1977).

⁹⁴ Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,113.

⁹⁵ As noted previously, many companies simply report under § 8(e), adding a disclaimer that the report does not constitute an admission that the chemical presents a substantial risk. See note 68 *supra*. Velsicol has included a sentence in its notices reserving the right to contest the propriety of Section 8(e) of TSCA. *Id.* Others have noted that the report does not constitute a waiver of legal privilege against self-incrimination or right of immunity. Section 8(e) Notice 8EHQ-0877-0002 (July 28, 1977) (Mobil Oil Corporation report on Mobilsol 44, a

C. Testing Order Under Section 4

Under section 4 of TSCA, the EPA Administrator must require the testing of a chemical if he finds that the chemical may present an unreasonable risk of injury to health or to the environment, that there is insufficient information to assess the effects of use of the chemical, and that testing is required to develop such data.⁹⁶ The testing requirement must be promulgated by rule,⁹⁷ with the additional right to oral presentations.⁹⁸ If EPA issues such a rule, the manufacturer or processor is required to perform the required testing. EPA must take into account the costs of the tests required and the availability of test facilities to perform the tests.⁹⁹

It is quite possible that a section 8(e) report could trigger a section 4 rulemaking proceeding. One recent section 8(e) notice by Velsicol Chemical Company prompted EPA to consider a section 4 order.¹⁰⁰ On December 16, 1977, Velsicol submitted information concerning occupational health problems related to the chemicals methendic anhydride and maleic anhydride. Upon review of information that the chemicals could cause irritation to eyes and the respiratory tract, the OTS staff recommended that consideration be given to initiation of a synergistic effects study, possibly under section 4.¹⁰¹

Again, it is too early in the development of agency TSCA procedures to determine to what extent section 8(e) reports will result in section 4 orders. However, since "substantial risk" and "unreasonable risk" are very similar standards, it is not beyond the realm of possibility that section 8(e) reports could result in EPA requiring testing of the suspect chemical. EPA could order massive testing of carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, and cumulative and synergistic effects.¹⁰² Thus, although the cost of testing is a factor to be considered by the agency in determining whether to require it, section 4 testing could nevertheless be very costly to a TSCA-regulated business.

D. Product Liability Consequences

A person suffering injury from the chemical could attempt to use a section 8(e) notice as an admission by the reporting company that its chemical is defective and unreasonably dangerous thus subjecting the company

flexibilizer diluent). Whichever tack a company takes, it is probably safer to report disclaiming liability and asserting that the chemical does not present a substantial risk than to risk penalties for not reporting.

⁹⁶ TSCA § 4(a), 15 U.S.C. § 2603(a) (1976). See note 7 *supra*.

⁹⁷ TSCA § 4(a), 15 U.S.C. § 2603(a) (1976).

⁹⁸ *Id.* § 4(b)(5), 15 U.S.C. § 2603(b)(5).

⁹⁹ *Id.* § 4(b)(1), 15 U.S.C. § 2603(b)(1).

¹⁰⁰ EPA, STATUS REPORT 8EHQ-0278-0063 (May 12, 1978).

¹⁰¹ *Id.*

¹⁰² TSCA § 4(b)(2)(A), 15 U.S.C. § 2603(b)(2)(A) (1976). It should be noted that in cases of occupational hazards, companies can request a health hazard evaluation by NIOSH. Section 20(a)(6) of OSHA, provides that the Secretary of Health, Education and Welfare shall determine, following a written request by an employer or authorized representative of employees, whether any substance normally found in the workplace has potentially toxic effects. 29 U.S.C. § 669(a)(6) (1976). If the substance does have such an effect, the information must be submitted immediately to the Secretary of Labor for possible promulgation of a health or safety standard. *Id.*

to strict liability exposure¹⁰³ or suit under traditional negligence or warranty principles.¹⁰⁴ The plaintiff in such a product liability suit will almost certainly have a difficult time proving causation.¹⁰⁵ It is possible in certain cases, however, such as those involving generally recognized carcinogens or disease causing chemicals, that a plaintiff will be able to present sufficient evidence of causation. For example, in *Industrial Indemnity Exchange v. Industrial Accident Commission*,¹⁰⁶ the court held that evidence of mere exposure to silicon dust was sufficient to support a finding that plaintiff's fatal pulmonary tuberculosis silicosis was job-related.¹⁰⁷ In such cases, plaintiffs could attempt to introduce a section 8(e) notice to show that a defendant chemical company recognized the dangerous nature of its product and indeed had evidence to demonstrate the danger.

It is possible that a court would admit a section 8(e) notice into evidence in a product liability suit concerning a toxic substance. In this regard, a section 8(e) notice can be analogized to automobile recall notices which inform car owners of a safety hazard associated with their automobile. A number of courts have admitted automobile recall notices into evidence in product liability cases even though in the past such evidence has been excluded under the hearsay rule, rules of relevancy, and the rule against introduction of subsequent remedial measures.¹⁰⁸

¹⁰³ RESTATEMENT (SECOND) OF TORTS § 402A (1965). Section 402A states the generally accepted principles of strict liability:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

¹⁰⁴ The product liability consequences of reporting under § 8(e) are in some ways similar to the product liability consequences of reporting under § 15 of CPSA. See generally Kahan, *supra* note 31.

¹⁰⁵ See, e.g., *Miller v. National Cabinet Com* 8 N.Y.2d 277, 288, 168 N.E.2d 111, 817, 204 N.Y.S.2d 129, 137 (1960) (causation not established in showing relationship between benzene exposure and leukemia); *Clark v. State Workmen's Compensation Comm'r*, 155 W.Va. 726, 732, 187 S.E.2d 213, 217 (1972) (no proof of cause and effect between multiple chemical exposure and leukemia). But see *McCallister v. Workmen's Compensation Appeals Bd.*, 69 Cal. 2d 408, 416-17, 71 Cal. Rptr. 697, 701, 445 P.2d 313, 317 (1968) (smoke inhaled by fireman was carcinogenic and it was "reasonably probable" that job-related smoke inhalation caused lung cancer and death of fireman).

¹⁰⁶ 87 Cal. App. 465, 197 P.2d 75 (1948).

¹⁰⁷ *Id.* at 468, 197 P.2d at 77. See also *Colonial Ins. Co. v. Industrial Accident Comm'n*, 29 Cal. 2d 79, 81-82, 172 P.2d 884, 886 (1946) (exposure to silicon caused fatal silicosis); *Heck v. Beryllium Corp.*, 424 Pa. 140, 143, 226 A.2d 87, 89-90 (1967) (defendant corporation can be liable for damages to plaintiff who resided near defendant's beryllium manufacturing facility if plaintiff can show the beryllium emission level caused her disease and defendant should have had reason to believe that its emissions could be harmful).

¹⁰⁸ See *Farner v. Paccar, Inc.*, 562 F.2d 518, 526-28 (8th Cir. 1977); *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788, 793-95 (8th Cir. 1977); *Shaffer v. Honeywell*, 249 N.W.2d 251, 257 n.7 (S.D. 1976). *Contra*, *Vockie v. General Motors Corp., Chevrolet Div.*, 66 F.R.D. 57, 61 (E.D. Pa.), *aff'd without published opinion*, 523 F.2d 1052 (3d Cir. 1975); *Landry v. Adams*, 282 So. 2d 590, 596 (La. App. 1973). For a detailed discussion of these cases see Kahan, *supra* note 31, at 306-09.

E. *Adverse Publicity and Protection of Confidential and Sensitive Information*

A section 8(e) report could result in adverse publicity if the information contained in the notice was made public. It is therefore important to examine exactly what section 8(e) information will be protected from disclosure by EPA. EPA has indicated in its Section 8(e) Statement of Interpretation that any person submitting a notice to EPA under section 8(e) may assert "a business confidentiality claim covering all or part of the information contained in the notice."¹⁰⁹ Any information subject to a claim of confidentiality will be disclosed only to the extent and by means of the procedures set forth by the Act and the EPA regulations.¹¹⁰

It is unlikely that a company would be able to keep the mere fact of its filing a section 8(e) notice and the contents of such a notice confidential. Under the Freedom of Information Act,¹¹¹ the public has access to all government records unless the requested information falls within one of the specific exemptions set forth in the Act.¹¹² The exemption that most companies would invoke to prevent the release of the name of the company reporting under section 8(e), as well as the chemical reported, is the fourth exemption.¹¹³ This exemption states that "trade secrets and commercial or financial information obtained from a person and privileged or confidential" are exempt from disclosure.¹¹⁴

The key question, then, is whether the name of a reporting company and the reported chemical could be considered confidential. The leading case on the fourth exemption states that in order to determine whether information is confidential within the meaning of the exemption, a court must focus on three factors: (1) whether the information would customarily be disclosed to the public by the person from whom it was obtained; (2) whether release would impair the government's ability to obtain necessary information in the future; and (3) whether release would cause substantial harm to the competitive position of the person from whom the information was obtained.¹¹⁵ Considering the last of these factors, it would be very difficult for any business to demonstrate that release of the mere fact that it has filed a section 8(e) notice in connection with a certain chemical would cause substantial harm to its competitive position. Moreover, reference to the legislative history of the fourth exemption indicates that it was designed to protect against the release of business sales statistics, inventories, customer lists, scientific or manufacturing processes or developments, not the fact that a company has filed a notice with the government.¹¹⁶

¹⁰⁹ 43 Fed. Reg. at 11,113.

¹¹⁰ *Id.*

¹¹¹ 5 U.S.C. § 552 (1976).

¹¹² *Id.* § 552(b).

¹¹³ *Id.* § 552(b)(4).

¹¹⁴ *Id.* For judicial interpretations of this exemption see *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 766 (D.C. Cir. 1974) and *Sterling Drug, Inc. v. FTC*, 450 F.2d 698, 708-09 (D.C. Cir. 1971).

¹¹⁵ *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 767-71 (D.C. Cir. 1974). The *National Parks and Conservation Ass'n* criteria for determining whether information is confidential within the meaning of the fourth exemption have been adopted by EPA. 40 C.F.R. § 2.208 (1978).

¹¹⁶ See S. REP. NO. 813, 89th Cong., 2d Sess. 9 (1964); H.R. REP. NO. 1497, 89th Cong., 2d Sess. 10 (1964). See also Note, *Public Disclosure of Confidential Business Information Under the Freedom of Information Act: Toward a More Objective Standard*, 60 CORNELL L. REV. 109 (1974). It

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Although a company is unlikely to succeed in any attempt to keep the fact that it has filed a section 8(e) notice and the nature of the reported chemical confidential, this does not mean that a company will be unable to protect any of the information contained in a section 8(e) notice. Section 14 of TSCA¹¹⁷ provides that confidential information and trade secret data, exempt from disclosure under the fourth exemption of FOIA, shall not be disclosed under TSCA. Therefore, any information satisfying the strictures of the fourth exemption will remain confidential. There are three limited exceptions to this rule¹¹⁸ and one rather broad exception which allows the Administrator to disclose all confidential information if it is "necessary to protect against unreasonable risk of injury to health or the environment."¹¹⁹ However, it should be the rare case where the Administrator should find it necessary to disclose confidential information to protect health and the environment. In those instances where EPA does determine that disclosure is necessary to protect health or the environment, the Administrator must give the affected business at least 24 hours notice so that it can seek judicial relief.¹²⁰ In all other cases where disclosure is permitted under another exception to the general rule of nondisclosure, the Administrator must give businesses 15 days notice before releasing data which is subject to a claim of confidentiality.¹²¹

Generally, trade secret information such as manufacturing processes and formulae contained in a section 8(e) notice will be protected from disclosure. Companies should realize, however, that health and safety data will not receive the same protection. Under section 14, health and safety data will be disclosed with respect to any chemical substance or mixture which, on the date the study is to be disclosed, has been offered for commercial distribution, is subject to a section 4 testing order, or is subject to a notification order under section 5.¹²²

should be noted that EPA did delete the name of the reporting company in some of the notices provided the author under FOIA. See, e.g., Section 8(e) Notice 8EHQ-0278-00575 (Nov. 30, 1977). It is questionable whether such a deletion would be upheld if challenged in court.

¹¹⁷ TSCA § 14(a), 15 U.S.C. § 2613(a) (1976).

¹¹⁸ *Id.* § 14(a)(1),(2),(4), 15 U.S.C. § 2613(a)(1),(2),(4). Confidential information can be disclosed to any officer or employee of the United States for the protection of health or the environment or for specific law enforcement purposes. It can also be disclosed to contractors of the United States if such disclosure is necessary for the satisfactory performance of a contract with the government entered into on or after October 11, 1976. Finally, the Administrator can disclose information when relevant in any TSCA proceeding, but such disclosure must be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding. *Id.*

¹¹⁹ *Id.* § 14(a)(3), 15 U.S.C. § 2613(a)(3).

¹²⁰ *Id.* § 14(c)(2)(B)(i), 15 U.S.C. § 2613(c)(2)(B)(i).

¹²¹ *Id.* EPA has been sensitive to the assertion of TSCA-regulated companies that the unauthorized release of confidential data provided to EPA could be of great competitive harm to the company which provided the information. Accordingly, EPA formed a TSCA Data Security Task Force, 42 Fed. Reg. 57,984 (1977), which recommended elaborate security procedures for maintaining the confidentiality of such information. 43 Fed. Reg. 1,896 (1978). The final draft of the TSCA security manual is now available to the public. 43 Fed. Reg. 32,186 (1978). Whether the procedures finally adopted, such as encryption of information, will successfully protect sensitive TSCA data remains to be seen.

¹²² TSCA § 14(b)(1)(A), 15 U.S.C. § 2613(b)(1)(A) (1976). This section specifically states that it should not be construed as authorizing release of manufacturing processes or disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

In sum, the general information contained in section 8(e) notices will be available for public inspection notwithstanding a request that such information be kept confidential.¹²³ TSCA-regulated companies must be prepared to meet any adverse publicity resulting from a section 8(e) report.¹²⁴ Such adverse publicity may not be as serious as that resulting from a notice in the consumer product area since purchasers of chemicals and toxic substances are much more sophisticated than the average consumer and tend to accept more readily the fact that there may be adverse effects resulting from the use of toxic substances. But the marketability of a chemical that is the subject of a section 8(e) notice can be affected and companies should be prepared to explain to their customers the basis for filing the report.

IV. CONCLUSION

It is clearly not a simple task to determine whether one is in possession of information that must be reported under section 8(e). However, by instituting proper evaluation procedures with input from legal and technical personnel, most companies should be able to fulfill their section 8(e) responsibilities. Detailed knowledge of the Section 8(e) Statement of Interpretation by management, coupled with an up-to-date familiarity with EPA's handling and evaluation of section 8(e) reports should go a long way towards assuring that a company fully complies with the dictates of section 8(e).

¹²³ The procedures for claiming confidentiality for information in a § 8(e) notice are as follows:

(b) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file to be available to the public without further notice to the submitter.

(c) To assert a claim of confidentiality for information contained in a notice, the submitter must submit two copies of the notice.

(1) One copy must be complete. In that copy the submitter must indicate what information, if any, is claimed as confidential by marking the specified information on each page with a label such as "confidential," "proprietary," or "trade secret."

(2) If some information in the notice is claimed as confidential, the submitter must submit a second copy. The second copy must be complete except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy of the notice will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2. The second copy will be placed in an open file to be available to the public.

(d) Any person submitting a notice containing information for which they are asserting a confidentiality claim should send the notice in a double envelope.

(1) The outside envelope should bear the same address outlined in [the Section 8(e) Statement of Interpretation] (Section IX)

(2) The inside envelope should be clearly marked "To be opened only by the OTS Document Control Officer."

Section 8(e) Statement of Interpretation, 43 Fed. Reg. at 11,113. See 40 C.F.R. §§ 2.201-2.213 (1978) for a detailed description of the general procedures employed by EPA in handling confidential business information.

¹²⁴ EPA issued a proposed rule on January 18, 1978, 43 Fed. Reg. 2,637, which proposed specific regulations to implement the confidentiality provisions of § 14 of TSCA, 15 U.S.C. § 2613 (1976). While adopting some of the general EPA confidentiality regulations, 40 C.F.R. §§ 2.201-2.313 (1978), the proposed regulations also embody the specific confidentiality requirements under § 14. *Id.*

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Once the decision is made to report, the company must be aware of and prepare for the consequences of reporting. Well-informed management can avoid harm to a business' competitive position and serious harm to the long-term financial viability of the business which could flow from a section 8(e) report. In most cases, section 8(e) reports will not result in either product liability suits or adverse EPA actions. If a company concludes that its chemical does present a substantial risk, however, it must be prepared to deal with the problem in a reasoned and expeditious manner. As EPA acts on more section 8(e) notices and its regulatory policies become clearer, companies will find it less difficult to make the decision whether a chemical hazard presents a substantial risk within the meaning of section 8(e).

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