TO: Distribution

FROM: M. J. Horowitz
DATE: December 18, 1989

Interoffice Communication

SUBJ: TSCA SECTION 8 REQUIREMENTS

VISTA

Vista Chemical has a continuing regulatory obligation to record allegations of significant adverse health or environmental affects resulting from the manufacture and use of our chemical products. These requirements are listed in Section 8(c) and 8(e) of the Toxic Substances Control Act, or TSCA, and are summarized below:

Section 8(c): Requires records and reports of all allegations that chemical substances cause significant adverse reactions to health or the environment.

Section 8(e): Requires reporting to the EPA where information which reasonably supports the conclusion that a chemical substance presents a substantial risk of injury to the health or environment is obtained.

Vista employees with frequent customer or community contact have the potential to hear health or environmental effects allegations regarding Vista products. Keep in mind, allegations are defined as "statements made without formal proof or regard for evidence. Allegations recorded to date have come to our attention from plant employees, TSR's and Research and Development personnel.

All Section 8 allegations should be documented and reported to Houston Environmental. Environmental will review all Section 8 allegations to determine whether any further action is necessary. The corporate 8(c) file will also be kept by Environmental.

Copies of the regulation and reporting forms are enclosed. If you are a supervisor, please provide a copy of this information to those employees you believe need to be aware of these requirements.

Michael J. Horowitz

dlj

Attachment

51 FR 17340, May 12, 1986; 51 FR 18326, May 19, 1986]

§ 716.18 Additions to lists of chemicals and mixtures to which this subpart applies.

The requirements of this subpart will periodically be extended to cover additional substances and designated mixtures. Two procedures will be used to add substances and mixtures.

(a) Except as provided in paragraph (b) of this section, substances and designated mixtures will be added after publication in the FEDERAL REGISTER of a notice of proposed amendment of this subpart. There will be a 30-day public comment period on the notice; after consideration of the comments, a final amendment will identify the substances and mixtures added.

(b) Except as provided in paragraph (c) of this section, chemical substances, mixtures and categories of chemicals that have been added to the TSCA section 4(e) Priority List by the Interagency Testing Committee, established under section 4 of TSCA, will be added to § 716.17 30 days after publication of a notice to that effect in the FEDERAL REGISTER.

(c) Prior to the effective date of an amendment under paragraph (b) of this section, the Assistant Administrator for Pesticides and Toxic Substances may for good cause withdraw a chemical substance, mixture or category of chemicals from § 716.17. Any information submitted showing why a chemical should be withdrawn from § 716.17 must be received by EPA within 14 days after the date of publication of the notice under paragraph (b) of this section. If a chemical substance, mixture or category of chemicals is withdrawn, a FEDERAL REGISTER notice announcing this decision will be published no later than the effective date of the amendment under paragraph (b) of this section. Any information submitted must be addressed to: Document Control Officer, Office of Pesticides and Toxic Substances, (TS-793), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, ATTN: 8(d) Auto-ITC.

[47 FR 38791, Sept. 2, 1982, as amended at 50 FR 34812, Aug. 28, 1985]

§ 716.19 Sunset provision.

(a) Effective October 3, 1985, the reporting period for the substances listed in § 716.17(a)(1), (a)(2), and (a)(3) shall terminate on October 4, 1986.

(b) For all listed substances and mixtures other than those specified in paragraph (a) of this section, the reporting period on a substance or designated mixture will terminate no later than three years after that substance or designated mixture is added to the list in § 716.17, or October 4, 1986, whichever occurs later. The automatic termination date for the three year reporting period on a substance or mixture will be the annual sunset date (May 1 or November 1) that falls no later than three years after reporting begins, e.g., a reporting requirement taking effect on January 1, 1984 would expire not later than November 1, 1986. A notice will be published in the FEDERAL REGISTER announcing the termination date for reporting for the substances and designated mixtures listed in § 716.17 (a) and (b). An earlier termination date may be published for a substance or designated mixture at the discretion of the Assistant Administrator for Pesticides and Toxic Substances.

(Approved by the Office of Management and Budget under control number 2070-0004)

[50 FR 39667, Sept. 30, 1985]

PART 717—RECORDS AND REPORTS OF ALLEGATIONS THAT CHEMICAL SUBSTANCES CAUSE SIGNIFICANT ADVERSE REACTIONS TO HEALTH OR THE ENVIRONMENT

Subpart A—General Provisions

Sec.

AUTHORITY: 15 U.S.C. 2607(c).

SOURCE: 48 FR 38187, Aug. 22, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 717.1 Scope and compliance.

Section 8 (c) of the Toxic Substances Control Act (TSCA) requires manufacturers, processors, and distributors of chemical substances and mixtures:

(a) To keep "records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture."

(b) To "permit inspection and submit copies of such records", upon request of any designated representative of the Administrator. This rule implements section 8(c) of TSCA. It describes the records to be kept and prescribes the conditions under which certain firms must submit or make the records available to a duly designated representative of the Administrator.

§ 717.3 Definitions.

The definitions set forth in section 3 of TSCA and the following definitions apply to this part:

(a) "Allegation" means a statement, made without formal proof or regard for evidence, that a chemical substance or mixture has caused a significant adverse reaction to health or the environment.

(b) "Firm" or "company" means any person, that is subject to this part, as defined in § 717.5.

(c)(1) "Known human effects" means a commonly recognized human health effect of a particular substance or mixture as described either in:

(i) Scientific articles or publications abstracted in standard reference sources.

(ii) The firm's product labeling or material safety data sheets (MSDS).

(2) However, an effect is not a "known human effect" if it:

(i) Was a significantly more servere toxic effect than previously described.

(ii) Was a manifestation of a toxic effect after a significantly shorter exposure period or lower exposure level than described.

(iii) Was a manifestation of a toxic effect by an exposure route different from that described.

(d) "Manufacture" or "process" means to manufacture or process for commercial purposes.

(e)(1) "Manufacture for commercial purposes" means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, such "manufacture" of any amount of a chemical substance or mixture:

(i) For distribution in commerce, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) "Manufacture for commercial purposes" also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substances or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

(f) "Person" includes any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, and any department, agency, or instrumentally of the Federal Government.

(g) "Process for commercial purposes" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(h) "Retailer" means a person who distributes in commerce a chemical substance, mixture, or article to ultimate purchasers who are not commercial entities.

(i) "Significant adverse reactions" are reactions that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment.

(j) "Site" means a contiguous property unit. Property divided only by a public right-of-way is considered one site. There may be multiple manufacturing, processing, or distribution activities occurring within a single site.

(k) "Substance" means a chemical substance or mixture unless otherwise indicated.

§ 717.5 Persons subject to this part.

(a) *Manufacturers.* (1) All manufacturers of chemical substances are subject to this part except as provided in § 717.7(a). If manufacture of a chemcial substance occurs at any site owned or controlled by a firm then that firm is subject to this part.

(2) A manufacturer must collect:

(i) Any allegation identifying a chemical substance it manufactures and any allegation identifying the operations in the manufacture of any chemical substance it manufactures.

(ii) Any allegation identifying any of its own processing or distribution in commerce activities with respect to any chemical substance it manufactures.

(iii) Any allegation identifying emissions, effluents, or other discharges from activities described in this paragraph.

(iv) Any allegation identifying a substance produced coincidentally during processing, use, storage or disposal of a chemical substance it manufactures.

(3) For the purpose of this part, owned or controlled means ownership of 50 percent or more of a firm's voting stock or other equity rights, or the power to control the management and policies of that firm.

(b) *Processors.* (1) A person who processes chemical substances, who is not also a manufacturer of those chemical substances, is subject to this Part if (i) the person processes chemical substances to produce mixtures, or (ii) the person repackages chemical substances or mixtures.

(2) As a processor subject to this part such person must collect:

(i) Any allegation identifying any mixture it produces and distributes in commerce and any allegation identifying any chemical substance or mixture it repackages and distributes in commerce.

(ii) Any allegation identifying any of its own further processing or distribution in commerce activities of the products described in paragraph (b)(2)(i) of this section.

(iii) Any allegation identifying emissions, effluents, or other discharges from activities described in this paragraph.

(iv) Any allegation identifying a substance produced coincidentally during the processing, use, storage or disposal of the products described in paragraph (b)(2)(i) of this section.

(c) *SIC code.* SIC codes applicable to this part are published in Standard Industrial Classification Manual—1972 and the 1977 Supplement. This manual and supplement may be obtained from the U.S. Government Printing Office, Washington, D.C. 20402—stock number 4101-0006 and stock number 003-005-0170-0 respectively. Where there is a conflict between the SIC code use of a term and the definition of that term in this part, the definition in this part applies.

[48 FR 38187, Aug 22, 1983, as amended at 50 FR 46769, Nov. 13, 1985]

§ 717.7 Persons not subject to this part.

(a) *Manufacturers.* (1) Persons or site activities are exempt from this part if the means by which they manufacture a chemical substance solely involves mining or other solely extractive functions, e.g., those companies or sites within a company whose sole function is to mine mineral ores, extract petroleum or natural gas, quarry non-metallic minerals (including extraction of salts from seawater or brines), mine or otherwise extract coal, or separate gases from the atmosphere. This exemption may include, but is not necessarily limited to, firms engaged in activities as described in

SIC Division B—Mining and SIC Code 2813—Industrial Gases.

(2) A person is not subject to this Part if the chemical substances that person causes to be produced are limited to:

(i) Chemical substances that result from chemical reactions that occur incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(ii) Chemical substances that result from chemical reactions that occur incidental to storage or disposal of other chemical substances, mixtures, or articles.

(iii) Chemical substances that result from chemical reactions that occur upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleaners or other housekeeping products, fuel additives, water softening and treatment agents, photographic films, batteries, matches, or safety flares, and that are not themselves manufactured or imported for distribution in commerce for use as chemical intermediates.

(iv) Chemical substances that result from chemical reactions that occur upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance.

(v) Chemical substances that result from chemical reactions that occur when (A) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation-inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH adjuster, sequestrant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or (B) a chemical substance, which is intended solely to impart a specific physicochemical characteristic, functions as intended.

(b) [Reserved]

(c) *Sole distributors.* A person solely engaged in the distribution of chemical substances is exempt from this part, unless such person is also a manufacturer or processor subject to this part. For example, a "distributor" who repackages chemical substances or mixtures is considered to be a processor and, thus, is not a sole distributor. Sole distributors may include, but are not limited to, those firms that distribute chemical substances as described in the wholesale trade SIC codes 5161—Chemicals and Allied Products, 5171—Petroleum Bulk Stations and Terminals, and 5172—Petroleum and Petroleum Products Wholesalers, Except Bulk Stations and Terminals.

(d) *Retailers.* A person who is a retailer is exempt from this part unless such person is also a manufacturer or a processor subject to this part.

[48 FR 38187, Aug 22, 1983, as amended at 50 FR 46770, Nov. 13, 1985]

§ 717.10 Allegations subject to this part.

(a) Allegations subject to this part are those allegations received on or after November 21, 1983 by persons subject to this part.

(b) Allegations subject to this part are those that:

(1) Are submitted either in writing and are signed by the alleger, or are submitted orally. In the case of an oral allegation, the firm must transcribe the allegation into written form, or it must inform the alleger that such allegation may be subject to this part and request that the alleger submit such allegation to the firm in writing and signed.

(2) Implicate a substance that caused the stated significant adverse reaction by one of the following:

(i) Naming the specific substance.

(ii) Naming a mixture that contains a specific substance.

(iii) Naming an article that contains a specific substance.

(iv) Naming a company process or operation in which substances are involved.

(v) Identifying an effluent, emission, or other discharge from a site of manufacturing, processing or distribution of a substance.

(c) Allegations subject to this part may be made to a firm by any person, such as an employee of the firm, individual consumer, a neighbor of the firm's plant, another firm on behalf of its employees or an organization on behalf of its members.

(d) EPA intends that firms should, to the maximum practical extent, provide allegers with information regarding the ultimate disposition of their allegations. For example, firms could provide a brief notice to the alleger stating that a record was created under this part based upon their allegation, or that a record was not created and briefly explain the reasons why not.

§ 717.12 Significant adverse reactions that must be recorded.

(a) Except as provided in paragraph (b) of this section, significant adverse reactions to human health that must be recorded include but are not limited to:

(1) Long-lasting or irreversible damage, such as cancer or birth defects.

(2) Partial or complete impairment of bodily functions, such as reproductive disorders, neurological disorders or blood disorders.

(3) An impairment of normal activities experienced by all or most of the persons exposed at one time.

(4) An impairment of normal activities which is experienced each time an individual is exposed.

(b) Firms are not required to record significant adverse reactions that are known human effects as defined in § 717.3(c).

(c) Except as provided in paragraph (d) of this section, significant adverse reactions to the environment that must be recorded, even if restricted to the environs of a plant or disposal site, include but are not limited to:

(1) Gradual or sudden changes in the composition of animal life or plant life, including fungal or microbial organisms, in an area.

(2) Abnormal number of deaths of organisms (e.g., fish kills).

(3) Reduction of the reproductive success or the vigor of a species.

(4) Reduction in agricultural productivity, whether crops or livestock.

(5) Alterations in the behavior or distribution of a species.

(6) Long lasting or irreversible contamination of components of the physical environment, especially in the case of ground water, and surface water and soil resources that have limited self-cleansing capability.

(d) Firms are not required to record a significant adverse reaction to the environment if the alleged cause of that significant adverse reaction can be directly attributable to an accidental spill or other accidental discharge, emission exceeding permitted limits, or other incident of environmental contamination that has been reported to the Federal Government under any applicable authority.

(Approved by the Office of Management and Budget under control number 2070-0017)

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984]

§ 717.15 Recordkeeping requirements.

(a) *Establishment and location of records.* A firm subject to this part shall establish and maintain records of significant adverse reactions alleged to have been caused by chemical substances or mixtures manufactured or processed by the firm. Such records shall be kept at the firm's headquarters or at any other appropriate location central to the firm's chemical operations.

(b) *Content of records.* The record shall consist of the following:

(1) The original allegation as received.

(2) An abstract of the allegation and other pertinent information as follows:

(i) The name and address of the plant site which received the allegation.

(ii) The date the allegation was received at that site.

(iii) The implicated substance, mixture, article, company process or operation, or site discharge.

(iv) A description of the alleger (e.g., "company employee," "individual consumer," "plant neighbor"). If the allegation involves a health effect, the sex and year of birth of the individual should be recorded, if ascertainable.

(v) A description of the alleged health effect(s). The description must relate how the effect(s) became known and the route of exposure, if explained in the allegation.

(vi) A description of the nature of the alleged environmental effect(s), identifying the affected plant and/or animal species, or contaminated portion of the physical environment.

(3) The results of any self-initiated investigation with respect to an allegation. (EPA does not require persons subject to this part to investigate allegations received, and no provision of this part shall be construed to imply that EPA recommends, encourages or requires such investigation.)

(4) Copies of any further required records or reports relating to the allegation. For example, if an employee allegation results in a requirement for the firm to record the case on Occupational Safety and Health Form 101 or appropriate substitute (see 29 CFR Part 1904 for requirements under the Occupational Safety and Health Act of 1970), a copy of that OSHA record must be included in the allegation record.

(c) *File structure.* Records must be retrievable by the alleged cause of the significant adverse reaction, which cause may be one of the following:

(1) A specific chemical identity.

(2) A mixture.

(3) An article.

(4) A company process or operation.

(5) A site emission, effluent or other discharge.

(d) *Retention period.* Records of significant adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. This provision requires persons subject to this part to retain for 30 years an employee health related allegation, arising from any employment related exposure, whether or not such allegation was submitted by or on the behalf of that recordkeeper's own employee. Any other record of significant adverse reactions shall be maintained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record.

(e) *Transfer of records.* (1) If a firm ceases to do business, the successor must receive and keep all the records that must be kept under this part.

(2) If a firm ceases to do business and there is no successor to receive and keep the records for the prescribed period, these records must be transmitted to EPA. See § 717.17(c) for the address to which such records must be sent.

(Approved by the Office of Management and Budget under control number 2070-0017)

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984]

§ 717.17 Inspection and reporting requirements.

(a) *Inspection.* Firms must make records of allegations available for inspection by any duly designated representative of the Administrator.

(b) *Reporting.* Each person who is required to keep records under this part must submit copies of those records to the Agency as required by the EPA Administrator or appropriate designee. EPA will notify those responsible for reporting by letter or will announce any such requirements for submitting copies of records by a notice in the FEDERAL REGISTER. Such letter or notice will be signed by the Administrator or appropriate designee, and will specify which records or portion of records must be submitted. The reporting period will be specified by the letter or notice but in no case will such reporting period be less than 45 days from the date of the letter or the effective date of the notice.

(c) *How to report.* When required to report, firms must submit copies of records (preferably by certified mail) to the Document Control Officer, Office of Pesticides and Toxic Substances (TS-793), Environmental Protection Agency, Washington, DC 20460.

(Approved by the Office of Management and Budget under control number 2070-0017)

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984]

§ 717.19 Confidentiality.

(a) Any person submitting copies of records may assert a business confidentiality claim covering all or part of the submitted information. Any information covered by a claim will be disclosed by EPA only as provided in procedures set forth at Part 2 of this title.

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

(c) To asset a claim of confidentiality for information contained in a submitted record, the respondent must submit two copies of the document.

(1) One copy must be complete. In that copy, the respondent must indicate what information, if any, is claimed as confidential by marking the specific information on each page with a label such as "confidential", "proprietary", or "trade secret" and briefly state the basis of the claim.

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

(3) The first copy will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of receipt of notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public file.

PART 720—PREMANUFACTURE NOTIFICATION

Subpart A—General Provisions

Subpart B—Applicability

Subpart C—Notice Form

Subpart D—Disposition of Notices

Subpart E—Confidentiality and Public Access to Information

Subpart F—Commencement of Manufacture or Import

Subpart G—Compliance and Inspections

VISTA
Vista Chemical Company
Vista Polymers Inc.

Report of a Possible Adverse Effect To Health or the Environment

If you think a chemical substance or mixture has caused an adverse human effect, identify that substance and describe how affected. If you think the environment (for example, the air, water, soil, animals, or plants) has been adversely affected by one of the facility's chemical substances or mixtures, identify the substance (if known) and the affected plant and/or animal or contaiminated area of the environment.

If you cannot identify the suspected chemical substance or mixture, identify the product, material, or item believed to be the cause of the adverse effect or describe the process or operation or the effluent, emission, or discharge from the facility that you think has caused the adverse effect.

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_____ _____

Signature of Reporter Date of Report

_____ _____

Name of Reporter (Printed) Date Adverse Effect Occured

Send Completed Form To:

_____

_____

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VVV 000011019

TOXIC SUBSTANCES CONTROL ACT (TSCA) RECORDING AND REPORTING REQUIREMENTS UNDER SECTIONS 8(c) AND 8 (e)

Responsibilities for You and VISTA

TSCA requires Vista Chemical to follow certain record keeping and reporting procedures if adverse effects arise from the manufacture, processing or distribution of our products. If significant adverse reactions to human health or to the environment are suspected, Vista Chemical must keep records of the allegations. If substantial risk of injury to health or the environment results from our operations, Vista Chemical must report the situation to the Environmental Protection Agency (EPA).

Vista Chemical intends to comply fully with the provisions of this law and its regulations...and wants all employees to assist.

What Should You Report?

Significant adverse reactions from exposure to chemical substances which substantially impair your normal activities or cause long-lasting damage to your health or to the environment should be brought to the attention of your supervisor. Any information which leads to a belief that a substance poses a substantial risk to health or the environment should also be brought to the attention of your supervisor. Conclusive proof of adverse reactions or substantial risk is not necessary.

What Not to Report

Information need not be reported if we are sure that EPA already has it. Information in published EPA reports, scientific literature, or in technical and trade journals should not be reported. Some information submitted to EPA or other federal agencies as part of mandatory reporting requirements of other laws (e.g., oil spills) may also be excluded from the notification requirements.

How You Initiate a Report

Supervisors have a supply of the forms which you must use for reporting any information.

Ask your supervisor for assistance if you need help in completing the form.

How Vista Chemical Meets the Law's Requirement

All Vista Chemical departments have established procedures which enable employees to provide written reports of significant adverse reaction or of substantial risk to health or the environment. Qualified professionals within the company will evaluate the submission. If the information is determined to be recordable or reportable to EPA, Vista Chemical will take appropriate actions.

You will receive a written reply on how your submittal was handled.

VVV 000011020

September 1986

But the Du Pont projects, to be constructed throughout the 1990s, constitute by far the largest effort to put nylon production capability in the region. At the moment, Monsanto (St. Louis), which has all of its nylon production in the U.S., says it has no plans to make the material in Asia. And while ICI (London) has proposed building a $255-million purified terephthalic acid plant for the region, the company's interest in the region "doesn't include nylon," according to a spokesman.

"Du Pont is the major supplier of nylon," says Robert M. Aiken, group vice president/petrochemicals. "By the year 2000, we should have the same market share [in Asia] that we have in the rest of the world, which is 25%." Aiken says Du Pont has "a very small market share" in Asia—less than 5%.

Du Pont will first build an adipic acid plant, partly, says Aiken, because the intermediate is "somewhat short" globally. The $200-million plant, expected on stream in 1993, will be located in Singapore. Its projected capacity of more than 200 million lbs/year will hike Du Pont's adipic acid capacity to more than 1.5 billion lbs/year. Recently, Du Pont expanded its other adipic acid facilities in Maitland, ON and Victoria, TX; it has also been authorized to expand at Sabine River Works, TX, but it is not specifying by how much.

Aiken says the Singapore plant will be Du Pont's "core facility" in the region. It will have polymerization capability, expected on-line in 1993, to serve compounding plants that will be built or expanded in Korea, Japan, and Singapore. In the late '90s the company plans world-scale production capability in the region for adiponitrile and hexamethylene diamine.

ELLEN GOLDBAUM

EPA GETS TOUGH ON TSCA

The Environmental Protection Agency has issued warning to U.S. chemical companies that they may be breaking the law by withholding key risk-assessment data from the agency. In a letter to 700 companies, Charles Elkins, EPA's director/office of toxic substances, warned the companies not to substitute their own risk criteria for those mandated by section 8(e) of the Toxic Substances Control Act (TSCA). The EPA move signals a stronger "proactive effort" to enforce the law, notes Elkins.

Under section 8(e), all companies that make, process, or ship chemicals must report within 15 days to EPA any new information "that reasonably supports a conclusion that [a substance] presents a substantial risk of injury to health or the environment," Elkins says in the letter. Du Pont (Wilmington, DE), Monsanto (St. Louis), Dow Chemical (Midland, MI), and American Cyanamid (Wayne, NJ) were among the companies to which EPA sent the letter, says an agency spokesman.

Sending such a letter "is not common" procedure, says Elkins. He explains that the agency had run across "a number of cases" showing that some companies were interpreting the law differently. "Based on these recent events, we're going to be putting much more emphasis on this section of [TSCA]," he says. Companies "will be hearing from us in less gentle ways." Elkins says he sent the letter because he "thought it would be helpful to give them an early warning, so when inspectors arrive no one will be surprised."

Earlier this month Monsanto agreed to pay EPA $196,230 for a section 8(e) violation. Monsanto also must review all past toxicology studies to determine the extent of its compliance. That probably will be an expensive undertaking, says Elkins, as each violation calls for a fine of $25,000/day. Such fines will be assessed for the approximately 100 reports Monsanto will send to EPA, he says.

Says a Monsanto spokeswoman, "We interpreted [TSCA] one way; EPA interpreted it another." She maintains that the agency's guidance on the law "changed over time" from what was first given to Monsanto. Replies Elkins: "If that were really the case, they could have taken it to court. We feel we interpreted the act consistently." Monsanto's differing view "may be in the eye of the beholder," he says.

Dow does not substitute its judgment for EPA's, according to Joseph LeBeau, director/health and environmental sciences for the company. If a material shows toxicity but exhibits no biologically or statistically significant risk, Dow may run another study on it, says LeBeau. But if there's reason to suspect a cause-and-effect relationship between a substance and a threat to human health, Dow reports it, he adds.

KEN STERNBERG

...as required by the law, EPA has defined ... significant adverse reactions to human health or the environment, as follows:

> Significant adverse reactions are reactions that may indicate substantial impairment of normal activities or long-lasting or irreversible damage to health or the environment.

Examples of significant adverse reactions to human health include:

- Long lasting or irreversible damage, such as cancer or birth defects.
- Partial or complete impairment of bodily functions, such as blood, reproductive, or neurological disorders.
- An impairment of normal activities, which is experienced by all or most of the persons exposed at one time.
- An impairment of normal activities, which is experienced each time an individual is exposed.

Examples of significant adverse reactions to the environment include:

- Gradual or sudden changes in the composition of animal or plant life in an area.
- An abnormal number of deaths of organisms (e.g., fish kills).
- A reduction of the reproductive success or vigor of a species.
- A reduction in agricultural productivity, whether crops or livestock.
- Alterations in the behavior or distribution of a species.
- Long lasting or irreversible contamination of components of the physical environment such as groundwater or soil.

The Toxic Substances Control Act (TSCA) was signed into law in October 1976. The purpose of TSCA is to ensure that chemical substances and mixtures are regulated in a manner that ensures that they do not present an unreasonable risk of injury to health or the environment.

This brochure provides a summary of the major provisions of EPA's TSCA Section 8(c) final rule, 40 CFR 717, which was published in its entirety in the August 22, 1983 *Federal Register*, Volume 48, Page 38178, and became effective on November 21, 1983.

It was the intent of Congress when it passed the Toxic Substances Control Act (TSCA) that the public be made aware of potential hazards to human health and the environment, and of the action to take if exposure takes place. This brochure has been developed to help inform you about this new TSCA 8(c) rule.

If you have questions beyond those covered here, please contact the TSCA Assistance Office:

Long Distance: (800) 424-9065
Washington, DC: (202) 554-1404

Answers to Your Questions About the TSCA Section 8(c) Rule

Office of Toxic Substances
Environmental Protection Agency

About the 8(c) Rule

EPA has issued a regulation that will, for the first time, require the chemical industry to keep records of allleged "significant adverse reactions" to chemical substances and mixtures. This is being done under the authority of Section 8(c) of the Toxic Substances Control Act (TSCA).

The Rule requires the chemical industry to keep these allegations on record for thirty (30) years in the case of employee health, and for five (5) years in all other cases. EPA can inspect such records and require that the industry report the information contained in such records to the Agency.

What Is an Allegation?

A worker on a new chemical process line tells his supervisor that he is experiencing spells of hand tremors and blurred vision while on the job. He thinks the problem is caused by the vapors he breathes in while refilling a mixing tank. His supervisor asks him to fill out and sign a brief form describing his problem. The worker does so. This is an 8(c) allegation.

Briefly, an allegation is a statement of an individual's belief that a chemical substance, mixture, etc., has caused harm to him, another person, or to the environment. But he is not required to provide proof or evidence of the adverse reaction.

The TSCA Section 8(c) rule defines an allegation as a "statement made without formal proof or regard for evidence, that a chemical substance or mixture caused a *significant adverse reaction* to human health or the environment."

Who Can Make an Allegation?

Any person can make an allegation.

This includes anyone who has experienced or witnessed a "significant adverse reaction to human health or the environment."

In addition to individual company employees, consumers, or plant neighbors, allegations can be submitted by one person or a group on behalf of another person or group. For example, a person could make an allegation on behalf of an injured or deceased relative, or a union representative could make an allegation on behalf of one or more members.

What Allegations Are Recordable?

The TSCA Section 8(c) rule is in *no way* attempting to limit or dictate the kinds of complaints or the content of allegations that a worker or any other citizen may make. Some companies may, as a matter of policy, keep every allegation they receive. But persons who submit allegations should be aware that under the 8(c) rule, industry is only *required* to record allegations that meet certain criteria. With this in mind, here are some basic suggestions for structuring an allegation.

Sign Any Written Allegation

- Companies subject to the rule are not required to record unsigned written allegations.
- Companies must also deal with oral allegations, but may do so in one of two ways - either by transcribing the allegation as orally presented to them, or by requesting that the alleger submit it in writing.

Link Cause with Effect

The allegation must make a link between a particular company's product, process, or effluent and the human health or environmental effect.

Clearly State What Caused the Reaction

It is very important that the cause of the reaction be clearly identified. This is important because companies will be acting such allegations by the chemical or other substance reported as a cause of the reaction. But, you don't have to know the exact chemical identity of the causative agent. You can cite a cause by:

- Naming the specific substance;
- *Naming a mixture* that contains a specific substance (e.g., a product brand name);
- Naming an article that contains a specific substance;
- Naming a company process or operation in which substances are involved; or
- Identifying an effluent emission, or other discharge from a site of manufacturing, processing, or distribution of a substance.

Fully Describe the Adverse Reaction

The nature of the adverse reaction should be explained. If the reaction is a health effect, it would be helpful to explain how you discovered it and how you feel you were exposed. If the adverse reaction is an environmental effect, identify as best you can the affected plants, animals, or the contaminated part of the environment as well as the kind of reaction you observed.

Significant Adverse Reactions

Finally, the industry is only required to record "significant adverse reactions."