TSCA Section 8(e) Reporting Guide

June 1991

NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS. Any person who manufactures, [imports,] 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 [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

-- Section 8(e), Toxic Substances Control Act (1976)

Office of Toxic Substances
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, D.C. 20460

Preface

This "reporting guide" has been compiled by EPA's Office of Toxic Substances (OTS) to assist potential respondents who manufacture, import, process or distribute chemical substances in complying with Section 8(e), the substantial risk information reporting provision of the Toxic Substances Control Act (TSCA).

There are two major objectives for presenting this guide. First, the guide will make certain information pertaining to Section 8(e) reporting even more accessible to members of the the regulated community and others. Second, the guide will provide reference to both general and specific examples of submitted information as well as EPA's comments regarding such submissions. The examples are intended to help persons who are subject to Section 8(e) understand better the types of information that should be submitted to the Agency under this very important mandatory hazard/risk information reporting provision of TSCA.

Most of this TSCA Section 8(e) reporting guide is presented in a basic question and answer format reflecting primarily the most common questions asked about Section 8(e) of TSCA. In addition, this reporting guide contains EPA's comments regarding the TSCA Section 8(e)-applicability/reportability of a number of toxicologic "case studies" provided by the Chemical Manufacturers Association (CMA). The guide also contains an index of Section 8(e) "status reports" reflecting Section 8(e) reporting guidance (Appendix A) and an index of all status reports prepared to date arranged by submitted information type (Appendix B).

EPA recommends that this TSCA Section 8(e) reporting guide be used as a tool in conjunction with EPA's March 16, 1978, Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110). EPA's TSCA Section 8(e) policy statement is included as Appendix C at the back of this reporting guide. Also included is Appendix D which contains a copy of a February 1, 1991 Federal Register notice that announced EPA's TSCA Section 8(e) "Compliance Audit Program" (CAP) and copies of EPA's April 26, 1991 and encoded June 20, 1991 Federal Register notices announcing certain modifications to the CAP.

This reporting guide is being distributed publicly through the TSCA Assistance Information Service (TSCA Hotline) in the Environmental Assistance Division (EAD/OTS). Persons wishing to obtain a copy of the guide should contact the TSCA Hotline. The telephone numbers, telefax numbers and/or addresses of the TSCA Hotline, other EPA Offices, and other organizations cited throughout this guide are presented for the reader's convenience on the next few pages.

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TSCA Hotline

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Address: TSCA Assistance Information Service
Environmental Assistance Division
Office of Toxic Substances (TS-799)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

TSCA Section 8(e) Document Processing Center

Address: Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
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"For Your Information" (FYI) Document Processing Center

Address: Document Processing Center (TS-790)
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Office of Toxic Substances
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TSCA Section 8(e) and FYI Document Control Officer

Name: Michel Stewart

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(202) 260-1532 (after 8/24/91)

TSCA Confidential Business Information (CBI) Issues

Address: Confidential Data Branch
Information Management Division
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 475-7425
(202) 260-0425 (after 8/24/91)

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Name: Jacqueline Favilla

Phone: (202) 475-8823
(202) 260-8823 (after 8/24/91)

Public Docket/Office of Toxic Substances

Address: OTS Public Docket
Room G-004, NorthEast Mall
U.S. Environmental Protection Agency
401 "M" Street S.W.
Washington, D.C. 20460

Hours of Operation: 8-12 and 1-4 Monday through Friday
(Closed on Federal Holidays)

Freedom of Information Office/EPA

Address: Freedom of Information Office (A-101)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Office of Compliance Monitoring

Address: Office of Compliance Monitoring (EN-342)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 382-3807
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Office of General Counsel

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U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 382-7505
(202) 260-7505 (after 8/24/91)

Office of Enforcement

Address: Pesticides and Toxics Enforcement Division
Office of Enforcement (LE-134-P)
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Phone: (202) 475-8690
(202) 260-8690 (after 8/24/91)

National Response Center

Toll-Free: (800) 424-8802

Local: (202) 426-2675

EPA Regional Office 24-Hour Phone Numbers

Region 1	(617) 223-7265	Region 6	(214) 655-2222
Region 2	(201) 548-8730	Region 7	(913) 236-3778
Region 3	(215) 597-9898	Region 8	(303) 293-1788
Region 4	(404) 347-4062	Region 9	(415) 744-2000
Region 5	(312) 353-2318	Region 10	(206) 442-1263

National Technical Information Service

Address: National Technical Information Service (NTIS)
U.S. Department of Commerce
5285 Port Royal Road
Springfield, Virginia 22161

Phone: (703) 487-4600

National Library of Medicine (NLM)

Address: National Library of Medicine
U.S. Department of Health and Human Services
8600 Rockville Pike
Bethesda, Maryland 20894

Phone: (301) 496-6193

Chemical Information Systems, Inc. (CIS)

Address: Chemical Information Systems, Inc.
7215 York Road
Baltimore, Maryland 21212

Phone: (800) CIS-USER (Toll-Free)

(301) 321-8440 (Local)

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REPORTING UNDER SECTION 8(E) OF TSCA

WHAT IS THE STATUTORY LANGUAGE OF TSCA SECTION 8(E)?

Section 8(e) of the Toxic Substances Control Act (TSCA) states that "any person who manufactures [including imports], 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 [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." [90 Stat. 2029, 15 U.S.C. 2607(e)]

WHY IS SECTION 8(E) REPORTING IMPORTANT?

In general, EPA considers Section 8(e) of TSCA to be a critically important information gathering tool that serves as an "early warning" mechanism for keeping the Agency and others apprised of new-found serious chemical hazards and/or exposures; Section 8(e) data are extremely valuable input for the hazard identification and risk assessment activities within and outside EPA.

HOW WAS EPA'S SECTION 8(E) POLICY STATEMENT DEVELOPED?

The Section 8(e) information reporting requirement took effect on January 1, 1977, the effective date of TSCA. Although Section 8(e) contains self-implementing reporting requirements, EPA sought public comment and input in order to make more informed decisions regarding implementation of Section 8(e). Following receipt and consideration of numerous public comments on a September 9, 1977 proposed policy statement, EPA published its March 16, 1978 final Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FEDERAL REGISTER 11110). The 1978 policy statement clarifies the types of information that are required for submission under Section 8(e), and describes the procedures for reporting such information to EPA. A minor technical amendment to EPA's 1978 TSCA Section 8(e) policy statement involved a change in the address to which Section 8(e) notices are to be sent (52 FEDERAL REGISTER 20083; May 29, 1987). For easy referral when using this reporting guide, the Agency's Section 8(e) policy statement has been reproduced as Appendix C at the back of the guide.

WHAT IS "SUBSTANTIAL RISK" INFORMATION?

The term "substantial risk" information refers to that information which reasonably supports a conclusion that the subject chemical or mixture presents a substantial risk of injury to health or the environment[1]; however, such information need not and most typically does not establish conclusively that a substantial risk exists.

In deciding whether information is "substantial risk" information, one must consider 1) the seriousness of the adverse effect, and 2) the fact or probability of the effect's occurrence. In determining TSCA Section 8(e)-applicability/reportability, these two criteria should be weighted differently depending upon the **seriousness of the effect** or the **extent of the exposure**, i.e., the more serious the effect, the less heavily one should weigh actual or potential exposure, and vice versa. For example, in cases where serious effects such as birth defects or cancer (as evidenced by benign and/or malignant tumors) are observed, the mere fact that the implicated chemical is in commerce (including chemicals at the research and development stage) constitutes sufficient evidence of exposure to submit the new-found toxicity data.

EPA has also received numerous Section 8(e) submissions alerting the Agency that chemical substances already known to be capable of causing serious health and/or environmental effects were detected in significant amounts in environmental media (e.g., soil, surface waters, groundwater, air (including workplace air)) or in products not known previously by the Agency to contain such chemicals. In such cases, the discovery of previously unknown and significant human and/or environmental exposure, when combined with knowledge that the subject chemical is already recognized or suspected as being capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious environmental effects (e.g., non-trivial aquatic species toxicity), can provide a sufficient basis to report the new-found exposure data to EPA under Section 8(e) of TSCA.

The decision-making process for Section 8(e)-reportability should focus primarily on whether the toxicity or exposure information offers **reasonable support** for a conclusion of substantial risk under the criteria described above, but should **not** focus at all on whether the information is conclusive regarding the risk. A

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[1] "Substantial risk" information must be reported to EPA unless the subject person has actual knowledge that the Agency has been adequately informed of such information. A detailed discussion of the types of information about which EPA considers itself to be adequately informed is presented on Page 8 of this reporting guide under **WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?**

decision to report information to the Agency under Section 8(e) should not involve exhaustive health and/or environmental risk assessments of the subject chemical(s). Further, determining reasonable support for a conclusion of substantial risk should not include any evaluation of either the economic or social benefits of the use(s) of the subject chemical substance(s). Finally, determining whether reasonable support exists for "substantial risk" is not synonymous with the determination of an "unreasonable risk" as that term is used elsewhere in TSCA.

WHO IS SUBJECT TO SECTION 8(E) REPORTING?

For the purposes of Section 8(e), the term "person" includes the following: any natural person, corporation, firm, company, sole-proprietorship, joint-venture, partnership, association, or any other business entity, any State or political subdivision of a State, any municipality, any interstate body, and any department or agency of the Federal Government.

Such "persons" are subject to TSCA Section 8(e) only to the extent they are engaged in commercial activities involving manufacture, importation, processing or distribution of chemical substances or mixtures under the jurisdiction of TSCA and therefore covered by Section 8(e) of TSCA. While it is clear that entities such as labor unions, trade associations, contract testing laboratories and agencies of the Federal Government are "persons" covered by TSCA Section 8(e), the mandatory obligation to report substantial risk information is incurred only to the extent that the entity is engaged commercially in manufacturing, importing, processing or distribution of the chemical substance or mixture about which substantial risk information is obtained; however, these particular entities are not typically involved in such commercial activities.

Under Section 8(e), there are **no exemptions** for small businesses, small production or importation volumes, or commercial activities such as manufacture for export only or research and development. However, Section 8(e) does not require a subject person to submit information about a chemical substance or mixture that the person does not manufacture, import, process or distribute commercially. Further, a person who obtains substantial risk information about a chemical or mixture that the person did at one time, but does not any longer, manufacture, import, process or distribute in commerce, is not required to submit the information under Section 8(e).

Despite these limitations in coverage, EPA has received numerous Section 8(e) submissions from respondents who obtained otherwise reportable Section 8(e) information but for some technical reason did not have any statutory obligation to submit the information to EPA pursuant to Section 8(e). EPA believes that such submissions are of significant benefit, in many cases, to others who currently

handle the subject chemical(s) and who can take actions that are designed generally or specifically to reduce or eliminate health or environmental hazards/risks. A formal TSCA Section 8(e) or "For Your Information" (FYI) notice under these circumstances is a clear demonstration of the respondent's stewardship. EPA encourages and welcomes these technically voluntary submissions either pursuant to Section 8(e) or on an FYI basis.

In implementing Section 8(e) of TSCA, EPA strives to ensure that pertinent information is reviewed promptly, and given appropriate consideration, by subject persons for submission to EPA, while at the same time minimizing duplicative or ill-considered notices. The Agency believes these objectives are served best by allowing commercial establishments to assume the exclusive responsibility to submit substantial risk information that is obtained by individual employees and officials. Accordingly, EPA's Section 8(e) policy statement explains that individual officers/employees are viewed as having discharged their individual Section 8(e) responsibilities once they notify a designated supervisor or official in full about pertinent information, **provided** that the employing entity has an established, internally publicized and affirmatively implemented procedure governing such notices. The Agency's Section 8(e) policy statement specifies that such procedures, at a minimum, must:

(1) specify the information that must be reported;

(2) indicate how the reports are to be prepared and submitted internally;

(3) note the Federal civil and criminal penalties for failure to report substantial risk information; and

(4) provide a mechanism for the timely notification of officers and employees who submitted reports about the disposition of those reports. Such notification should inform the reporting employee/officer as to whether or not the information was submitted to EPA, and if not, inform the employee or officer of their protected right (under Section 23 of TSCA) to report the information directly to EPA.

The Agency believes that the above procedures serve to ensure prompt and appropriate processing and consideration of pertinent information by persons subject to Section 8(e) of TSCA. It is important to note, however, that despite the establishment of such procedures, those employees and officers who are responsible for actual management of the organizations's Section 8(e) reporting obligations retain personal civil and/or criminal liability for ensuring that substantial risk information is submitted to the Agency. In the absence of such established internal procedures, all employees and officers retain their individual responsibilities and liabilities for ensuring that substantial risk information is reported to EPA.

WHAT CHEMICALS ARE SUBJECT TO SECTION 8(E) REPORTING?

Chemicals not under TSCA jurisdiction and therefore not covered by Section 8(e) are discussed in Section 3 of TSCA and include:

(1) pesticides (as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)) when manufactured, processed, or distributed in commerce for use as a pesticide;

(2) tobacco and tobacco products;

(3) source materials, special nuclear materials and byproducts (as defined in the 1954 Atomic Energy Act (AEA) and regulations issued under the AEA);

(4) foods, food additives, drugs, cosmetics, and devices (as defined in the Federal Food, Drug and Cosmetic Act (FFDCA)) when manufactured, processed or distributed in commerce as a food, food additive, drug, cosmetic or device.

Except for those chemicals specifically excluded by definition from TSCA jurisdiction, Section 8(e) of TSCA pertains to all chemical substances and mixtures **including but not limited to** the following:

(1) research and development (R&D) chemicals (including those intended for use as pesticides prior to application for an Experimental Use Permit (EUP) or a registration under FIFRA);

(2) laboratory reagents;

(3) low volume chemicals;

(4) polymers;

(5) chemicals that are manufactured solely for export;

(6) intermediates (including non-isolated intermediates as well as pesticide intermediates);

(7) catalysts;

(8) byproducts;

(9) impurities;

(10) TSCA-covered microorganisms and products therefrom.

Specifically with regard to "pesticides," a chemical substance that is manufactured, processed or distributed in commerce solely as a pesticide is excluded by Section 3 of TSCA from TSCA regulation. However, **a chemical substance which is in the process of research and development (R&D) as a pesticide is subject to TSCA until such time as the manufacturer or importer demonstrates the intent to**

produce a pesticide by submitting to the Agency an application for an "Experimental Use Permit" (EUP) or registration under FIFRA. For further information about this TSCA/FIFRA jurisdictional issue, the reader is directed to EPA's initial TSCA Chemical Substance Inventory reporting regulation (43 FR 64585; December 23, 1977; Appendix A Comment 37, 38 and 39) and the 1986 amendments to the TSCA Section 5 "Premanufacture Notification Rule" (51 FR 15098; April 22, 1986). Prior to the FIFRA EUP or registration stage, such R&D materials are chemical substances under the jurisdiction of TSCA including Section 8(e).

It is important to note also that while some rules promulgated by EPA under other sections of TSCA, or under other authorities which are administered by EPA, may exempt certain chemical substances and/or mixtures or certain types of commercial activities, such exemptions typically apply only to the rule issued by the Agency and not to TSCA in general or Section 8(e) of TSCA specifically.

WHAT DOES THE TERM "OBTAINS INFORMATION" MEAN?

Section 8(e) pertains to information that a person possesses or about which the person knows. The Section 8(e) policy statement explains that an establishment obtains information at the time any officer or employee who is capable of appreciating the significance of the information obtains that information. "Known" information includes that information about which a prudent person of similar training, job function, etc., could be reasonably expected to know. Although Section 8(e) of TSCA does not compel subject persons to actively search for reportable information or to undertake extraordinary efforts to retrieve reportable information, negligence or the intentional avoidance of information does not absolve a person of his/her individual Section 8(e) reporting obligations. TSCA Section 8(e)-reportable information that is "obtained" by a company includes:

a) information obtained before January 1, 1977 and reviewed after January 1, 1977, but prior to March 16, 1978 (the publication date of EPA's TSCA Section 8(e) policy statement);

b) information obtained for the first time after January 1, 1977 but before March 16, 1978; or

c) information obtained by the company for the first time after March 16, 1978.

NOTE: For information regarding the specific time frames for reporting such "obtained" information, the reader's attention is directed to WHEN MUST TSCA SECTION 8(E) INFORMATION BE REPORTED TO EPA? on Page 11 of this guide.

With regard to a), b) and c) on the preceding page, Section 8(e)-reportable information includes not only written reports, memoranda and other such documents examined after January 1, 1977, but also information referred to in formal or informal discussions and conferences in which a company participated after January 1, 1977.

Specifically with regard to a public scientific conference/meeting, visually or verbally obtained information from such a meeting is subject to Section 8(e) reporting unless the obtained information is captured accurately/adequately in a meeting transcript, abstract or other such written record or document that is to be formally released to the public within a reasonable time frame. Information obtained from a private conference or meeting, however, should be considered for reporting under Section 8(e) within 15 working days.

WHAT ARE THE SOURCES OF SECTION 8(E)-REPORTABLE INFORMATION?

TSCA Section 8(e)-reportable information can come from a variety of sources including, but not limited to draft, interim or final written reports (including study reports, letters, telegrams, telex reports) or verbal reports (received at meetings or by phone) that involve observations (including preliminary observations) from, for example, controlled or uncontrolled:

(1) human or animal studies/events (including but not limited to studies/events that involve high dose levels or non-routine routes of exposure); or

(2) environmental events/studies (including but not limited to aquatic toxicity studies, bioaccumulation studies, chemical monitoring studies (supplemented if need be by information derived from computer modeling studies based on actual or reasonably anticipated chemical exposures and exposure-related parameters)). It is important to note, however, that modeling studies, including those based solely on theoretical exposure data (e.g., "worst-case" scenarios), are not considered by EPA to be sufficient in and of themselves to meet the Section 8(e) reporting requirements. Further, environmental or health risk assessments (including those using computer modeling) based on either 1) theoretical exposure data, or 2) actual exposure data submitted on a mandatory basis under an EPA-administered statute typically need not be reported under Section 8(e).

The evidence that offers reasonable support for a conclusion of substantial risk need not be complete nor definitive but should provide a plausible link between 1) an observed serious effect and one or few chemicals (e.g., in a discrete process/operation), or 2) a specific product/activity and a previously unrecognized exposure to a chemical that is known or reasonably anticipated to cause serious adverse health or environmental effects.

EPA's March 16, 1978 Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110) also requires immediate reporting of "Emergency Incidents of Environmental Contamination" (EIEC). An EIEC is an environmental contamination (accidental or intentional in nature) involving a chemical known to be a serious human or environmental toxicant and which because of the extent, pattern and amount of the contamination (1) seriously threatens humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation (e.g., neurotoxicologic effects, serious reproductive system effects), or (2) seriously threatens non-human organisms with large-scale or ecologically significant population destruction.

WHAT INFORMATION IS NOT REPORTABLE UNDER SECTION 8(E)?

There are several kinds of information about which the Agency considers itself to be adequately informed already for the purposes of Section 8(e) of TSCA. For example, information that otherwise meets the criteria for Section 8(e) reporting need not be submitted **if** the information meets one or more of the following criteria:

(1) is contained in an EPA study or report.

(2) is published in the open scientific literature.

(3) has been submitted already to EPA under another mandatory reporting provision of 1) TSCA, or 2) some other authority that is administered by EPA.

(4) is contained in a formal publication/report or a formal statement made available to the general public by another Federal agency.

(5) is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species, strain, etc.) of a **well-established** adverse effect.

It is important to note, however, that information that newly identifies a serious toxic effect **at a lower dose level** for example, or **confirms a serious effect that was previously only suspected**, is **not** considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.

(6) is information for which the EPA Administrator has waived compliance with TSCA in general or Section 8(e) specifically upon a request and determination of the President of the United States that such a waiver is required in the interest of the national defense; Section 22 of TSCA outlines the procedures by which such waivers are to be requested/issued.

With regard to item (2) on the preceding page, EPA believes that for the purposes of Section 8(e) reporting, a subject person need not report information that is obtained from well-established/well-recognized scientific journals, such as those typically abstracted in a) major computerized abstract data bases, or 2) publications such as **Current Contents** published by the Institute for Scientific Information (ISI), Inc. (Philadelphia, Pennsylvania). Similarly, information that is obtained from major U.S. news publications (e.g., newspapers or news magazines with national circulation) or nationally broadcast U.S. radio and/or television news reports typically need not be submitted to EPA under Section 8(e) of TSCA. However, with regard to information obtained from lesser known scientific journals, or from other magazines, newspapers, radio or television reports, a subject person must have actual knowledge that EPA has been adequately informed about such information.

Specifically with regard to item (3) on the preceding page, it is clear that information submitted or otherwise formally reported (within 15 working days of obtaining the information) pursuant to a mandatory reporting requirement of a statute administered by EPA **need not be submitted** duplicatively under Section 8(e) of TSCA. Part VII(b) of EPA's March 16, 1978 Section 8(e) policy statement is illustrative in that it provides a list of only a few such EPA-administered statutes. The following is a more current list of the statutes administered by EPA.

Toxic Substances Control Act (**TSCA**)

Federal Insecticide, Fungicide and Rodenticide Act (**FIFRA**)

Clean Air Act (**CAA**)

Clean Water Act (**CWA**)

Safe Drinking Water Act (**SDWA**)

Federal Water Pollution Control Act (**FWPCA**)

Marine Protection, Research and Sanctuaries Act (**MPRSA**)

Resource Conservation and Recovery Act (**RCRA**)

RCRA Hazardous and Solid Waste Amendments (**HSWA**)

Comprehensive Environmental Response,
Compensation and Liability Act (**CERCLA; SUPERFUND**)

Superfund Amendments Reauthorization Act (**SARA**)

Specifically with regard to item (4) on Page 8, it cannot be automatically assumed that the Agency has been adequately informed about information in a report or study by another Federal or other governmental agency if the report or study has not been formally published or otherwise released to the general public. Therefore, if a person obtains (i.e., possesses or knows of), for example, certain unpublished Section 8(e)-reportable information from a study that is conducted by or for an agency of the U.S. Government (other than EPA), that person must consider the need to immediately submit those findings under Section 8(e). Since 1977, EPA has received a number of Section 8(e) notices filed by companies who had obtained unpublished results of studies conducted by or for other Federal or other governmental agencies. In most cases, such submissions are limited to 1-2 pages and the Agency immediately establishes direct contact with the responsible agency to minimize or eliminate the company's Section 8(e) reporting burden.

HOW DOES 8(E) RELATE TO TSCA SECTIONS 4, 5 & 8(D) REPORTING?

The TSCA Section 8(e) reporting requirement applies to "substantial risk" information obtained during any study conducted under TSCA Sections 4 or 5, or any study "listed" under TSCA Section 8(d) as being underway unless such information is otherwise required to be reported immediately to EPA under 1) Sections 4, 5 or 8(d) of TSCA, 2) some other section of TSCA, or 3) some other authority that is administered by EPA. To date, the Agency has received numerous TSCA Section 8(e) notices concerning the interim results of studies conducted pursuant to Sections 4 or 5 of TSCA, or listed under Section 8(d) of TSCA. The Section 8(e) reporting that took place in these instances typically occurred because the obligation to report under Section 8(e) was incurred before reporting of the study findings was required under Sections 4, 5 or 8(d) of TSCA. If other required reporting occurs **before or coincidental with** incurring a Section 8(e) reporting obligation, that information does not need to be reported also under Section 8(e) of TSCA. This exemption does not change substantially the Section 8(e) reporting obligation; it is designed merely to avoid duplicative notices except in cases where timeliness considerations become paramount.

DOES A "FOR YOUR INFORMATION" SUBMISSION SATISFY 8(E) REQUIREMENTS?

Section 8(e)-reportable information submitted to EPA on a "For Your Information" (FYI) basis does not satisfy the requirements for the submission of information under Section 8(e). TSCA Section 8(e) information must be reported to EPA in full accordance with the procedures outlined in Part IX of the Agency's March 16, 1978 Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110)

and its technical amendment (52 FR 20083). The TSCA Section 8(e) policy statement/technical amendment appear at the back of this reporting guide as Appendix C. In addition, the reader's attention is directed to **WHERE MUST SECTION 8(E) INFORMATION BE REPORTED?** and **HOW MUST SECTION 8(E) INFORMATION BE REPORTED?** found on Page 12 and Page 13 of this reporting guide, respectively. Finally, it should be noted that EPA's Office of Compliance Monitoring (OCM/OPTS) has issued a number of "Notices of Non-Compliance" to companies that have submitted TSCA Section 8(e)-reportable information in a timely manner but simply on an FYI basis and not under Section 8(e). For further information with regard to EPA's enforcement activities relating to TSCA Section 8(e), the reader's attention is directed also to **HAS EPA TAKEN FORMAL SECTION 8(E) ENFORCEMENT ACTIONS?** which can be found on Page 27 of this reporting guide.

DOES REPORTING TO ANOTHER AGENCY SATISFY SECTION 8(E) REQUIREMENTS?

Mandatory or other reporting of information to another agency does not satisfy a company's obligation to immediately inform EPA under Section 8(e) of TSCA. EPA's TSCA Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110), which appears as Appendix C at the back of this guide, explains clearly that "substantial risk information must be reported to EPA." (emphasis added)

WHEN MUST SECTION 8(E) INFORMATION BE REPORTED?

A person is considered to have discharged the TSCA Section 8(e) reporting obligation if the information is received at EPA Headquarters in writing within 15 working days after the person obtained the information. Relevant or significant supplemental data obtained after an initial Section 8(e) submission should also be reported in writing to EPA immediately (i.e., within 15 working days). The reader's attention is directed to **WHAT DOES THE TERM "OBTAINS INFORMATION" MEAN?** found on Page 6 of this reporting guide.

For an "Emergency Incident of Environmental Contamination" (EIEC), a telephone call to the appropriate EPA Regional Office must be placed immediately (i.e., as soon as reasonably possible); these phone numbers are given in the next section of this guide. A written follow-up report must also sent to EPA Headquarters within 15 working days of the date on which the telephone report was made.

Specifically with regard to 1) Section 8(e)-reportable information obtained before January 1, 1977 and reviewed after January 1, 1977, but prior to March 16, 1978 (the publication date of EPA's TSCA Section 8(e) policy statement), or 2) Section 8(e)-reportable

information obtained for the first time after January 1, 1977 but before March 16, 1978, such information should have been submitted already to EPA on or before the 60th day following March 16, 1978.

TSCA Section 8(e)-reportable information (including pre-1977 information) that is (was) obtained by a company for the first time following March 16, 1978 should be submitted (or should have been submitted already) to EPA within 15 working days of the date on which the information is (was) obtained by the company for the first time after March 16, 1978.

WHERE MUST SECTION 8(E) INFORMATION BE REPORTED?

As explained in a technical amendment (52 FR 20083; May 29, 1987) to EPA's Section 8(e) policy statement, Section 8(e) submissions (including written follow-up reports for "Emergency Incidents of Environmental Contamination" (EIEC)) must be transmitted to EPA at the following address:

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

The initial phone report for an EIEC should be placed immediately (i.e., as soon as is reasonably possible) to the EPA Regional Office in whose jurisdiction the EIEC occurred or was discovered; the current 24-hour phone numbers for EPA's 10 Regional Offices are as follows.

Region 1	(617) 223-7265	Region 6	(214) 655-2222
Region 2	(201) 548-8730	Region 7	(913) 236-3778
Region 3	(215) 597-9898	Region 8	(303) 293-1788
Region 4	(404) 347-4062	Region 9	(415) 744-2000
Region 5	(312) 353-2318	Region 10	(206) 442-1263

In the event that a respondent cannot reach the EPA Regional Office in whose jurisdiction the EIEC occurred or was discovered, the respondent should immediately call the **National Response Center at (800)-424-8802 or 202-426-2675** and provide all known information

requested by the officer on duty. Under these circumstances, the respondent will be considered to have satisfied the initial phase of the Section 8(e) reporting obligation; a written "follow-up" report regarding the EIEC, however, must still be submitted to EPA Headquarters within 15 working days of the EIEC phone report.

Persons wishing to submit data to EPA's Office of Toxic Substances simply on a "For Your Information" (FYI) basis and not pursuant to Section 8(e) of TSCA should send the information to:

Document Processing Center (TS-790)
(Attn: FYI Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Persons submitting information to EPA on an FYI basis should be aware that the Agency's processing of documents received under mandatory reporting provisions of TSCA always takes precedence over those submitted simply as FYI. The reader should also be aware that the submission of data to the Agency on an FYI basis does not satisfy a TSCA Section 8(e) reporting obligation. For further information on this particular subject, the reader's attention is directed to **DOES A FOR YOUR INFORMATION SUBMISSION SATISFY SECTION 8(E) REQUIREMENTS?** found on Page 10 of this reporting guide.

HOW MUST SECTION 8(E) INFORMATION BE REPORTED?

Section 8(e) submissions must be transmitted to EPA in a manner that permits the Agency to verify receipt of the submission (e.g., certified or registered mail). In addition, the submission must state clearly that it is being provided under Section 8(e) of TSCA. Further, the submission must contain the name, title and telephone number of the person sending the information, the name and address of the establishment with which the reporting person is affiliated, the name(s) (including Chemical Abstract Service (CAS) Registry Number(s), if known) of the subject chemical(s), and a summary describing the nature of adverse effects or exposure being reported together with the source of any supporting technical data.

For an "Emergency Incident of Environmental Contamination" (EIEC), the initial telephone report must provide the time and location of the incident and as much of the above information as is known at the time. A written EIEC follow-up report to EPA Headquarters must contain the same types of information that are required in a non-EIEC initial Section 8(e) submission.

HOW CAN CONFIDENTIAL DATA BE CLAIMED/SENT UNDER SECTION 8(E)?

In claiming any submitted information to be "Confidential Business Information" (CBI) under TSCA, respondents should be aware that all of the information reported under specific TSCA requirements (e.g., Section 8(e)) or in support of TSCA is subject to 1) provisions of Section 14 of TSCA, and 2) EPA's regulations on confidentiality of business information (40 CFR Part 2). Any person who submits CBI to EPA under Section 8(e) should be aware that **two copies must be provided.** The first copy should be complete, with all CBI marked carefully and clearly by boxing, circling or underlining; all of the pages containing CBI should be stamped **"CONFIDENTIAL".** The other copy should have all of the confidential information excised; this "sanitized" version is required for EPA's public files. Any person who submits CBI to EPA under Section 8(e) of TSCA should also be aware that the Agency does request a **detailed written substantiation** for all TSCA CBI claims. (A copy of a two-page document entitled "Support Information for Confidentiality Claims" is included as Appendix E to this reporting guide.) Finally, a person who submits TSCA CBI to EPA under Section 8(e) should also be aware that the Agency is under no formal obligation to review, and typically does not review, company-sanitized documents for errors made in sanitizing those documents.

HOW DOES EPA IDENTIFY/TRACK INCOMING SECTION 8(E) NOTICES?

A Document Control Number is used by EPA to identify TSCA Section 8(e) submissions and takes the following form: 8EHQ-0000-0000. Starting at the left, the first four symbols identify the information as a Section 8(e) submission received by EPA Headquarters; the next four digits identify the month and year (e.g., -0591-) of the Agency's receipt of the information; the final four digits identify the submission's chronological number. In addition to the basic numerical sequence, additional characters may be added to the right end of the Document Control Number to convey other information. These additional characters and their meaning are as follows:

S: indicates that the Section 8(e) notice was sanitized to delete information claimed by the submitter to be TSCA Confidential Business Information (TSCA CBI);

P: indicates that the Section 8(e) notice contained a name or other identification (e.g., a Social Security Number) of an individual, the release of which may violate the Privacy Act; such documents are sanitized by EPA to remove such identifiers;

*: indicates that based on EPA's preliminary evaluation, the submission was either considered to be unwarranted for reporting under Section 8(e) of TSCA or that it was not clear to EPA that submission was warranted and further clarifying information was requested from the submitter.

INIT: denotes that the submission is an initial submission;

FLWP: indicates that the submission is a followup response; and

SUPP: indicates that the notice is a supplemental submission.

By definition, follow-up response submissions contain information submitted directly in response to a specific EPA request, whereas supplemental submissions are those that contain information not specifically requested by the Agency.

HOW DOES OTS REVIEW/USE SECTION 8(E) INFORMATION?

Although EPA's receipt of information under Section 8(e) of TSCA does not necessarily trigger immediate regulatory action under TSCA or another authority administered by EPA, the submitted information is processed and evaluated on a priority basis to determine an appropriate level of concern and initial course of Agency action.

Thus far, EPA and the chemical industry have devoted significant efforts in fulfilling their respective responsibilities under Section 8(e) of TSCA. Since January 1, 1977, over 1250 initial Section 8(e) notices covering a broad range of toxicity and exposure-related data on a wide variety of chemicals have been received by OTS and been given priority evaluation and follow-up attention.

In general, each initial TSCA Section 8(e) submission is promptly reviewed and evaluated by OTS scientific staff to determine both the degree of concern that should be attached to the submitted information and the initial course of any warranted OTS follow-up action(s). A "status report" is prepared containing a brief description of the submitted information, the results of the OTS preliminary evaluation, a statement regarding production and use of the subject chemical(s) and recommendations for appropriate follow-

up actions.[2] Upon approval of the status report, recommended follow-up actions are initiated. A letter forwarding the status report and any EPA requests for additional information is sent to the submitting organization. In addition, copies of all status reports are transmitted to EPA's public files, other designated EPA Program Offices and Federal Agencies, and to the OTS Environmental Assistance Division (EAD/OTS) for further distribution.

Other OTS follow-up actions include the consideration of further, more in-depth assessment of the reported chemical's hazard or risk. OTS staff also immediately reviews, evaluates, and initiates appropriate follow-up actions or activities on information that is contained in "follow-up" and "supplemental" TSCA Section 8(e) submissions; over 2000 TSCA Section 8(e) supplemental and follow-up submissions have been received and promptly evaluated by OTS staff since January 1, 1977.

OTS utilizes TSCA Section 8(e) submission data for hazard/risk identification purposes primarily in the initial stages of the OTS Existing Chemical Program (ECP). OTS also uses these data in ongoing health and exposure assessments of both existing and new chemicals and in support of regulation development under TSCA, e.g., development of chemical testing rules under TSCA Section 4.

EPA's proactive implementation of Section 8(e) of TSCA has resulted in heightened overall awareness of the risks posed by exposure to chemical substances and mixtures. Many benefits and impacts are evident from EPA's dissemination of TSCA Section 8(e) and related information to other EPA Offices, other Federal agencies, the general public and the international community. This heightened awareness has led, in many cases, to specific activities designed to directly or indirectly protect health and/or the environment.

OTS has established high level scientific and administrative contacts in each of the major EPA Program Offices and Regional Offices to provide a mechanism for the timely and prioritized dissemination of information about newly discovered chemical hazards or risks. These other EPA Program and Regional Offices effectively and routinely utilize TSCA Section 8(e) information in

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[2] As of October 1, 1990, OTS began to issue "summaries" rather than "status reports" for incoming initial Section 8(e) submissions. These summaries contain a detailed accounting of toxicologic and other information (e.g., voluntary pollution prevention/risk reduction information, exposure data) presented in the initial TSCA Section 8(e) submission. The summaries do not reflect, however, the Agency's evaluation or disposition of the reported information. Copies of Section 8(e) submission summaries can be obtained in the same manner used to obtain copies of Section 8(e) status reports.

implementing their regulatory programs. The following examples illustrate just some of the actions/activities initiated by other EPA Offices in response to Section 8(e) and related data.

Office of Water (OW/EPA)

- preparing/revising Water Quality Criteria Documents and Drinking Water Standards.

Office of Solid Waste and Emergency Response (OSWER/EPA)

- determining the need for/revision of listing and delisting actions under the Resource Conservation and Recovery Act (RCRA); and

- establishing/revising "Reportable Quantities" (RQs) and "Threshold Planning Quantities" (TPQs) for the chemicals that are under the jurisdiction of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; "Superfund").

Office of Research and Development (ORD/EPA)

- preparing/revising Health and Environmental Effects Profiles (HEEPs), Health Effects Assessments (HEAs) and Acceptable Daily Intakes (ADIs) for use by other EPA Program Offices; and

- determining the need for new EPA research or impact on ongoing EPA research activities.

Office of Air and Radiation (OAR/EPA)

- determining the need for and revising rules which govern chemical substances released to the air from stationary and/or mobile sources.

Office of Pesticide Programs (OPP/OPTS/EPA)

- assessing or reassessing the toxicity of or exposure to active ingredients/inerts in pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

EPA Regional Offices

- EPA's 10 Regional Offices routinely receive copies of all updated indices for OTS holdings of Section 8(e) and FYI notices. In addition to providing new information about reported chemical hazards/risks, Regional receipt of this information has led numerous cases to compliance inspections under TSCA and other EPA administered authorities.

EPA has also established high level scientific and administrative contacts in other Federal agencies in order to provide a mechanism for the timely and prioritized dissemination of new information on chemical hazards/risks. The following examples illustrate some of the activities that have been initiated by other Federal agencies in direct response to TSCA Section 8(e) and related information supplied to those agencies by EPA.

National Institute for Occupational Safety and Health (NIOSH)

- preparing/revising Current Intelligence Bulletins;
- determining the need for workplace investigations leading to published Health Hazard Evaluations;
- recommending to OSHA the need for new workplace standards or revisions to existing workplace standards;
- determining the need for new research or the impact on ongoing chemical research activities; and
- input of data into the Registry of Toxic Effects of Chemical Substances (RTECS) publication and on-line computerized data base.

Occupational Safety and Health Administration (OSHA)

- internally reviewing and distributing information to OSHA Regional/Area Offices and inspectors;
- filling data gaps in ongoing OSHA assessments/studies or determining the need for such assessments/studies; and
- determining the need for new OSHA workplace standards or revising existing workplace standards.

Consumer Product Safety Commission (CPSC)

- determining the need for new CPSC regulatory efforts or the revision of existing CPSC regulations; and
- internal and external information circulation as part of CPSC's "Current Awareness Activities."

National Library of Medicine (NLM)

- input of toxicologic/exposure information to the NLM's publicly accessible computerized data bases.

National Toxicology Program (NTP)

- evaluating chemicals for toxicologic testing;
- monitoring results of non-NTP toxicity studies; and
- supplementing results of ongoing NTP studies.

Interagency Testing Committee (ITC)

- determining need for recommending chemicals for TSCA Section 4 health/environmental effects testing.

DO STATUS REPORTS REPRESENT EPA'S "BOTTOM LINE" REGARDING RISK?

When reviewing TSCA Section 8(e) status reports, the reader should realize that the purpose of the OTS preliminary evaluation is to determine the significance of the submitted information in terms of a need for possible follow-up action by EPA. This determination involves a critical analysis of the submitted data to assess the extent that the reported hazard/risk is supported by the provided information. The scope of this initial evaluation, however, is generally limited to the submitted documents and to any closely related information known by and/or readily available to the OTS staff reviewer. Neither a literature search to identify other reported effects nor an in-depth analysis of possible sources of exposure to subject chemicals is part of the initial evaluation process. Therefore, a status report should be viewed only as a preliminary evaluation of the submitted information and not as a comprehensive assessment of the chemical substance or mixture for which a TSCA Section 8(e) notice has been filed.

HAS EPA ISSUED OTHER SECTION 8(E) GUIDANCE-RELATED INFORMATION?

The 1978 Section 8(e) policy statement, as frequently cited and quoted in 1) publicly available EPA "Question and Answer" (Q&A) documents on TSCA implementation issues raised at periodic public and individual meetings with Agency staff and management, and 2) numerous publicly available Section 8(e) "status reports" that provide illustrative examples of Section 8(e)-applicability, continues to serve as a sound and adequate basis for potential respondents to determine their mandatory reporting obligations under Section 8(e) of TSCA. In addition, EPA's publication of bound volumes of Section 8(e) status reports serves a two-fold purpose. First, volumes of status reports with indices help to make the information reported under Section 8(e) more readily accessible. Second, these Section 8(e) status report volumes, by providing easy access to specific examples of submitted information and EPA's preliminary evaluation of the information, help subject persons to understand better the kinds of information that should be reported to EPA under Section 8(e) of TSCA. The six (6) bound Section 8(e) status report volumes published by the Agency to date can be purchased directly from the National Technical Information Service (NTIS). The NTIS publication numbers of, and the TSCA Section 8(e) submission numbers covered by, these volumes are as follows:

NTIS Publication Number	Submission Numbers
PB# 80-221609	8EHQ-0777-**0001** to 8EHQ-0679-**0291**
PB# 81-145732	8EHQ-0779-**0292** to 8EHQ-0180-**0330**
PB# 83-187815	8EHQ-0280-**0331** to 8EHQ-1282-**0467**
PB# 87-129409	8EHQ-0183-**0468** to 8EHQ-1284-**0541**
PB# 87-176004	8EHQ-0185-**0542** to 8EHQ-1286-**0648**
PB# 89-182687	8EHQ-0187-**0649** to 8EHQ-1288-**0778**

It should be noted that a seventh Section 8(e) status report volume covering initial Section 8(e) submission numbers 8EHQ-0189-**0779** to 8EHQ-0989-**1084** should be published by EPA in the summer of 1991; notice of the availability of this new status report compendium will be given in the OTS "Chemicals-in-Progress Bulletin." EPA plans to print only a limited number of copies of the new status report volume for distribution by the TSCA Hotline. After that supply is exhausted, copies of the new compendium can be purchased from NTIS. The addresses and telephone numbers for NTIS as well as the TSCA Hotline can be found in the "**Preface**" to this guide.

With the exception of certain TSCA Section 8(e) Q&As that were made available by EPA in July 1989, all of the Agency's other published Section 8(e)-related Q&As (1986 and 1987) are embodied in full or in part in other sections of this reporting guide. For the sake of completeness, the specific Q&As from that July 1989 Section 8(e) Q&A document follow.

Q. Does Section 8(e) of TSCA intend the submission of animal test information: (a) when a determination of "substantial risk" has been made, or (b) where merely a finding of positive animal test results useful in the further assessment of human risk has been determined?

A. TSCA Section 8(e) requires the timely submission of evidence (including preliminary evidence) from animal studies that implicates the tested chemical as causing serious toxicologic effects (e.g., cancer, neurotoxicity, birth defects). A decision to report the observance of such serious toxicological effects should not hinge in any way on a judgement of either the actual or potential exposure to the chemical or a judgement about the degree of relevancy of the findings to an overall assessment of human risk. In other words, the decision to report under Section 8(e) in such cases should be based simply on the observance of the serious toxicologic effects.

Q. What criteria should be used to determine if the results from cancer bioassay studies in animals should be submitted to the Agency under Section 8(e) of TSCA? For example, when should animal studies showing only a significant increase in benign tumors over controls be submitted?

A. Reporting of benign and/or malignant tumors should take place, for example, when either **statistically or biologically significant increases** over controls are observed. The observation of such increases are made in many cases at interim sacrifices performed typically during long term exposure studies in animals.

Q. How should reproductive or developmental toxicity data be evaluated for possible Section 8(e) submission if maternal toxicity is also present?

A. **Statistically or biologically significant increases** in teratogenic effects or other serious embryotoxic or fetotoxic effects (e.g., significant embryo or fetal lethality, spontaneous abortion) should be reported under Section 8(e) **regardless of the level of maternal toxicity** observed in the study.

Q. What are the criteria that should be used to determine which reproductive/developmental effects observed in animal tests are reportable under Section 8(e)? For example, should reversible developmental effects, such as reduced birth weight and/or incomplete ossification, trigger TSCA Section 8(e) reporting?

A. In addition to teratogenic effects, serious adverse developmental effects (e.g., significant embryo or fetal lethality, significantly reduced fetal/birth weights, significantly retarded/incomplete skeletal ossification) should be reported. In addition, serious adverse effects on the male/female reproductive system (e.g., significant testicular or ovarian atrophy, significantly reduced fertility, sterility) should be reported under Section 8(e).

Q. What criteria should be used in determining if results of acute toxicity studies constitute information that reasonably supports a conclusion of substantial risk?

A. Criteria used to determine Section 8(e) reporting in the case of acute/subacute toxicity findings will depend on the nature of the effects observed and the dose at which the effects occurred. For example, information that shows a tested chemical to be extremely toxic (e.g., causes lethality at very low doses) by, for example, inhalation, dermal application or oral administration should be reported. On the other hand, the reporting of information showing a chemical to be moderately toxic will depend on the degree of actual or potential exposure to the tested chemical. Information showing a chemical to be slightly or minimally toxic on an acute/subacute basis is not considered typically to be reportable. In addition to extreme toxicity, certain other serious toxicologic effects (e.g., neurotoxicity, adverse reproductive system effects) seen in an acute or subacute animal study should be reported under Section 8(e).

Q. When evaluating subchronic animal studies, what criteria should be used to determine reportability of adverse effects? For example, should increased or decreased organ(s) size in the absence of histopathological changes be reported to EPA under Section 8(e) of TSCA?

A. Serious toxic effects (e.g., neurotoxic effects, serious reproductive system effects) observed during the conduct of subchronic studies should be reported. This includes readily observable serious effects or serious effects seen only as the result of gross and/or histopathological examination. As is the case for acute and

subacute toxicity studies, the degree of the observed toxicity is important. The more serious (or significant) the observed effect, the less heavily one should consider actual/potential exposure for Section 8(e) reporting and vice versa.

Q. What criteria constitute evidence of reportable neurotoxicity in animal studies? For example, are reversible effects such as narcosis or effects observed in the presence of marked systemic toxicity considered reportable?

A. Typically, neurotoxic effects seen in dying animals are not, in and of themselves, considered by EPA to be reportable under Section 8(e). In many cases, however, already reportable data regarding extremely or highly toxic (lethal) substances will be accompanied by information concerning observed neurotoxic effects. In short or long term exposure studies in which serious neurotoxic signs and symptoms (e.g., convulsions, sleep induction, motor dysfunction, narcosis, behavioral dysfunction) are seen in non-moribund animals, however, specific reporting of the neurotoxic effects should occur.

Q. What criteria should be applied in determining whether positive results of <u>in vivo</u> or <u>in vitro</u> mutagenicity assays trigger Section 8(e) reporting?

A. **Serious** <u>in vivo</u> genotoxicological effects (e.g., gene or chromosomal mutations) are reportable in and of themselves under Section 8(e). On the other hand, a positive <u>in vitro</u> genotoxicity test, when considered alone, is usually insufficient to cause reporting under Section 8(e). However, EPA believes that such information is of value in assessing the possible risk(s) posed by exposure to the tested chemical or mixture. Further, the Agency believes that a positive <u>in vitro</u> genotoxicity test result, in combination with other information (e.g., knowledge of actual/potential exposure to and/or high production of the tested chemical), would suggest the need, in many cases, to conduct further studies designed to determine the toxicity of or the exposure to that chemical. EPA expects the results of such additional studies to be considered also for 8(e) submission.

Any person wishing to obtain full copies of the 1986 and 1987 Q&A documents (which also contain numerous Q&As related to rules that have been promulgated by EPA under other sections of TSCA) should contact the TSCA Hotline at the address or the telephone/telefax numbers listed in the **"Preface"** to this reporting guide.

HOW CAN THE PUBLIC OBTAIN SECTION 8(E) SUBMISSIONS?

Non-confidential versions of TSCA Section 8(e) initial, followup response and supplemental submissions, status reports, submission summaries, and EPA followup letters can be viewed/copied in the OTS Public Docket. Copies of non-confidential Section 8(e) documents can also be obtained by writing to EPA's Freedom of Information Office. The addresses of the OTS Public Docket and the Freedom of Information Office are given in the **"Preface"** to this guide.

Information on each new initial Section 8(e) and FYI submission (i.e., submission number, name of the subject chemical(s), and nature of the information received) is presented in index form in the OTS "Chemicals-In-Progress Bulletin" published periodically by the Environmental Assistance Division (EAD/OTS) and sent by the TSCA Assistance Information Service (TSCA Hotline) to over 9,000 individuals in industry, environmental groups, labor, academia and Federal, State, and Local Governments. Persons who wish to receive the "Bulletin" should contact the TSCA Hotline via the addresses or phone/telefax numbers in the **"Preface"** to this guide.

As explained in more detail in **HAS EPA ISSUED OTHER SECTION 8(E)-RELATED GUIDANCE?** on Page 20 of this reporting guide, volumes of TSCA Section 8(e) status reports have been published by OTS on a biannual basis; six volumes have been published to date and contain status reports covering the first 778 initial TSCA Section 8(e) submissions) and a seventh volume is scheduled to be published by OTS during the summer of 1991. Persons interested in obtaining copies of these TSCA Section 8(e) status report volumes should contact the TSCA Hotline or the National Technical Information Service (NTIS) at the addresses and phone numbers given in the **"Preface"** to this reporting guide.

Data from TSCA Section 8(e) and FYI submissions are entered into **TSCATS** (Toxic Substances Control Act Test Submissions), a publicly available computerized data base that serves as an on-line index of unpublished health and safety studies submitted to EPA under or in conjunction with TSCA. The submitted studies themselves are stored on microfiche. Persons who wish to obtain access to the on-line TSCATS should contact either the National Library of Medicine (NLM) located in Rockville, Maryland, or Chemical Information Systems, Inc. (CIS) located in Baltimore, Maryland. Microfiche copies of the submitted studies cited in TSCATS can be obtained from either CIS or the National Technical Information Service (NTIS) located in Springfield, Virginia. The addresses/telephone numbers for NLM, CIS and NTIS are presented in the **"Preface"** to this reporting guide.

In order to assure that the public sector is kept apprised about new adverse health effects and exposure information, OTS actively disseminates TSCA Section 8(e) and FYI submission information to many individuals and organizations in the following ways.

- all non-confidential TSCA Section 8(e) and FYI notices, status reports, summaries and follow-up letters are placed in **public files** located at EPA Headquarters.

- **volumes of Section 8(e) status reports** are published by OTS on a biannual basis; six volumes have been published to date and contain status reports covering the first 778 initial TSCA Section 8(e) submissions); a seventh volume is scheduled to be published by the Agency during the summer of 1991.

- in response to numerous **"Freedom of Information Act"** (FOIA) requests that are received by OTS and that mention a chemical that is the subject of a TSCA Section 8(e) or FYI submission, OTS staff provides appropriate citations for, and in some cases full copies of, all such relevant documents;

- **American Conference of Governmental Industrial Hygienists** (ACGIH) publishes on occasion complete copies of selected Section 8(e) "Status Reports" in the ACGIH scientific journal, Applied Industrial Hygiene.

The international community is routinely notified by EPA about the availability of TSCA Section 8(e) and FYI submissions via the OTS "Chemicals-In-Progress Bulletin." Approximately 1000 persons in international organizations, foreign governments, agencies and companies are on the mailing list. The "Bulletin" is also used to routinely solicit unpublished chemical toxicity/exposure data from the international community. Under the established "Freedom of Information Act" (FOIA) procedures as well as the Organization for Economic Cooperation and Development (OECD) information-gathering "Switchboard" project, OTS responds to numerous international requests for unpublished health and safety data on chemicals of concern to OECD members.

IS THERE A SECTION 8(E) ENFORCEMENT RESPONSE POLICY?

On May 15, 1987, EPA's Office of Compliance Monitoring (OCM) issued a final "Enforcement Response Policy" (ERP) covering Section 8(e) as well as the record-keeping and reporting rules issued by EPA under Sections 8, 12 and 13 of TSCA. This ERP describes various enforcement alternatives (including notices of non-compliance, civil penalties, criminal action and injunctive relief) available to the Agency in enforcing these TSCA record-keeping/reporting provisions. Copies of the TSCA Sections 8, 12 and 13 ERP can be obtained from OCM or the TSCA Hotline; the addresses and/or phone numbers for these EPA offices are presented in the **"PREFACE"** to this reporting guide.

On Friday, February 1, 1991, EPA announced in the Federal Register (56 FR 4128), a one-time voluntary TSCA Section 8(e) "Compliance Audit Program" (CAP). The Section 8(e) CAP, which incorporates stipulated monetary penalties and an overall monetary penalty ceiling, is designed primarily to 1) achieve the Agency's goal of obtaining any outstanding Section 8(e) information, and 2) provide maximum encouragement to companies to voluntarily audit their files for Section 8(e)-reportable information.

Modifications made to the Section 8(e) CAP were announced by EPA in the Federal Register on Friday, April 26, 1991 (56 FR 19514). The major modifications were 1) an extension of the CAP registration and termination dates, 2) addition of an opportunity to petition EPA for a case-by-case extension of the CAP termination date, 3) modification of the CAP "Agreement" provision involving admission of a Section 8(e) violation, and 4) an announcement of the Agency's plans to prepare and disseminate this TSCA Section 8(e) reporting guide.

Additional modifications to the Section 8(e) CAP were announced in the Federal Register on Thursday, June 20, 1991 (56 FR Part IV). The additional modifications announced by EPA were 1) an extension of the Section 8(e) CAP registration deadline, 2) announcement of the availability of this Section 8(e) reporting guide, 3) addition to the CAP of a "listing" provision and reduced stipulated penalty for certain types of Section 8(e)-reportable information now in EPA's possession as the result of either i) formal submission under a mandatory reporting provision of TSCA or other EPA-administered statute, or ii) submission to EPA and filing within EPA's Office of Toxic Substances formal "For Your Information" (FYI) submission filing system, and 4) suspension of Parts V(b)(1) and V(c) of EPA's TSCA Section 8(e) policy statement for purposes of judging the reportability of information concerning "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination" under the Section 8(e) CAP.

With regard to Parts V(b)(1) and V(c) of the Section 8(e) policy statement, the June 20, 1991 Federal Register announcement also informed the regulated community that until such time as the Agency determines with greater specificity what types of environmental release, environmental detection and environmental contamination information should be submitted under Section 8(e) of TSCA, the statutory language of Section 8(e) was to be utilized to determine reportability of such information for purposes of the Section 8(e) CAP as well as ongoing compliance with Section 8(e).

For the reader's ease, complete copies of EPA's Federal Register announcements of the Section 8(e) CAP and the CAP modifications are presented in chronological order in Appendix D at the back of this reporting guide.

HAS EPA TAKEN FORMAL SECTION 8(E) ENFORCEMENT ACTIONS?

Since 1977, EPA has initiated a number of formal enforcement actions relating to Section 8(e) of TSCA. In almost all cases, EPA's actions have dealt with the late reporting of animal study findings that offer reasonable support for the conclusion that the tested chemical substance(s) presents a substantial risk of injury to health. Persons interested in reviewing the filings pertaining to specific Section 8(e) enforcement-related actions should contact either the Office of Compliance Monitoring (OCM) or the Office of Enforcement (OE) at the addresses in the **"Preface"** to this guide.

DOES EPA'S 8(E) IMPLEMENTATION ENCOURAGE POLLUTION PREVENTION?

EPA's longstanding proactive implementation of Section 8(e) of TSCA has resulted in heightened overall chemical industry awareness of risks posed by exposure to chemical substances and mixtures. This heightened awareness has led, in many cases, to specific voluntary pollution prevention/risk reduction activities designed to directly or indirectly protect health and the environment. It can be argued that EPA's Section 8(e) implementation encourages these voluntary actions to occur earlier than they might occur otherwise. The following discussion describes some of these voluntary actions.

The chemical industry's increased awareness of the potential hazards/risks posed by chemical substances is evidenced in part by the voluntary reporting of over 800 initial "For Your Information" (FYI) submissions containing valuable toxicity and exposure data. In direct response to OTS followup efforts, many chemical companies have established review committees responsible for evaluating chemical toxicity and exposure information to consider the need to report to EPA (e.g., under Section 8(e) of TSCA) or to initiate actions designed to minimize or eliminate chemical exposure. Many companies have also established information distribution networks to facilitate the flow of health/safety data to workers, customers and other producers. Many companies have reported that in direct response to new chemical toxicity or exposure data reported under Section 8(e) or on an FYI basis, the following types of health and/or environmental protection measures have been initiated on a voluntary basis:

Notification

- formal notification of workers, customers, others
- changes made to product labels and/or Material Safety Data Sheets (MSDSs) to ensure proper and safe handling

Further Study

- additional studies performed in order to determine better the toxicity of and/or the exposure to chemicals

Pollution Prevention/Exposure Reduction

- engineering changes made in manufacturing and processing facilities to reduce/eliminate chemical exposure
- chemical manufacture or use halted temporarily or discontinued altogether.

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TSCA SECTION 8(E)-REPORTABILITY OF TOXICOLOGIC CASE STUDIES

A. NUMERICAL REPORTING GUIDANCE FOR LETHALITY INFORMATION

Case Study

"An acute oral (gavage) LD50 study was conducted on a commercial chemical. Following administration of the test material, rats were observed for 14 days for clinical signs of toxicity. At the end of this observation period, all surviving rats were sacrificed and examined for gross pathological changes. Rats found dead were also subjected to gross pathological examination. The oral LD50 was calculated to be 40 mg/kg. Nonspecific clinical signs were initially observed in all treated rats; all signs had receded by Day 14 in those animals which survived. Gross pathology revealed nothing unexpected."

The case study did not contain any other relevant information for EPA to consider in judging the Section 8(e)-reportability of this acute oral toxicity study of a commercial chemical substance. Also at issue for this particular case study is the perceived need to have 1) numerical guidance for reporting lethality seen in acute and other types of animal toxicity studies, and 2) reaffirmation of EPA's policy on whether and how exposure should be considered by companies in evaluating acute lethality data for reporting.

EPA Discussion

The Agency believes that the following general "rules-of-thumb" should be used in determining the Section 8(e)-reportability of significant lethality observed in any animal study (including acute, sub-acute and other types of studies such as teratology studies) of a TSCA-covered chemical substance (including a research and development [R&D] chemical):

- Significant lethality which is observed at a dose or concentration comparable to an acute oral LD50 value of $\leq$5 mg/kg, an acute dermal LD50 value of $\leq$20 mg/kg, or an acute (generally 4-hour) inhalation LC50 value of $\leq$50 ppm (or $\leq$0.5 mg/l) should be recognized immediately as being

indicative of **"extreme"** toxicity and should be considered for immediate reporting to EPA under Section 8(e) of TSCA **without** any consideration of actual or potential exposure or other factors.

- Significant lethality observed at a dose or concentration comparable to an acute oral LD50 value in the range of >5 mg/kg to ≤50 mg/kg, an acute dermal LD50 value in the range of >20 mg/kg to ≤200 mg/kg, or an acute (generally 4-hour) inhalation LC50 value in the range of >50 ppm (or >.0.5 mg/l) to ≤200 ppm (or ≤2 mg/l) should be recognized as indicating **"high"** toxicity and should be considered for immediate reporting under Section 8(e) **if** there is actual or reasonably anticipated exposure to the subject chemical substance.

- Significant lethality observed at doses **greater** than those cited previously (i.e., doses indicating **"moderate"** toxicity) should be considered for reporting to EPA under Section 8(e) based on the company's review of additional information (including but not limited to information about actual or potential exposure to the tested chemical substance or mixture).

Specifically regarding findings of **"high"** toxicity, EPA expects a company to be especially prudent and to err on the side of caution for reporting (i.e., there is a clear bias toward reporting). EPA also believes that the greater the toxicity, the less heavily one should weigh the actual or potential exposure to (or other factors involving) the tested chemical. Further, if the tested chemical is a "commercial" substance (e.g., not one that is exclusively R&D), there must be a strong presumption of actual or potential exposure for reporting toxicity data in this range. On the other hand, many exclusively R&D chemical substances with toxicities in the **"high"** range, would not typically be reported under Section 8(e) of TSCA. It should be noted also that any consideration of exposure and additional information in cases involving the **"high"** toxicity range should be accomplished expeditiously and should not be exhaustive nor equated in any way with the need to conduct a full scale risk assessment for the tested chemical(s).

The preface to Part V of the Agency's March 16, 1978 Section 8(e) policy statement provides further guidance regarding the types of additional factors to consider in determining the need to report information under Section 8(e) of TSCA. For the reader's ease in use, the specific lethality values/ranges discussed herein are presented in **Table 1** at the top of the next page.

Table 1 Factors to Consider in Determining Reportability of Lethality Information Under TSCA Section 8(e)

LD50 Oral Dose	LD50 Dermal Dose	4-Hour LC50 Inhalation Dose	Consider Exposure/Other Factors?
≤5 mg/kg	≤20 mg/kg	≤50 ppm (≤.5 mg/1)	No (EXTREMELY TOXIC)
>5 mg/kg to ≤50 mg/kg	>20 mg/kg to ≤200 mg/kg	>50 ppm (>.5 mg/1) to ≤200 ppm (≤2 mg/1)	Only to Some Reasonable Degree (HIGHLY TOXIC)
>50 mg/kg	>200 mg/kg	>200 ppm (>2 mg/1)	Yes (MODERATELY TOXIC)

EPA Conclusion

Based on the preceding discussion and EPA's review of this acute animal lethality study, the oral LD50 value of 40 mg/kg indicates that the tested chemical substance is "highly" toxic (i.e., an oral LD50 of less than 50 mg/kg but greater than 5 mg/kg). Considering that the tested chemical is "commercial," and in the absence of any relevant exposure-related information to the contrary, EPA makes the prudent assumption that there is or there reasonably could be exposure to the tested chemical. Therefore, EPA believes that these acute lethality findings showing the chemical to be highly toxic should be reported immediately under Section 8(e) of TSCA.

B. ACUTE TOXICITY TESTS WITH NON-LETHAL NEUROBEHAVIORAL FINDINGS

Case Study

"An oral LD50 study is conducted in which animals [(rats)] are administered 50, 200, 500, 1000, or 2000 mg/kg of a test material. Shortly after dosing, intermittent lethargy, ataxia and convulsions

are observed in the 1000 and 2000 mg/kg groups. Salivation, ataxia and lethargy are observed in animals in the 200 and 500 mg/kg groups. No effects are observed in the 50 mg/kg dose group. All rats died at the 2000 mg/kg dose level. The lower dose animals survived to necropsy."

The case study did not contain any other relevant information for EPA to consider in judging the Section 8(e)-reportability of the findings from this acute oral toxicity study. Also at issue for this study is the need for EPA to verify that statistically or biologically significant "frank" neurotoxicologic effects seen in acute or other animal studies should be reported immediately.

EPA Discussion

In reviewing these results of this acute oral toxicity study, EPA made the following assumptions about the study conduct/findings:

1. the study had a 14-day post-dosing observation period;

2. no animals in the 50, 200, 500 or 1000 mg/kg dose groups were found moribund during the 14-day observation period;

3. "shortly" means a time period of less than a day;

4. "intermittent" means on a number of occasions throughout the observation period;

5. the terms "convulsions" and "ataxia" accurately reflect the observations made during the study; and

6. a significant (biologically or statistically) number of rats in the study were affected.

Given the above assumptions, EPA believes that the findings from this acute oral toxicity study can be meaningfully interpreted. Shortly after dosing and at some unknown time prior to death, the animals in the 2000 mg/kg group exhibited intermittent lethargy, ataxia and convulsions; all of the animals in the 2000 mg/kg dose group died at some unknown point after dosing. Although interpretation of the findings for the 2000 mg/kg dose group animals would depend upon whether the adverse effects were observed in moribund or non-moribund animals, by considering the information provided for the lower dose groups, it is possible to determine that the tested chemical substance caused distinct neurotoxicologic effects. Based on EPA's assumption that no animals in the 1000 mg/kg dose were found moribund during the study, the observations that a significant number of animals at this dose exhibited intermittent lethargy, convulsions and ataxia, show that the tested chemical caused serious neurotoxicologic effects. Furthermore, although the

animals in the 200 and 500 mg/kg dose groups did not exhibit convulsions, the animals in both of these groups exhibited a combination of signs indicating a neurotoxicologic effect (i.e., salivation, lethargy and ataxia.) Considering that the oral LD50 of the test material is somewhere between 1000 and 2000 mg/kg, the finding of distinct neurotoxic effects at doses that are perhaps between 10% and 25% of the lethal dose further heightens concern for the tested chemical substance.

In general, the Agency would agree that it may not be possible to distinguish or attribute neurobehavioral effects or neurological signs in moribund animals to a direct neurotoxic action of the tested chemical substance. However, statistically or biologically significant neurotoxic effects observed in non-moribund animals (including animals in groups receiving doses equal to or greater than lethal doses) in any type of study **cannot** be dismissed simply as reflecting a "system overload" and should be considered for immediate reporting to the Agency under Section 8(e) of TSCA. Further, EPA believes that good product stewardship dictates that studies designed to more specifically assess neurotoxic effects should be considered for any chemical found to produce possible neurotoxic effects during an acute or other general toxicity test.

EPA Conclusion

Based on the preceding discussion and EPA's review of this acute oral toxicity case study, the distinguishable neurotoxicological effects caused by the subject chemical should be reported under Section 8(e). The reportability of the findings would simply be enhanced if the tested chemical was already on the market.

To provide a sense of scale for the Section 8(e)-reportability of neurotoxic/neurobehavioral findings from acute and other types of animal toxicity studies (e.g., 28-day studies, teratology studies), the Agency is most interested in receiving reports that involve "serious or prolonged effects." In general, the acute toxicity LD50 values/ranges listed in **Table 1** (found on Page 31 of this reporting guide) should be consulted first and an appropriate level of consideration should be given to exposure and/or other factors in determining reportability based solely on lethality in acute or other types of animal toxicity studies. In those cases involving biologically or statistically significant evidence of serious neurotoxicological effects (e.g., paralysis, convulsions, ataxia), virtually no consideration of exposure or other factors should be given in determining the TSCA Section 8(e)-reportability of such serious toxic effects. As neurotoxicologic observations become more limited or as confidence in the accuracy of such observations becomes more uncertain, the Section 8(e)-reportability of such findings diminishes. In some studies, for example, it may not be possible to determine with any degree of precision if observations

such as ataxia accurately characterize the study findings or the testing laboratory simply recorded ataxia as indicating a state other than normal. In the above case study, however, the observed convulsions and ataxia were judged by the Agency as being serious neurotoxic effects and the other effects (lethargy and salivation) were viewed as providing additional evidence of neurotoxicity. In the absence of other more serious effects, however, observations of lethargy and/or salivation, in and of themselves, would not be viewed typically as providing reasonable support for a conclusion of substantial risk. Similarly, the Section 8(e)-reportability of effects such as convulsions or ataxia would be diminished if such effects 1) were seen only in moribund animals or in only one or a few isolated cases in non-moribund animals, or 2) were found simply to be transient rather than either intermittent or continuous in nature.

C. SKIN/EYE IRRITATION AND SKIN SENSITIZATION TESTS

Note

For the following case study involving three tests on a "moderately acidic" chemical, it was reported that the tests were "performed during the development phase of a new product for primary use as an industrial intermediate, with some consumer use probable." It was also reported that the "present production quantities are therefore quite small, but [are] expected to increase." Also at issue for this particular case study is the need for EPA to 1) reaffirm its position that results from acute skin or eye irritation tests do not routinely warrant submission under Section 8(e) of TSCA, 2) discuss the reportability of skin sensitization study findings, and 3) reaffirm that lethality caused at doses indicative of extreme toxicity or serious or prolonged adverse effects in organs/systems away from the site of exposure may indeed warrant the immediate reporting of such findings.

Skin Irritation Test

"A skin irritation assay is conducted on rabbit skin (in vivo). A series of ten applications are applied to the skin of the abdomen. After three applications, the skin is described as having moderate degrees of hyperemia, edema and necrosis. At the end of the 14 day observation period, the skin reaction is still present, and now includes scab and scar formation. Gross pathological examination reveals no systemic toxicity but does confirm the topical corrosive lesion at the site of application."

Eye Irritation Test

"An eye irritation study is conducted in the rabbit eye. Instillation of 0.1 ml into the washed and unwashed eye elicits immediate pain and irritation of the conjunctiva, cornea, and iris after days 1, 2, and 9. The animal appears to not to be able to see through the treated eye and is sent to necropsy on day 9 because of the advanced state of inflammation in the treated eye."

Skin Sensitization Test

"A guinea pig [dermal] sensitization assay is performed. The test material is applied to the clipped integument of 10 guinea pigs during the induction phase. This is followed by a rest period of 10 days. A challenge application is applied to a previously untreated skin site. The skin response is evaluated at 25 and 48 hours after application. Eight of the 10 animals are considered to have been sensitized by the test material based on the presence of erythema at the challenge site."

EPA Discussion

As stated in EPA's March 16, 1978 Section 8(e) policy statement, as well as numerous Section 8(e) "status reports," the Section 8(e)-reportability of irritation and/or corrosivity findings from acute animal eye or skin irritation studies is quite limited. This should not be interpreted to mean, however, that EPA is not concerned in general about the irritation/corrosion findings from such studies. Further, previously unknown or unexpected effects that occur and are observed/determined during such routine tests may have to be submitted under Section 8(e) if the effects are serious and meet the reporting criteria outlined in Part V of EPA's Section 8(e) policy statement (e.g., lethality, neurotoxicity). Therefore, when evaluating the results of skin and eye irritation studies, EPA expects a company to consider such factors as lethal dose, pH of the test material, the route(s) of administration, occurrence of unexpected serious effects (which can be determined via "cage-side" observation or during necropsy), and the extent and pattern of the actual or potential exposure to the tested chemical or mixture. When evaluating such information for possible TSCA Section 8(e) reporting, the greater the acute toxicity, the less heavily one should weigh the actual or potential exposure to the test materials and vice versa.

With regard to sensitization studies, it must be noted that sensitization is a systemic reaction that is manifested in many cases locally (i.e., directly at the site of re-exposure) but may be manifested also away from the site of exposure. Further, the

nature of the reaction can vary from slight to severe and can, in some cases, result in death. In reviewing results of sensitization studies for submission under Section 8(e), EPA expects companies to evaluate a variety of factors including, but not limited to, the severity of the response, the site(s) of the response, the number of animals affected, and/or the actual or potential exposure to the tested chemical substance(s). In general, the more severe the observed sensitization response(s) and the greater the number of animals affected, the less heavily one should weigh the actual or potential exposure to the tested chemical(s) and vice versa.

EPA Conclusion

Based on an evaluation of the eye and skin irritation studies and the skin sensitization study, and considering the above discussion, it is the Agency's opinion that, based on the provided information on current exposure, the results of these studies do not appear to be reportable now under Section 8(e) of TSCA. The findings may be reportable, however, at some future date under Section 8(e); this would depend upon an evaluation of new information reflecting a significant change in the magnitude/type of exposure and/or the consideration of other factors such as those previously cited.

D. SUBCHRONIC TOXICITY

Case Study

"A subchronic dermal repeated dose study in rats was conducted at doses of 0, 100, 300, and 1000 mg/kg. The tested material is extensively used in consumer products and exposure to the chemical is exclusively dermal. A statistically significant 25% increase in liver weight was observed at the high dose. A statistically significant incidence of clear signs of liver pathology typical of cirrhosis was observed at the mid and high doses. The NOAEL [(No-Observable-Adverse-Effect-Level)] was determined to be 100 mg/kg. No other effects were observed."

As background, it was reported that acute and range-finding data on the tested chemical indicate "it is relatively nontoxic" and the high dose, which was chosen for the subchronic dermal study, was the OECD ([Organization for European Cooperation and Development)] recommended limit of 1 g/kg. Also at issue for this case study is the need for EPA to reaffirm its position that organ weight changes in the absence of concurrent pathology may not routinely reflect serious or prolonged incapacitation and that other factors (e.g., histopathologic findings, dose, or actual/expected exposure, etc.)

may need to be considered in deciding whether to report such organ weight changes. There is also a need to discuss and reaffirm EPA's position that a statistically or biologically significant histopathologic finding indicating a serious or prolonged incapacitation should be immediately reported with little if any consideration of factors such as exposure.

EPA Discussion

Although an organ weight change, in an of itself, may not reflect a serious or prolonged incapacitation, the reportability of such a finding could depend upon an evaluation of one or more factors, such as, but not limited to, the overall magnitude of the organ weight change, the biological significance of the change, blood chemistry, dose, route of administration, actual or expected exposure, etc. However, the more significant the magnitude of the organ weight change (e.g., severe atrophy of the testes, thymus, kidneys), much less consideration should be given to such factors in determining reportability of the findings. On the other hand, a statistically or biologically significant histopathologic finding indicating a serious or prolonged incapacitation should be reported with little if any consideration given to factors such as exposure. When the histopathologic findings are of a less serious or less significant nature, other relevant factors (e.g., actual/expected exposure, dose, etc.) should be considered in determining the TSCA Section 8(e)-reportability of the study results.

The subchronic dermal application case study results clearly show a statistically significant, dose-dependent, relatively rare, and serious toxic effect (cirrhosis) in the liver, accompanied by a 25% increase in liver weight in the high dose animals.

EPA Conclusion

Based on an evaluation of the provided toxicologic findings, and considering the above discussion, it is EPA's position that the results of the subchronic dermal application study are reportable pursuant to Section 8(e) of TSCA. The facts that 1) the tested chemical is a commercial substance, and 2) consumers are dermally exposed to the chemical, simply enhance the reportability of the observed serious toxic effects in the liver.

* * * * *

APPENDIX A

SECTION 8(E) GUIDANCE/POLICY REFLECTED IN STATUS REPORTS

This index is divided into the following two (2) major areas: "TOXICOLOGICAL/EXPOSURE FINDINGS" and "GENERAL ISSUES." In using this particular index, please note that the numbers in the column on the right represent the last four (4) digits of the chronological Section 8(e) submission file number displayed on all status reports; the ascending numerical sequence, therefore, is also chronological. Please note that due to the fact that the majority of the first 200 Section 8(e) notices were submitted by a single company and EPA had asked that company for additional information about the Section 8(e)-applicability of the provided findings, the Agency has chosen to not include in this index any status reports pertaining to those first 200 notices.

I. TOXICOLOGICAL/EXPOSURE FINDINGS

A. ACUTE TOXICITY (ANIMAL)

0259
0282
0380
0408
0428
0429
0430
0431
0432
0433
0436
0456
0487
0531
0540
0638
0665
0669
0985
1059

B. ACUTE TOXICITY (HUMAN)

0258
0315
0344
0493
0502

B. ACUTE TOXICITY (HUMAN) [CON'T]

0508
0612
0622
0632
0694
0885
0905
0929

C. SUBACUTE TOXICITY (ANIMAL)

0325
0653

D. IMMUNOTOXICITY (ANIMAL)

0585

E. NEUROTOXICITY (ANIMAL)

0369
0706
0815
0867
1041
1043
1065

F. NEUROTOXICITY (HUMAN)

0641
1041
1065

G. ONCOGENICITY (ANIMAL)

0234
0401
0503
0509
0583
0600
0619
0681
0763
0847

H. ONCOGENICITY (HUMAN)

0641

I. REPRODUCTIVE/DEVELOPMENTAL (ANIMAL)

0211
0213
0572
0626
0653
0764
0807
0820
0835
0842
0872
0999
1042
1043

J. REPRODUCTIVE/DEVELOPMENTAL (HUMAN)

0551

K. GENOTOXICITY (IN VITRO)

0213
0214
0383
0396

NOTE: Almost all of the TSCA Section 8(e) status reports pertaining to in vitro genotoxicity test findings contain the following language:

"Although a positive in vitro genotoxicity test result, when considered alone, may not be sufficient to offer reasonable support for a conclusion of substantial risk (as that term is defined in EPA's Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110; March 16, 1978)), EPA does believe that such information is of value in assessing the possible risk(s) posed by exposure to the tested chemical or mixture. Further, the Agency believes that a positive genotoxicity test result, in combination with other important information (e.g., knowledge of the actual/ potential exposure to and/or high production of the tested chemical or mixture),

suggests the need, in many cases, to conduct further studies that are designed to determine the toxicity of and/or exposure to that chemical substance or mixture. EPA expects the results of such additional studies to be considered also for submission pursuant to Section 8(e) of TSCA."

L. GENOTOXICITY (IN VIVO)

0208
0213

M. AQUATIC TOXICITY/BIOCONCENTRATION

0209
0249
0899
0994

N. EMERGENCY INCIDENTS OF ENVIRONMENTAL CONTAMINATION

0255
0260
0277
0466
0566
0769

O. GENERAL/NON-EMERGENCY ENVIRONMENTAL CONTAMINATION

0209
0720

II. GENERAL REPORTING ISSUES

A. INTRACORPORATE REPORTING PROCEDURES

0358
0672
0681
0698
0701
0705
0835

B. SUBJECT PERSONS

0543
0546
0551
0577
0587
0642
0689
0818
0823
0824
0846

C. SUBJECT CHEMICALS

0325
0543
0545
0546
0551
0583
0587
0698
0701
0705
0706
0763
0818
0823
0824
0835

D. RESEARCH & DEVELOPMENT CHEMICALS

0545
0583
0763
0815
0824
0835

E. DRUG EXPORT

0818

F. PESTICIDE EXPORT

0823

G. PREVIOUS MANUFACTURE/IMPORT/PROCESS/DISTRIBUTION

0698
0701
0705
0847

H. OBTAINING INFORMATION

0315
0325
0358
0503
0543
0546
0572
0587
0619
0626
0653
0681
0698
0701
0704
0705
0713
0847
1041
1043
1065

I. PRE-1977 INFORMATION

0213
0369
0847
1041
1043
1065

J. ACTUAL KNOWLEDGE BY EPA

0467
0509
0600
0641
0672
0689

J. ACTUAL KNOWLEDGE BY EPA (CON'T)

0704
0706
0712
0713
0718
0720
0807
0809
0835
0847

K. PUBLISHED SCIENTIFIC LITERATURE

0383
0588
0600
0641
0672

L. INFORMATION OBTAINED FROM OTHER FEDERAL AGENCIES

0467
0689
0704

M. INFORMATION CORROBORATING WELL-ESTABLISHED EFFECTS

0509
0706
0807
0835

N. RELATIONSHIP TO OTHER TSCA REPORTING REQUIREMENTS

0493
0600
0612
0622
0632
0667
0675
0694
0706
0718

N. RELATIONSHIP TO OTHER TSCA REPORTING REQUIREMENTS (CON'T)

0720
0769
0797
0800
0813
0817
0824
0846
0856
0876
0884
0900
0905
0929

O. RELATIONSHIP TO OTHER EPA ADMINISTERED AUTHORITIES

0466
0485
0494
0502
0508
0542
0566
0583
0600
0706
0712
0718
0720
0726
0769
0797
0800
0813
0815
0818
0823
0824
0835
1034

P. RELATIONSHIP TO AUTHORITIES NOT ADMINISTERED BY EPA

0551
0706
1043

Q. SECTION 8(E) REPORTING PROCEDURES

0234
0324
0330
0369
0400
0543
0546
0566
0587
0626
0653
0681
0698
0701
0705
0855

* * * * *

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:								
8EHQ-0977-0004	*	8EHQ-0977-0005	*	8EHQ-0377-0035				
8EHQ-0178-0039 P	*	8EHQ-0178-0041	*	8EHQ-0278-0042				
8EHQ-0278-0050	*	8EHQ-0278-0062		8EHQ-0278-0064				
8EHQ-0278-0065	*	8EHQ-0278-0066	*	8EHQ-0278-0070				
8EHQ-0278-0072	*	8EHQ-0278-0074	*	8EHQ-0378-0087	*			
8EHQ-0378-0088	*	8EHQ-0378-0090	*	8EHQ-0378-0091	*			
8EHQ-0378-0092	*	8EHQ-0378-0094	*	8EHQ-0378-0103	*			
8EHQ-0478-0131	*	8EHQ-0478-0134		8EHQ-0478-0137	*			
8EHQ-0578-0143	*	8EHQ-0578-0144	*	8EHQ-0578-0151				
8EHQ-0578-0152		8EHQ-0578-0153 S	*	8EHQ-0578-0154 P				
8EHQ-0578-0155	*	8EHQ-0578-0158 S	*	8EHQ-0578-0159 S	*			
8EHQ-0578-0162 S	*	8EHQ-0578-0163		8EHQ-0578-0166				
8EHQ-0578-0169 S	*	8EHQ-0678-0172	*	8EHQ-0678-0174	*			
8EHQ-0678-0175	*	8EHQ-0678-0176	*	8EHQ-0678-0177	*			
8EHQ-0678-0178		8EHQ-0678-0184	*	8EHQ-0678-0185	*			
8EHQ-0678-0193	*	8EHQ-0678-0194	*	8EHQ-0678-0195	*			
8EHQ-0678-0196	*	8EHQ-0678-0197	*	8EHQ-0678-0198	*			
8EHQ-0678-0199	*	8EHQ-0678-0200	*	8EHQ-0678-0203	*			
8EHQ-0678-0204	*	8EHQ-0678-0205	*	8EHQ-0678-0206	*			
8EHQ-0678-0207	*	8EHQ-0778-0209		8EHQ-0778-0210	*			
8EHQ-0778-0217		8EHQ-0778-0220	*	8EHQ-0778-0222	*			
8EHQ-0778-0224	*	8EHQ-0778-0225	*	8EHQ-0778-0226	*			
8EHQ-0778-0227	*	8EHQ-0778-0229	*	8EHQ-1178-0256				
8EHQ-1178-0259		8EHQ-1178-0261		8EHQ-1278-0263	*			
8EHQ-0179-0271		8EHQ-0179-0273		8EHQ-0279-0274				

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:								
8EHQ-0479-0278		8EHQ-0479-0279		8EHQ-0479-0282	S			
8EHQ-0579-0284		8EHQ-0779-0293		8EHQ-0779-0296				
8EHQ-0979-0311		8EHQ-0380-0335	S	8EHQ-0480-0340				
8EHQ-0680-0347		8EHQ-0680-0349		8EHQ-0980-0359				
8EHQ-0980-0362		8EHQ-0980-0365		8EHQ-0780-0369				
8EHQ-1180-0372		8EHQ-0181-0380	*	8EHQ-0181-0381				
8EHQ-0281-0382		8EHQ-0381-0392		8EHQ-0581-0398				
8EHQ-0581-0400		8EHQ-0881-0408	S *	8EHQ-0981-0409				
8EHQ-1081-0417		8EHQ-1081-0418		8EHQ-0282-0427	S			
8EHQ-0282-0428	*	8EHQ-0282-0429	*	8EHQ-0282-0430	*			
8EHQ-0282-0431	*	8EHQ-0282-0432	*	8EHQ-0282-0433	*			
8EHQ-0282-0435		8EHQ-0282-0436	*	8EHQ-0282-0437				
8EHQ-0382-0438	S	8EHQ-0382-0440	S	8EHQ-0682-0448	S			
8EHQ-0982-0456	S *	8EHQ-1082-0459		8EHQ-1082-0460				
8EHQ-1182-0462		8EHQ-0183-0468		8EHQ-0283-0471	S			
8EHQ-0483-0476	S	8EHQ-0583-0478	S	8EHQ-0583-0479	S			
8EHQ-0683-0482		8EHQ-0783-0485	S *	8EHQ-0783-0486				
8EHQ-0783-0487	S *	8EHQ-0883-0490		8EHQ-0983-0492	S			
8EHQ-1083-0494	*	8EHQ-1083-0495		8EHQ-1083-0496				
8EHQ-1083-0497		8EHQ-1283-0501		8EHQ-0484-0510				
8EHQ-0484-0513		8EHQ-0584-0519		8EHQ-0884-0528				
8EHQ-0984-0530		8EHQ-0984-0531	S *	8EHQ-1084-0532				
8EHQ-1084-0535		8EHQ-1284-0540	S *	8EHQ-0485-0548				
8EHQ-0485-0549	S	8EHQ-0485-0550		8EHQ-0585-0556	S			
8EHQ-0685-0559		8EHQ-0785-0563		8EHQ-0885-0565	S			

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:

8EHQ-0985-0568	S		8EHQ-1085-0569			8EHQ-1085-0571	S	
8EHQ-1185-0573			8EHQ-1185-0575			8EHQ-1285-0578		
8EHQ-1285-0579	S		8EHQ-1285-0580			8EHQ-1285-0581		
8EHQ-0186-0584			8EHQ-0186-0585	S		8EHQ-0386-0589	S	
8EHQ-0486-0596			8EHQ-0486-0597			8EHQ-0486-0599		
8EHQ-0786-0607	S		8EHQ-0786-0609	S		8EHQ-0786-0616		
8EHQ-0886-0621			8EHQ-0986-0631	S		8EHQ-1086-0636	S	
8EHQ-1086-0638		*	8EHQ-1086-0639	S		8EHQ-1086-0640	S	*
8EHQ-1186-0644			8EHQ-1186-0647			8EHQ-0287-0652	S	
8EHQ-0287-0653			8EHQ-0287-0654			8EHQ-0287-0655	S	
8EHQ-0387-0656			8EHQ-0287-0657	S		8EHQ-0387-0659		
8EHQ-0387-0660			8EHQ-0487-0661	S		8EHQ-0487-0663		
8EHQ-0487-0665	S	*	8EHQ-0487-0666	S		8EHQ-0487-0667	S	*
8EHQ-0487-0669		*	8EHQ-0487-0670	S		8EHQ-0587-0673		
8EHQ-0587-0678			8EHQ-0687-0680			8EHQ-0787-0686	S	
8EHQ-1087-0696			8EHQ-1287-0700			8EHQ-1287-0706		
8EHQ-1287-0707	S		8EHQ-0188-0714			8EHQ-0388-0721		
8EHQ-0388-0723			8EHQ-0588-0732			8EHQ-0688-0739		
8EHQ-0688-0740	S		8EHQ-0788-0742		*	8EHQ-0788-0744	S	
8EHQ-0988-0753	S		8EHQ-0988-0754			8EHQ-1088-0760	S	
8EHQ-1088-0762			8EHQ-1188-0768	S		8EHQ-1288-0778		
8EHQ-0189-0779			8EHQ-0389-0780			8EHQ-0389-0787	S	
8EHQ-0389-0788	S		8EHQ-0589-0800			8EHQ-0689-0803		
8EHQ-0789-0806	S		8EHQ-0789-0808	S		8EHQ-0789-0809		*
8EHQ-0889-0810	S		8EHQ-0889-0818	S		8EHQ-0889-0819	S	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (ANIMAL)

SUBMISSION #:								
8EHQ-0989-0826	S		8EHQ-1089-0830		8EHQ-1089-0833	S		
8EHQ-1089-0834	S		8EHQ-1089-0837	S	8EHQ-1089-0838	S		
8EHQ-1189-0841			8EHQ-1189-0845		8EHQ-1189-0848	S		
8EHQ-1289-0850			8EHQ-1289-0852	S	8EHQ-1289-0857	S		
8EHQ-1289-0859			8EHQ-0190-0860	S	8EHQ-0190-0867		*	
8EHQ-0290-0893			8EHQ-0390-0898		8EHQ-0490-0919	S		
8EHQ-0490-0920	S		8EHQ-0490-0954	S	8EHQ-0490-0957	S		
8EHQ-0490-0958	S		8EHQ-0490-0959	S	8EHQ-0590-0964			
8EHQ-0590-0985		*	8EHQ-0590-0991	S	8EHQ-0690-1003			
8EHQ-0690-1004	S		8EHQ-0690-1005	S	8EHQ-0690-1009			
8EHQ-0690-1016	S		8EHQ-0790-1021		8EHQ-0790-1023	S		
8EHQ-0790-1031	S		8EHQ-0790-1035		8EHQ-0790-1036	S		
8EHQ-0890-1040			8EHQ-0890-1045		8EHQ-0890-1047			
8EHQ-0890-1048	S		8EHQ-0890-1052	S	8EHQ-0890-1054	S		
8EHQ-0990-1057			8EHQ-0990-1058	S	8EHQ-0990-1059	S	*	
8EHQ-0990-1060	S		8EHQ-0990-1061		8EHQ-0990-1062			
8EHQ-0990-1068			8EHQ-0990-1076	S	8EHQ-0990-1084			

ACUTE TOXICITY (HUMAN)

SUBMISSION #:								
8EHQ-0178-0036		*	8EHQ-0178-0038		8EHQ-0178-0039	P	*	
8EHQ-0178-0040	P		8EHQ-0278-0052	P	8EHQ-0278-0063		*	
8EHQ-0278-0067	P	*	8EHQ-0278-0075	P	*	8EHQ-0278-0076	P	*
8EHQ-0278-0077	P	*	8EHQ-0278-0078	P	*	8EHQ-0278-0079	P	*
8EHQ-0278-0080	P	*	8EHQ-0278-0081	P	*	8EHQ-0378-0086		*
8EHQ-0378-0097		*	8EHQ-0378-0105			8EHQ-0478-0118	P	*

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ACUTE TOXICITY (HUMAN)

SUBMISSION #:	8EHQ-0478-0138	P	*	8EHQ-0578-0141		*	8EHQ-0578-0142	*
	8EHQ-0578-0145		*	8EHQ-0578-0146			8EHQ-0578-0149	
	8EHQ-0578-0154	P		8EHQ-0578-0165			8EHQ-0678-0180	*
	8EHQ-0678-0181		*	8EHQ-0678-0182	P	*	8EHQ-0678-0184	*
	8EHQ-0778-0217			8EHQ-0978-0238		*	8EHQ-1178-0258	*
	8EHQ-1178-0260		*	8EHQ-0179-0273			8EHQ-0879-0304	*
	8EHQ-1079-0315		*	8EHQ-1279-0322		*	8EHQ-0180-0324	
	8EHQ-0280-0333			8EHQ-0480-0338			8EHQ-0580-0341	
	8EHQ-0680-0344	P	*	8EHQ-0880-0355			8EHQ-0881-0407	
	8EHQ-0981-0409			8EHQ-1182-0466		*	8EHQ-0283-0471	S
	8EHQ-0783-0486			8EHQ-0983-0493	S	*	8EHQ-1283-0502	P *
	8EHQ-0384-0508	P	*	8EHQ-0484-0513			8EHQ-0984-0529	
	8EHQ-1084-0532			8EHQ-1084-0535			8EHQ-0485-0552	
	8EHQ-0985-0566			8EHQ-0186-0585	S		8EHQ-0886-0622	S
	8EHQ-0986-0632			8EHQ-0487-0666	S		8EHQ-0487-0671	
	8EHQ-1287-0700			8EHQ-0688-0736			8EHQ-1088-0755	
	8EHQ-0889-0818	S		8EHQ-1089-0832			8EHQ-0290-0885	
	8EHQ-0390-0905	S	*	8EHQ-0490-0929	S	*	8EHQ-0590-0991	S
	8EHQ-0890-1042			8EHQ-0990-1071			8EHQ-0990-1078	

ALLERGENICITY (ANIMAL)

SUBMISSION #:	8EHQ-0578-0152			8EHQ-0578-0156		*	8EHQ-0578-0166	
	8EHQ-0678-0184		*	8EHQ-0678-0185		*	8EHQ-0678-0206	*
	8EHQ-0480-0340			8EHQ-1180-0371			8EHQ-0282-0427	S
	8EHQ-0682-0448	S		8EHQ-1182-0462			8EHQ-0283-0471	S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ALLERGENICITY (ANIMAL)

SUBMISSION #:			
8EHQ-0683-0482	8EHQ-0783-0486		8EHQ-0883-0490
8EHQ-1083-0495	8EHQ-1084-0532		8EHQ-0485-0550
8EHQ-1285-0580	8EHQ-0186-0585 S		8EHQ-0386-0589 S
8EHQ-0486-0597	8EHQ-1186-0647		8EHQ-0287-0653
8EHQ-0287-0657 S	8EHQ-0487-0661 S		8EHQ-0687-0680
8EHQ-0787-0686 S	8EHQ-0887-0690		8EHQ-1287-0700
8EHQ-1287-0711	8EHQ-0188-0712	*	8EHQ-0388-0721
8EHQ-0588-0733	8EHQ-0688-0739		8EHQ-0688-0740 S
8EHQ-1188-0768 S	8EHQ-1288-0777		8EHQ-1288-0778
8EHQ-0489-0795	8EHQ-0589-0796		8EHQ-0689-0802
8EHQ-0989-0826 S	8EHQ-1189-0839		8EHQ-1189-0845
8EHQ-1289-0852 S	8EHQ-0290-0876		8EHQ-0290-0894
8EHQ-0490-0919 S	8EHQ-0790-1033		8EHQ-0990-1062
8EHQ-0990-1069	8EHQ-0990-1082		

ALLERGENICITY (HUMAN)

SUBMISSION #:			
8EHQ-1177-0017 PS	*	8EHQ-1177-0018 PS	*	8EHQ-0178-0031 P	*
8EHQ-0178-0040 P		8EHQ-0278-0081 P	*	8EHQ-0578-0164	
8EHQ-0578-0165		8EHQ-0678-0181	*	8EHQ-0678-0182 P	*
8EHQ-0678-0184	*	8EHQ-0678-0185	*	8EHQ-0279-0274	
8EHQ-0379-0280		8EHQ-0779-0292		8EHQ-0880-0355	
8EHQ-0282-0427 S		8EHQ-0283-0471 S		8EHQ-1084-0532	
8EHQ-0485-0550		8EHQ-0186-0585 S		8EHQ-0386-0589 S	
8EHQ-0786-0612		8EHQ-0886-0622 S		8EHQ-0987-0694	*
8EHQ-0488-0728		8EHQ-0290-0885		8EHQ-0590-0991 S	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ALLERGENICITY (HUMAN)

SUBMISSION #:	8EHQ-0890-1039 S				

CELL TRANSFORMATION (IN VITRO)

SUBMISSION #:	8EHQ-1277-0022		8EHQ-0278-0071		8EHQ-0378-0094 *
	8EHQ-0378-0098 *		8EHQ-0378-0100 *		8EHQ-0478-0132 *
	8EHQ-0578-0141 *		8EHQ-0578-0164		8EHQ-0578-0166
	8EHQ-0179-0268 S		8EHQ-0479-0278		8EHQ-0479-0279
	8EHQ-0579-0286		8EHQ-0579-0287		8EHQ-0579-0288
	8EHQ-0579-0289		8EHQ-0679-0291		8EHQ-0779-0294
	8EHQ-0280-0334		8EHQ-0281-0385		8EHQ-1280-0401 S
	8EHQ-0681-0404		8EHQ-0981-0412		8EHQ-1081-0415
	8EHQ-1081-0418		8EHQ-0982-0455		8EHQ-0583-0477 S
	8EHQ-0883-0490		8EHQ-1083-0495		8EHQ-1083-0496
	8EHQ-1083-0498		8EHQ-0484-0511		8EHQ-0484-0512
	8EHQ-0584-0516 S		8EHQ-1184-0536		8EHQ-1184-0537
	8EHQ-0685-0558 S		8EHQ-0785-0561 S		8EHQ-0786-0610
	8EHQ-0786-0613		8EHQ-0886-0620		8EHQ-0886-0621
	8EHQ-0986-0630		8EHQ-0687-0679		8EHQ-0889-0814
	8EHQ-0690-1018				

CHEMICAL/PHYSICAL PROPERTIES

SUBMISSION #:	8EHQ-0178-0034		8EHQ-0278-0044		8EHQ-0279-0274
	8EHQ-0879-0301		8EHQ-1179-0317		8EHQ-0280-0333
	8EHQ-0480-0340		8EHQ-0680-0348		8EHQ-0780-0353
	8EHQ-1080-0366		8EHQ-0481-0397		8EHQ-0382-0440 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

CHEMICAL/PHYSICAL PROPERTIES

SUBMISSION #: 8EHQ-0483-0475

CHRONIC TOXICITY (ANIMAL)

SUBMISSION #: 8EHQ-1277-0026 S	8EHQ-0478-0117 *	8EHQ-0578-0140
8EHQ-0578-0148	8EHQ-0578-0165	8EHQ-0578-0170
8EHQ-0678-0202	8EHQ-0778-0209	8EHQ-0778-0212
8EHQ-0778-0215	8EHQ-0878-0234	8EHQ-0878-0236 *
8EHQ-1078-0248	8EHQ-1078-0250	8EHQ-1078-0251
8EHQ-1078-0253	8EHQ-1278-0262	8EHQ-0179-0269 S
8EHQ-0279-0274	8EHQ-0479-0281	8EHQ-0579-0283
8EHQ-0779-0297	8EHQ-0979-0305	8EHQ-0580-0342
8EHQ-0481-0397	8EHQ-0282-0439	8EHQ-1282-0467
8EHQ-0283-0469 S	8EHQ-0283-0472 S	8EHQ-0383-0474
8EHQ-0683-0480	8EHQ-0683-0483 S	8EHQ-0783-0488
8EHQ-1083-0497	8EHQ-1283-0503	8EHQ-1083-0509
8EHQ-0584-0514	8EHQ-0584-0517	8EHQ-0884-0525
8EHQ-0884-0526	8EHQ-0984-0530	8EHQ-1284-0538
8EHQ-0285-0545 S	8EHQ-0485-0550	8EHQ-0485-0553
8EHQ-0785-0562 S	8EHQ-0985-0567	8EHQ-0685-0583 S
8EHQ-0386-0592	8EHQ-0486-0600	8EHQ-0686-0604
8EHQ-0786-0606 S	8EHQ-0786-0614	8EHQ-0886-0618 S
8EHQ-0386-0619	8EHQ-0986-0624 S	8EHQ-0986-0625 S
8EHQ-1086-0642	8EHQ-0187-0650	8EHQ-0487-0668
8EHQ-0587-0675 *	8EHQ-0786-0681	8EHQ-0787-0684 S
8EHQ-0887-0687	8EHQ-0887-0691 S	8EHQ-0987-0692
8EHQ-1187-0697	8EHQ-1287-0704	8EHQ-1287-0708 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

CHRONIC TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1287-0710	8EHQ-0188-0713	8EHQ-0388-0725
	8EHQ-0588-0730	8EHQ-0788-0741	8EHQ-0788-0745 S
	8EHQ-0988-0752 S	8EHQ-1088-0760 S	8EHQ-1288-0773
	8EHQ-1288-0774	8EHQ-1288-0775	8EHQ-0589-0797
	8EHQ-0889-0812	8EHQ-0989-0822	8EHQ-1189-0847
	8EHQ-1289-0856	8EHQ-1289-0858 S	8EHQ-0290-0873 S
	8EHQ-0290-0881 S	8EHQ-0390-0900	8EHQ-0390-0914 S
	8EHQ-0490-0930 S	8EHQ-0490-0952 S	8EHQ-0490-0960
	8EHQ-0590-0968	8EHQ-0590-0993 S	8EHQ-0790-1029
	8EHQ-0890-1043	8EHQ-0890-1050 S	8EHQ-0890-1053
	8EHQ-0890-1056 S		

CHRONIC TOXICITY (HUMAN)

SUBMISSION #:	8EHQ-0378-0096	*	8EHQ-0878-0230		8EHQ-0978-0241
	8EHQ-0981-0409		8EHQ-0383-0473		8EHQ-0884-0523
	8EHQ-0285-0546		8EHQ-0585-0557		8EHQ-0486-0598
	8EHQ-0586-0601		8EHQ-0786-0615		8EHQ-0986-0629
	8EHQ-0986-0634		8EHQ-0187-0651	*	8EHQ-0887-0688
	8EHQ-0987-0694	*	8EHQ-1187-0698		8EHQ-1287-0699
	8EHQ-1287-0701	*	8EHQ-1188-0772		8EHQ-1089-0831
	8EHQ-0190-0863		8EHQ-0190-0864		8EHQ-0290-0886
	8EHQ-0390-0915		8EHQ-0490-0917		8EHQ-0490-0924
	8EHQ-0790-1034		8EHQ-0990-1072		8EHQ-0990-1080 S

CLASTOGENICITY (ANIMAL)

SUBMISSION #: 8EHQ-0483-0476 S

CLASTOGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-0579-0287	8EHQ-0779-0294	8EHQ-1082-0459
	8EHQ-1082-0460	8EHQ-0683-0481	8EHQ-1283-0500 S
	8EHQ-0384-0506 S	8EHQ-1083-0509	8EHQ-0484-0510
	8EHQ-0584-0515 S	8EHQ-0584-0516 S	8EHQ-0584-0518 S
	8EHQ-0784-0522	8EHQ-1084-0533 S	8EHQ-1284-0539
	8EHQ-0685-0558 S	8EHQ-1285-0580	8EHQ-0386-0595
	8EHQ-0586-0602 S	8EHQ-0786-0608 S	8EHQ-0786-0610
	8EHQ-0886-0621	8EHQ-0986-0630	8EHQ-1186-0646 S
	8EHQ-1186-0647	8EHQ-0687-0679	8EHQ-0787-0685
	8EHQ-0787-0686 S	8EHQ-0987-0693	8EHQ-0288-0715
	8EHQ-1088-0758 S	8EHQ-0389-0780	8EHQ-0389-0791 S
	8EHQ-0789-0805 S	8EHQ-0889-0814	8EHQ-1189-0847
	8EHQ-0890-1051 S	8EHQ-0990-1079 S	

DNA ADDUCT (IN VITRO)

SUBMISSION #: 8EHQ-0386-0592

DNA DAMAGE/REPAIR

SUBMISSION #:	8EHQ-0478-0132	*	8EHQ-0578-0165	8EHQ-0678-0191	*
	8EHQ-0678-0206	*	8EHQ-0778-0213	8EHQ-0778-0221	*
	8EHQ-0579-0285		8EHQ-0579-0288	8EHQ-0679-0291	
	8EHQ-0583-0477 S		8EHQ-0683-0481	8EHQ-1283-0503	
	8EHQ-0384-0506 S		8EHQ-1083-0509	8EHQ-0484-0511	
	8EHQ-0484-0512		8EHQ-1184-0536	8EHQ-1184-0537	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

DNA DAMAGE/REPAIR

SUBMISSION #:	8EHQ-0785-0561 S	8EHQ-0586-0602 S	8EHQ-0786-0613
	8EHQ-0886-0621	8EHQ-1186-0646 S	8EHQ-0187-0649 S
	8EHQ-0687-0679	8EHQ-0787-0685	8EHQ-0987-0692
	8EHQ-0288-0715	8EHQ-0688-0737	8EHQ-0889-0814
	8EHQ-1289-0853 S	8EHQ-0890-1051 S	

DNA REPAIR (IN VITRO)

SUBMISSION #:	8EHQ-0280-0334	8EHQ-0980-0359	8EHQ-1080-0366

ECOTOXICITY/AQUATIC TOXICITY

SUBMISSION #:	8EHQ-0178-0032		8EHQ-0278-0048		8EHQ-0278-0058	*
	8EHQ-0278-0059	*	8EHQ-1277-0060	*	8EHQ-0278-0061	
	8EHQ-0378-0108	*	8EHQ-0378-0111	*	8EHQ-0378-0114	*
	8EHQ-0478-0119	*	8EHQ-0478-0120	*	8EHQ-0478-0121	*
	8EHQ-0478-0124	*	8EHQ-0478-0125	*	8EHQ-0478-0126	*
	8EHQ-0478-0132	*	8EHQ-0578-0141	*	8EHQ-0578-0142	*
	8EHQ-0578-0150	*	8EHQ-0678-0171	*	8EHQ-0678-0184	*
	8EHQ-0678-0185	*	8EHQ-0678-0201	*	8EHQ-0778-0209	
	8EHQ-0778-0223	*	8EHQ-1078-0249		8EHQ-1178-0260	*
	8EHQ-0881-0407		8EHQ-0783-0486		8EHQ-0983-0491 S	
	8EHQ-1083-0495		8EHQ-0486-0597		8EHQ-0287-0653	
	8EHQ-0487-0666 S		8EHQ-0288-0718	*	8EHQ-0989-0826 S	
	8EHQ-0390-0899	*	8EHQ-0390-0906 S		8EHQ-0390-0908 S	
	8EHQ-0590-0994	*	8EHQ-0690-1017		8EHQ-0790-1032	
	8EHQ-0990-1083 S					

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

EMERGENCY INCIDENT OF ENV. CONTAMINATION

SUBMISSION #:	8EHQ-0378-0084	*		8EHQ-0678-0183		8EHQ-0878-0237	
	8EHQ-0978-0240			8EHQ-1078-0255	*	8EHQ-1178-0260	*
	8EHQ-0379-0277			8EHQ-0779-0299	*	8EHQ-0879-0300	*
	8EHQ-1179-0319			8EHQ-1279-0322	*	8EHQ-1279-0329	*
	8EHQ-0580-0343			8EHQ-0181-0378		8EHQ-0881-0407	
	8EHQ-1182-0466	*		8EHQ-0985-0566		8EHQ-0386-0593	
	8EHQ-0786-0617			8EHQ-1188-0769	*	8EHQ-0490-0921	S
	8EHQ-0490-0933			8EHQ-0790-1032			

ENV. OCCURRENCE/RELEASE/FATE

SUBMISSION #:	8EHQ-1077-0008			8EHQ-1177-0013		8EHQ-0178-0037	
	8EHQ-0178-0038			8EHQ-0278-0043		8EHQ-0278-0045	*
	8EHQ-0278-0054			8EHQ-0378-0085		8EHQ-0378-0089	*
	8EHQ-0378-0093	*		8EHQ-0378-0099		8EHQ-0378-0110	
	8EHQ-0478-0129			8EHQ-0578-0146		8EHQ-0578-0147	
	8EHQ-0578-0168			8EHQ-0678-0179	*	8EHQ-0678-0183	
	8EHQ-0678-0184	*		8EHQ-0678-0189	P	8EHQ-0678-0208	
	8EHQ-0778-0209			8EHQ-0878-0237		8EHQ-0978-0240	
	8EHQ-1078-0245			8EHQ-1078-0249		8EHQ-1078-0255	*
	8EHQ-1178-0256			8EHQ-1178-0260	*	8EHQ-1278-0264	
	8EHQ-0179-0266			8EHQ-0379-0277		8EHQ-0779-0299	*
	8EHQ-0879-0300	*		8EHQ-0979-0310		8EHQ-1279-0329	*
	8EHQ-0180-0330			8EHQ-0580-0343		8EHQ-0680-0345	
	8EHQ-0880-0358	*		8EHQ-1080-0368		8EHQ-0181-0378	
	8EHQ-0881-0407			8EHQ-0981-0409		8EHQ-0981-0413	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ENV. OCCURRENCE/RELEASE/FATE

SUBMISSION #:							
8EHQ-1081-0416		8EHQ-0982-0457		8EHQ-1182-0462			
8EHQ-1182-0466	*	8EHQ-0983-0491	S	8EHQ-1083-0495			
8EHQ-0384-0508	P *	8EHQ-0784-0521	S	8EHQ-0985-0566			
8EHQ-0386-0593		8EHQ-0486-0597		8EHQ-0786-0617			
8EHQ-0287-0653		8EHQ-0487-0662		8EHQ-0487-0671			
8EHQ-0688-0735		8EHQ-1088-0759		8EHQ-1088-0761			
8EHQ-1188-0769	*	8EHQ-0589-0799		8EHQ-0989-0826	S		
8EHQ-0290-0882		8EHQ-0390-0905	S *	8EHQ-0490-0921	S		
8EHQ-0490-0933		8EHQ-0490-0953		8EHQ-0790-1032			
8EHQ-0890-1038		8EHQ-0990-1077					

EPIDEMIOLOGY/CLINICAL

SUBMISSION #:							
8EHQ-1177-0016		8EHQ-1277-0021		8EHQ-0278-0056			
8EHQ-0378-0096	*	8EHQ-0378-0105		8EHQ-0478-0117	*		
8EHQ-0478-0123		8EHQ-0478-0128		8EHQ-0478-0135			
8EHQ-0578-0146		8EHQ-0578-0149		8EHQ-0578-0167	P		
8EHQ-0578-0168		8EHQ-0678-0192	S	8EHQ-0878-0230			
8EHQ-0978-0241		8EHQ-0978-0246		8EHQ-0379-0280			
8EHQ-0280-0332		8EHQ-0580-0341		8EHQ-1080-0366			
8EHQ-1080-0367		8EHQ-1180-0374	S	8EHQ-0281-0382			
8EHQ-0381-0390		8EHQ-0381-0394	S	8EHQ-1280-0401	S		
8EHQ-0282-0427	S	8EHQ-0382-0440	S	8EHQ-0582-0444			
8EHQ-0383-0473		8EHQ-1083-0497		8EHQ-0884-0523			
8EHQ-0285-0546		8EHQ-0485-0551	*	8EHQ-0485-0552			
8EHQ-0585-0557		8EHQ-0985-0567		8EHQ-0186-0585	S		

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

EPIDEMIOLOGY/CLINICAL

SUBMISSION #:	8EHQ-0286-0588 *	8EHQ-0386-0589 S	8EHQ-0486-0598
	8EHQ-0586-0601	8EHQ-0786-0611	8EHQ-0786-0612
	8EHQ-0786-0615	8EHQ-0986-0629	8EHQ-0986-0632
	8EHQ-0986-0634	8EHQ-1086-0641	8EHQ-0187-0651 *
	8EHQ-0487-0671	8EHQ-0887-0688	8EHQ-0987-0694 *
	8EHQ-1187-0698	8EHQ-1287-0699	8EHQ-1287-0701 *
	8EHQ-0288-0722	8EHQ-0688-0736	8EHQ-1088-0755
	8EHQ-1188-0772	8EHQ-0889-0818 S	8EHQ-0989-0821 S
	8EHQ-1089-0831	8EHQ-1089-0832	8EHQ-0190-0863
	8EHQ-0190-0864	8EHQ-0290-0886	8EHQ-0390-0905 S *
	8EHQ-0390-0915	8EHQ-0490-0917	8EHQ-0490-0924
	8EHQ-0490-0929 S *	8EHQ-0590-0991 S	8EHQ-0790-1034
	8EHQ-0890-1053	8EHQ-0990-1065	8EHQ-0990-1071
	8EHQ-0990-1072	8EHQ-0990-1078	8EHQ-0990-1080 S

GROUNDWATER CONTAMINATION

SUBMISSION #:	8EHQ-0578-0147	8EHQ-0678-0189 P	8EHQ-0979-0310
	8EHQ-0180-0330	8EHQ-0680-0345	8EHQ-1080-0368
	8EHQ-0982-0457	8EHQ-0487-0662	8EHQ-1088-0759
	8EHQ-0490-0953		
8EHQ-0990-1077			

HUMAN EXPOSURE (ACCIDENTAL)

SUBMISSION #:	8EHQ-1077-0008	8EHQ-1077-0011	8EHQ-0178-0038
	8EHQ-0278-0067 P *	8EHQ-0278-0075 P *	8EHQ-0278-0076 P *
	8EHQ-0278-0077 P *	8EHQ-0278-0078 P *	8EHQ-0278-0079 P *

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (ACCIDENTAL)

SUBMISSION #:	8EHQ-0278-0080	P	*	8EHQ-0378-0086	*	8EHQ-0478-0118	P	*
	8EHQ-0578-0146			8EHQ-0578-0149		8EHQ-0578-0154	P	
	8EHQ-0678-0180		*	8EHQ-0778-0217		8EHQ-0978-0238		*
	8EHQ-0978-0240			8EHQ-1178-0260	*	8EHQ-0179-0273		
	8EHQ-0379-0277			8EHQ-0879-0304	*	8EHQ-1079-0315		*
	8EHQ-1279-0322		*	8EHQ-0180-0324		8EHQ-0480-0338		
	8EHQ-0580-0341			8EHQ-0580-0343		8EHQ-0381-0390		
	8EHQ-0981-0413			8EHQ-1081-0416		8EHQ-1182-0466		*
	8EHQ-0384-0508	P	*	8EHQ-0484-0513		8EHQ-0985-0566		
	8EHQ-0786-0617			8EHQ-0487-0671		8EHQ-0688-0736		
	8EHQ-1089-0832			8EHQ-0290-0885		8EHQ-0390-0905	S	*
	8EHQ-0490-0929	S	*	8EHQ-0490-0933		8EHQ-0490-0962		
	8EHQ-0990-1065							

HUMAN EXPOSURE (MONITORING)

SUBMISSION #:	8EHQ-1277-0021			8EHQ-0378-0096	*	8EHQ-0378-0109		
	8EHQ-0378-0110			8EHQ-0378-0112	*	8EHQ-0378-0113		
	8EHQ-0478-0115		*	8EHQ-0578-0146		8EHQ-0578-0147		
	8EHQ-0578-0168			8EHQ-0578-0170		8EHQ-0678-0179		*
	8EHQ-0678-0189	P		8EHQ-0678-0208		8EHQ-0778-0209		
	8EHQ-0778-0213			8EHQ-0778-0219	*	8EHQ-0778-0228		*
	8EHQ-1278-0264			8EHQ-0179-0267		8EHQ-0479-0281		
	8EHQ-0779-0292			8EHQ-0779-0293		8EHQ-0979-0310		
	8EHQ-1179-0320			8EHQ-0979-0326	S	8EHQ-0180-0330		
	8EHQ-0280-0331	S		8EHQ-0380-0336	S	8EHQ-0580-0343		

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (MONITORING)

SUBMISSION #:	8EHQ-0680-0345	8EHQ-0680-0348	8EHQ-1080-0367
	8EHQ-1080-0368	8EHQ-1280-0376	8EHQ-1280-0401 S
	8EHQ-0981-0413	8EHQ-0382-0440 S	8EHQ-0482-0442
	8EHQ-0982-0457	8EHQ-1182-0462	8EHQ-0383-0473
	8EHQ-1083-0495	8EHQ-1083-0497	8EHQ-0184-0504
	8EHQ-0784-0521 S	8EHQ-1084-0535	8EHQ-0185-0542 S
	8EHQ-0285-0546	8EHQ-0385-0547	8EHQ-0485-0550
	8EHQ-0485-0551 *	8EHQ-0485-0553	8EHQ-0585-0554 S
	8EHQ-0985-0566	8EHQ-0286-0588 *	8EHQ-0586-0601
	8EHQ-0986-0633 S	8EHQ-1286-0648	8EHQ-0487-0662
	8EHQ-0487-0671	8EHQ-0587-0672 S	8EHQ-0687-0682
	8EHQ-0288-0722	8EHQ-0688-0735	8EHQ-0988-0752 S
	8EHQ-1088-0761	8EHQ-0289-0784	8EHQ-0389-0789
	8EHQ-0489-0793	8EHQ-0589-0801	8EHQ-0889-0818 S
	8EHQ-1289-0856	8EHQ-0190-0863	8EHQ-0290-0882
	8EHQ-0490-0924	8EHQ-0490-0933	8EHQ-0490-0953
	8EHQ-0490-0962	8EHQ-0690-1018	8EHQ-0890-1038
	8EHQ-0890-1053	8EHQ-0990-1077	8EHQ-0990-1078

HUMAN EXPOSURE (PRODUCT CONTAMINATION)

SUBMISSION #:	8EHQ-1077-0012	8EHQ-0378-0104	8EHQ-0378-0113
	8EHQ-0478-0117 *	8EHQ-0478-0133	8EHQ-0578-0139
	8EHQ-0778-0219 *	8EHQ-1278-0264	8EHQ-0579-0284
	8EHQ-0779-0292	8EHQ-1179-0320	8EHQ-0979-0326 S
	8EHQ-0280-0331 S	8EHQ-0380-0336 S	8EHQ-0680-0348

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

HUMAN EXPOSURE (PRODUCT CONTAMINATION)

SUBMISSION #:	8EHQ-0780-0352	8EHQ-0880-0358 *	8EHQ-1280-0376
	8EHQ-0381-0390	8EHQ-0981-0409	8EHQ-1281-0420
	8EHQ-0482-0442	8EHQ-0682-0449 S	8EHQ-0283-0469 S
	8EHQ-0383-0473	8EHQ-0784-0521 S	8EHQ-0185-0542 S
	8EHQ-0585-0554 S	8EHQ-0885-0564 S	8EHQ-1186-0643
	8EHQ-1186-0644	8EHQ-0288-0720	8EHQ-0688-0735
	8EHQ-1088-0761	8EHQ-0589-0799	8EHQ-0689-0804
	8EHQ-0490-0962		

IMMUNOTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0186-0585 S	8EHQ-0386-0594 S	8EHQ-0588-0732
	8EHQ-0889-0817		

IMMUNOTOXICITY (HUMAN)

SUBMISSION #: 8EHQ-0290-0876

MATERIAL SAFETY DATA SHEETS/LABELS

SUBMISSION #:	8EHQ-0190-0867 *	8EHQ-0390-0903 S	8EHQ-0490-0919 S
	8EHQ-0490-0945	8EHQ-0590-0967	8EHQ-0590-0969
	8EHQ-0590-0983	8EHQ-0590-0991 S	8EHQ-0590-1001 S
	8EHQ-0690-1017	8EHQ-0690-1018	8EHQ-0990-1062
	8EHQ-0990-1071	8EHQ-0990-1078	

METABOLISM/PHARMACOKINETICS (ANIMAL)

SUBMISSION #: 8EHQ-0780-0350
8EHQ-1280-0401 S

METABOLISM/PHARMACOKINETICS (HUMAN)

SUBMISSION #:	8EHQ-0578-0149	8EHQ-0379-0277	8EHQ-0484-0513
	8EHQ-0285-0546	8EHQ-0485-0551 *	8EHQ-0486-0600

MUTAGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-1077-0010	8EHQ-1277-0025	8EHQ-1277-0026 S
	8EHQ-0178-0030	8EHQ-0278-0047	8EHQ-0278-0051 *
	8EHQ-0278-0053	8EHQ-0278-0057	8EHQ-0278-0073
	8EHQ-0278-0082	8EHQ-0378-0102	8EHQ-0378-0107 *
	8EHQ-0478-0127 *	8EHQ-0478-0136 *	8EHQ-0578-0164
	8EHQ-0578-0165	8EHQ-0578-0166	8EHQ-0678-0184 *
	8EHQ-0678-0185 *	8EHQ-0678-0187 *	8EHQ-0778-0213
	8EHQ-0778-0214	8EHQ-0778-0216	8EHQ-0978-0239
	8EHQ-1078-0254	8EHQ-0179-0266	8EHQ-0179-0267
	8EHQ-0179-0268 S	8EHQ-0179-0270	8EHQ-0479-0278
	8EHQ-0479-0279	8EHQ-0579-0285	8EHQ-0579-0286
	8EHQ-0579-0287	8EHQ-0579-0288	8EHQ-0579-0289
	8EHQ-0679-0291	8EHQ-0779-0293	8EHQ-0779-0294
	8EHQ-0879-0301	8EHQ-1179-0321	8EHQ-1279-0323
	8EHQ-0180-0328	8EHQ-0280-0333	8EHQ-0280-0334
	8EHQ-0480-0339	8EHQ-0480-0340	8EHQ-0780-0350
	8EHQ-0780-0351	8EHQ-0980-0359	8EHQ-0980-0361 S
	8EHQ-0980-0363	8EHQ-1080-0366	8EHQ-0281-0383 *
	8EHQ-0281-0385	8EHQ-0381-0391	8EHQ-0481-0396 *
	8EHQ-0581-0400	8EHQ-0681-0402	8EHQ-0681-0403 S
	8EHQ-0681-0404	8EHQ-0781-0406 S	8EHQ-0981-0412

MUTAGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-1081-0415	8EHQ-1081-0417	8EHQ-1081-0418
	8EHQ-1281-0426	8EHQ-0282-0427 S	8EHQ-0682-0448 S
	8EHQ-0982-0455	8EHQ-0982-0458	8EHQ-1082-0459
	8EHQ-1082-0460	8EHQ-1182-0465	8EHQ-0183-0468
	8EHQ-0283-0470	8EHQ-0283-0471 S	8EHQ-0483-0476 S
	8EHQ-0583-0477 S	8EHQ-0683-0481	8EHQ-0683-0482
	8EHQ-0783-0486	8EHQ-0883-0489	8EHQ-0883-0490
	8EHQ-1083-0495	8EHQ-1083-0496	8EHQ-1283-0500 S
	8EHQ-1283-0503	8EHQ-0384-0506 S	8EHQ-1083-0509
	8EHQ-0484-0510	8EHQ-0484-0511	8EHQ-0484-0512
	8EHQ-0584-0515 S	8EHQ-0584-0516 S	8EHQ-0584-0518 S
	8EHQ-0584-0519	8EHQ-0784-0522	8EHQ-0984-0530
	8EHQ-1084-0532	8EHQ-1084-0533 S	8EHQ-1184-0537
	8EHQ-1284-0539	8EHQ-1284-0541 S	8EHQ-0685-0558 S
	8EHQ-0785-0561 S	8EHQ-1085-0571 S	8EHQ-1285-0579 S
	8EHQ-1285-0580	8EHQ-0186-0584	8EHQ-0186-0585 S
	8EHQ-0486-0597	8EHQ-0586-0602 S	8EHQ-0786-0606 S
	8EHQ-0786-0608 S	8EHQ-0786-0610	8EHQ-0786-0613
	8EHQ-0886-0620	8EHQ-0886-0621	8EHQ-0986-0627
	8EHQ-1286-0645	8EHQ-1186-0646 S	8EHQ-1186-0647
	8EHQ-0187-0649 S	8EHQ-0287-0653	8EHQ-0287-0654
	8EHQ-0687-0677	8EHQ-0687-0679	8EHQ-0787-0685
	8EHQ-0787-0686 S	8EHQ-0987-0692	8EHQ-0987-0693
	8EHQ-1287-0706	8EHQ-1287-0709 S	8EHQ-0288-0715
	8EHQ-0288-0719	8EHQ-0688-0737	8EHQ-0788-0743

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

MUTAGENICITY (IN VITRO)

SUBMISSION #:	8EHQ-1088-0758	S		8EHQ-1088-0760	S	8EHQ-0389-0780	
	8EHQ-0389-0791	S		8EHQ-0589-0798	S	8EHQ-0789-0805	S
	8EHQ-0889-0814			8EHQ-0989-0826	S	8EHQ-1089-0837	S
	8EHQ-1289-0854	S		8EHQ-1289-0858	S	8EHQ-0390-0903	S
	8EHQ-0390-0916	S	*	8EHQ-0490-0930	S	8EHQ-0490-0932	
	8EHQ-0490-0960			8EHQ-0690-1009		8EHQ-0690-1015	
	8EHQ-0690-1016	S		8EHQ-0890-1044	S	8EHQ-0890-1051	S
	8EHQ-0990-1066	S		8EHQ-0990-1067		8EHQ-0990-1079	S

MUTAGENICITY (IN VIVO)

SUBMISSION #:	8EHQ-0278-0082			8EHQ-0378-0107	*	8EHQ-0578-0170	
	8EHQ-0678-0208			8EHQ-0778-0213		8EHQ-1078-0248	
	8EHQ-0179-0267			8EHQ-0579-0285		8EHQ-0579-0287	
	8EHQ-0579-0288			8EHQ-0679-0291		8EHQ-0879-0301	
	8EHQ-1179-0321			8EHQ-1279-0323		8EHQ-0780-0350	
	8EHQ-0980-0359			8EHQ-1080-0366		8EHQ-0281-0384	
	8EHQ-0381-0387			8EHQ-0981-0412		8EHQ-1081-0418	
	8EHQ-1281-0426			8EHQ-0483-0476	S	8EHQ-1083-0499	
	8EHQ-0785-0560			8EHQ-1285-0577		8EHQ-0786-0613	
	8EHQ-0290-0892			8EHQ-0390-0916	S *	8EHQ-0590-0981	

NEUROTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1177-0015	S		8EHQ-0278-0055		8EHQ-0678-0173	*
	8EHQ-0678-0188		*	8EHQ-0778-0218		8EHQ-0279-0275	
	8EHQ-0880-0356			8EHQ-0880-0357		8EHQ-0780-0369	

NEUROTOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-0382-0440 S	8EHQ-0682-0451	8EHQ-1182-0462
	8EHQ-0583-0478 S	8EHQ-1083-0494 *	8EHQ-1283-0501
	8EHQ-0684-0520	8EHQ-1084-0532	8EHQ-0585-0556 S
	8EHQ-1085-0571 S	8EHQ-0186-0584	8EHQ-0386-0590
	8EHQ-0486-0599	8EHQ-0886-0628	8EHQ-0287-0655 S
	8EHQ-0587-0678	8EHQ-1287-0706	8EHQ-0188-0714
	8EHQ-0588-0733	8EHQ-0688-0739	8EHQ-0688-0740 S
	8EHQ-0788-0744 S	8EHQ-1088-0757	8EHQ-1288-0776
	8EHQ-0489-0793	8EHQ-0489-0794 S	8EHQ-0889-0811 S
	8EHQ-0886-0815	8EHQ-1089-0837 S	8EHQ-1089-0838 S
	8EHQ-1189-0841	8EHQ-1189-0843 S	8EHQ-1189-0846
	8EHQ-1189-0848 S	8EHQ-0190-0867 *	8EHQ-0290-0893
	8EHQ-0390-0898	8EHQ-0390-0913 S	8EHQ-0390-0914 S
	8EHQ-0490-0919 S	8EHQ-0490-0931 S	8EHQ-0490-0934 S
	8EHQ-0490-0936	8EHQ-0490-0954 S	8EHQ-0490-0957 S
	8EHQ-0490-0958 S	8EHQ-0490-0959 S	8EHQ-0490-0963
	8EHQ-0590-0964	8EHQ-0590-0996	8EHQ-0590-1001 S
	8EHQ-0690-1002	8EHQ-0690-1003	8EHQ-0690-1004 S
	8EHQ-0690-1005 S	8EHQ-0690-1007	8EHQ-0790-1028 S
	8EHQ-0890-1041	8EHQ-0890-1043	8EHQ-0890-1052 S
	8EHQ-0990-1057	8EHQ-0990-1063	8EHQ-0990-1076 S

NEUROTOXICITY (HUMAN)

SUBMISSION #:	8EHQ-1277-0021	8EHQ-0378-0105	8EHQ-0478-0118 P *
	8EHQ-0578-0146	8EHQ-0480-0338	8EHQ-0786-0611

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

NEUROTOXICITY (HUMAN)

SUBMISSION #:			
8EHQ-1086-0641		8EHQ-0590-0991 S	8EHQ-0990-1065

ONCOGENICITY (ANIMAL)

SUBMISSION #:			
8EHQ-0877-0002		8EHQ-1077-0006	8EHQ-1077-0012
8EHQ-1177-0016		8EHQ-1177-0019	8EHQ-1277-0026 S
8EHQ-0178-0028		8EHQ-0178-0029	8EHQ-0278-0044
8EHQ-0278-0046	*	8EHQ-0278-0083	8EHQ-0478-0117 *
8EHQ-0578-0140		8EHQ-0578-0148	8EHQ-0578-0165
8EHQ-0578-0170		8EHQ-0678-0202	8EHQ-0778-0209
8EHQ-0778-0212		8EHQ-0778-0215	8EHQ-0878-0234
8EHQ-0878-0236	*	8EHQ-0978-0246	8EHQ-1078-0248
8EHQ-1078-0251		8EHQ-1078-0253	8EHQ-1278-0262
8EHQ-0279-0274		8EHQ-0479-0281	8EHQ-0579-0283
8EHQ-0779-0297		8EHQ-0979-0305	8EHQ-0979-0306
8EHQ-1079-0314		8EHQ-1179-0316	8EHQ-1179-0318
8EHQ-0180-0327		8EHQ-0180-0328	8EHQ-0480-0337
8EHQ-0580-0342		8EHQ-0780-0350	8EHQ-0780-0353
8EHQ-0980-0360		8EHQ-1080-0370	8EHQ-0381-0389
8EHQ-0381-0393		8EHQ-0481-0397	8EHQ-0581-0400
8EHQ-1280-0401 S		8EHQ-0681-0402	8EHQ-0981-0410
8EHQ-0981-0411		8EHQ-1281-0422	8EHQ-1281-0423
8EHQ-0282-0434		8EHQ-0282-0439	8EHQ-0482-0443
8EHQ-0682-0447		8EHQ-0882-0453	8EHQ-0882-0454
8EHQ-1082-0461		8EHQ-1182-0463	8EHQ-1282-0467
8EHQ-0283-0469 S		8EHQ-0283-0472 S	8EHQ-0383-0474

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ONCOGENICITY (ANIMAL)

SUBMISSION #:			
8EHQ-0683-0480	8EHQ-0683-0483 S	8EHQ-0783-0486	
8EHQ-0783-0488	8EHQ-1083-0497	8EHQ-1283-0503	
8EHQ-0384-0507	8EHQ-1083-0509	8EHQ-0584-0514	
8EHQ-0584-0517	8EHQ-0884-0525	8EHQ-0884-0526	
8EHQ-0984-0530	8EHQ-1284-0538	8EHQ-0485-0550	
8EHQ-0485-0553	8EHQ-0785-0561 S	8EHQ-0785-0562 S	
8EHQ-0985-0567	8EHQ-0685-0583 S	8EHQ-0386-0592	
8EHQ-0486-0600	8EHQ-0686-0604	8EHQ-0786-0606 S	
8EHQ-0786-0614	8EHQ-0886-0618 S	8EHQ-0386-0619	
8EHQ-1086-0642	8EHQ-0187-0650	8EHQ-0587-0675	*
8EHQ-0786-0681	8EHQ-0787-0684 S	8EHQ-0887-0687	
8EHQ-0887-0691 S	8EHQ-0987-0692	8EHQ-1187-0697	
8EHQ-1287-0704	8EHQ-1287-0708 S	8EHQ-1287-0710	
8EHQ-0188-0713	8EHQ-0388-0725	8EHQ-0588-0730	
8EHQ-0788-0741	8EHQ-0788-0745 S	8EHQ-1088-0760 S	
8EHQ-1088-0763 S	8EHQ-1288-0773	8EHQ-1288-0774	
8EHQ-1288-0775	8EHQ-0789-0809 *	8EHQ-0889-0812	
8EHQ-0989-0822	8EHQ-1189-0847	8EHQ-1289-0856	
8EHQ-1289-0858 S	8EHQ-0290-0873 S	8EHQ-0290-0881 S	
8EHQ-0490-0952 S	8EHQ-0490-0960	8EHQ-0590-0993 S	
8EHQ-0790-1029	8EHQ-0890-1050 S		

ONCOGENICITY (HUMAN)

SUBMISSION #:			
8EHQ-0777-0001	8EHQ-0378-0096 *	8EHQ-0478-0117	*
8EHQ-0478-0135	8EHQ-0578-0167 P	8EHQ-0578-0168	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

ONCOGENICITY (HUMAN)

SUBMISSION #:	8EHQ-0878-0230		8EHQ-0978-0241		8EHQ-0978-0246		
	8EHQ-0582-0444		8EHQ-0383-0473		8EHQ-0884-0523		
	8EHQ-0285-0546		8EHQ-0585-0557		8EHQ-0486-0598		
	8EHQ-0586-0601		8EHQ-0786-0615		8EHQ-0986-0629		
	8EHQ-0986-0634		8EHQ-0187-0651	*	8EHQ-0887-0688		
	8EHQ-1187-0698		8EHQ-1287-0699		8EHQ-1287-0701	*	
	8EHQ-1188-0772		8EHQ-0190-0863		8EHQ-0190-0864		
	8EHQ-0290-0886		8EHQ-0390-0915		8EHQ-0490-0917		
	8EHQ-0490-0924		8EHQ-0790-1034		8EHQ-0890-1053		
	8EHQ-0990-1080 S						

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1077-0008		8EHQ-1077-0011		8EHQ-1177-0014		
	8EHQ-1177-0016		8EHQ-1277-0021		8EHQ-1277-0026 S		
	8EHQ-0278-0044		8EHQ-0278-0045	*	8EHQ-0278-0054		
	8EHQ-0378-0085		8EHQ-0378-0089	*	8EHQ-0378-0093	*	
	8EHQ-0378-0104		8EHQ-0378-0105		8EHQ-0478-0117	*	
	8EHQ-0478-0133		8EHQ-0578-0139		8EHQ-0578-0150	*	
	8EHQ-0578-0153 S	*	8EHQ-0578-0155	*	8EHQ-0578-0163		
	8EHQ-0578-0164		8EHQ-0578-0165		8EHQ-0578-0169 S	*	
	8EHQ-0678-0187	*	8EHQ-0678-0200	*	8EHQ-0678-0205	*	
	8EHQ-0778-0209		8EHQ-0778-0214		8EHQ-0778-0219	*	
	8EHQ-0778-0220	*	8EHQ-0778-0228	*	8EHQ-0978-0240		
	8EHQ-1078-0245		8EHQ-1078-0249		8EHQ-1078-0251		
	8EHQ-1078-0253		8EHQ-1078-0255	*	8EHQ-1178-0256		

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1178-0260	*	8EHQ-1178-0261		8EHQ-1278-0264		
	8EHQ-0179-0268	S	8EHQ-0179-0269	S	8EHQ-0179-0272		
	8EHQ-0279-0275		8EHQ-0479-0278		8EHQ-0379-0280		
	8EHQ-0579-0283		8EHQ-0579-0288		8EHQ-0779-0292		
	8EHQ-0779-0293		8EHQ-0879-0301		8EHQ-1179-0317		
	8EHQ-1179-0321		8EHQ-1279-0323		8EHQ-0180-0328		
	8EHQ-0280-0331	S	8EHQ-0280-0333		8EHQ-0380-0335	S	
	8EHQ-0380-0336	S	8EHQ-0780-0350		8EHQ-0880-0358		*
	8EHQ-1180-0373	S	8EHQ-1180-0374	S	8EHQ-1180-0375	S	
	8EHQ-0381-0394	S	8EHQ-0481-0397		8EHQ-0581-0399		
	8EHQ-0781-0406	S	8EHQ-0482-0442		8EHQ-0682-0446	S	
	8EHQ-0882-0454		8EHQ-0982-0456	S *	8EHQ-0283-0469	S	
	8EHQ-0283-0471	S	8EHQ-0583-0477	S	8EHQ-0583-0479	S	
	8EHQ-0683-0480		8EHQ-0683-0483	S	8EHQ-0683-0484	S	
	8EHQ-0783-0485	S *	8EHQ-0783-0487	S *	8EHQ-0983-0491	S	
	8EHQ-0983-0492	S	8EHQ-0983-0493	S *	8EHQ-1283-0500	S	
	8EHQ-1283-0501		8EHQ-1283-0502	P *	8EHQ-1283-0503		
	8EHQ-0384-0508	P *	8EHQ-0484-0510		8EHQ-0484-0511		
	8EHQ-0484-0513		8EHQ-0584-0515	S	8EHQ-0584-0516	S	
	8EHQ-0584-0517		8EHQ-0584-0519		8EHQ-0784-0521	S	
	8EHQ-0884-0526		8EHQ-1284-0540	S *	8EHQ-0185-0542	S	
	8EHQ-0285-0545	S	8EHQ-0485-0548		8EHQ-0485-0551		*
	8EHQ-0485-0553		8EHQ-0585-0554	S	8EHQ-0585-0555		
	8EHQ-0585-0556	S	8EHQ-0785-0562	S	8EHQ-0885-0564	S	
	8EHQ-0985-0568	S	8EHQ-1085-0571	S	8EHQ-0585-0572		

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:								
8EHQ-1185-0576			8EHQ-1285-0577			8EHQ-0186-0582	S	
8EHQ-0685-0583	S		8EHQ-0386-0589	S		8EHQ-0386-0594	S	
8EHQ-0486-0597			8EHQ-0586-0602	S		8EHQ-0686-0605	S	
8EHQ-0786-0606	S		8EHQ-0786-0608	S		8EHQ-0786-0609	S	
8EHQ-0786-0610			8EHQ-0786-0614			8EHQ-0886-0621		
8EHQ-0986-0623	S		8EHQ-0986-0624	S		8EHQ-0986-0625	S	
8EHQ-0986-0626	S		8EHQ-0986-0627			8EHQ-0986-0631	S	
8EHQ-0986-0632			8EHQ-0986-0633	S		8EHQ-1086-0636	S	
8EHQ-1086-0637			8EHQ-1086-0639	S		8EHQ-1086-0640	S	*
8EHQ-1186-0643			8EHQ-1186-0644			8EHQ-1186-0646	S	
8EHQ-0187-0649	S		8EHQ-0287-0652	S		8EHQ-0287-0655	S	
8EHQ-0387-0656			8EHQ-0487-0661	S		8EHQ-0487-0664	S	
8EHQ-0487-0665	S	*	8EHQ-0487-0667	S	*	8EHQ-0487-0668		
8EHQ-0487-0669		*	8EHQ-0487-0670	S		8EHQ-0487-0671		
8EHQ-0587-0674	S		8EHQ-0687-0680			8EHQ-0787-0684	S	
8EHQ-0787-0686	S		8EHQ-1187-0697			8EHQ-1287-0707	S	
8EHQ-1287-0708	S		8EHQ-1287-0709	S		8EHQ-0188-0714		
8EHQ-0288-0716	S		8EHQ-0288-0717	S		8EHQ-0288-0720		
8EHQ-0388-0724	S		8EHQ-0388-0725			8EHQ-0488-0727		
8EHQ-0488-0728			8EHQ-0488-0729	S		8EHQ-0588-0731	S	
8EHQ-0588-0733			8EHQ-0688-0734	S		8EHQ-0688-0735		
8EHQ-0688-0740	S		8EHQ-0788-0744	S		8EHQ-0788-0745	S	
8EHQ-0988-0749	S		8EHQ-0988-0750	S		8EHQ-0988-0751	S	
8EHQ-0988-0752	S		8EHQ-0988-0753	S		8EHQ-1088-0755		
8EHQ-1088-0758	S		8EHQ-1088-0760	S		8EHQ-1088-0761		

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-1088-0763 S	8EHQ-1088-0764 S	8EHQ-1188-0765 S
	8EHQ-1188-0766 S	8EHQ-1188-0767 S	8EHQ-1188-0768 S
	8EHQ-1188-0770 S	8EHQ-1188-0771 S	8EHQ-1288-0776
	8EHQ-0389-0780	8EHQ-0289-0782 S	8EHQ-0289-0783 S
	8EHQ-0289-0784	8EHQ-0289-0785 S	8EHQ-0389-0787 S
	8EHQ-0389-0788 S	8EHQ-0389-0789	8EHQ-0389-0790 S
	8EHQ-0389-0791 S	8EHQ-0489-0794 S	8EHQ-0589-0798 S
	8EHQ-0589-0799	8EHQ-0689-0804	8EHQ-0789-0805 S
	8EHQ-0789-0806 S	8EHQ-0789-0808 S	8EHQ-0889-0811 S
	8EHQ-0889-0816 S	8EHQ-0889-0817	8EHQ-0889-0819 S
	8EHQ-0989-0821 S	8EHQ-0989-0824 S	8EHQ-0989-0825 S
	8EHQ-0989-0827 S	8EHQ-0989-0828 S	8EHQ-1089-0833 S
	8EHQ-1089-0834 S	8EHQ-1089-0835 S	8EHQ-1089-0837 S
	8EHQ-1089-0838 S	8EHQ-1189-0840 S	8EHQ-1189-0842 S
	8EHQ-1189-0843 S	8EHQ-1189-0844	8EHQ-1189-0847
	8EHQ-1189-0848 S	8EHQ-1289-0849 S	8EHQ-1289-0851 S
	8EHQ-1289-0853 S	8EHQ-1289-0854 S	8EHQ-1289-0857 S
	8EHQ-1289-0858 S	8EHQ-1289-0859	8EHQ-0190-0861 S
	8EHQ-0190-0862 S	8EHQ-0190-0865 S	8EHQ-0190-0866 S
	8EHQ-0190-0868 S	8EHQ-0190-0869 S	8EHQ-0190-0870 S
	8EHQ-0190-0871 S	8EHQ-0290-0872 S	8EHQ-0290-0873 S
	8EHQ-0290-0874 S	8EHQ-0290-0875 S	8EHQ-0290-0879 S
	8EHQ-0290-0880	8EHQ-0290-0881 S	8EHQ-0290-0883 S
	8EHQ-0290-0887 S	8EHQ-0290-0888 S	8EHQ-0290-0889 S
	8EHQ-0290-0890 S	8EHQ-0290-0891 S	8EHQ-0390-0895 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:		
8EHQ-0390-0896 S	8EHQ-0390-0897 S	8EHQ-0390-0903 S
8EHQ-0390-0905 S *	8EHQ-0390-0906 S	8EHQ-0390-0907 S
8EHQ-0390-0908 S	8EHQ-0390-0913 S	8EHQ-0390-0914 S
8EHQ-0390-0916 S *	8EHQ-0490-0918 S	8EHQ-0490-0919 S
8EHQ-0490-0920 S	8EHQ-0490-0921 S	8EHQ-0490-0922 S
8EHQ-0490-0923 S	8EHQ-0490-0925 S	8EHQ-0490-0926 S
8EHQ-0490-0927 S	8EHQ-0490-0928 S	8EHQ-0490-0929 S *
8EHQ-0490-0930 S	8EHQ-0490-0931 S	8EHQ-0490-0932
8EHQ-0490-0934 S	8EHQ-0490-0935 S	8EHQ-0490-0938
8EHQ-0490-0952 S	8EHQ-0490-0955 S	8EHQ-0490-0956 S
8EHQ-0490-0957 S	8EHQ-0490-0958 S	8EHQ-0490-0959 S
8EHQ-0490-0961 S	8EHQ-0490-0962	8EHQ-0590-0983
8EHQ-0590-0986 S	8EHQ-0590-0987 S	8EHQ-0590-0988 S
8EHQ-0590-0989 S	8EHQ-0590-0990	8EHQ-0590-0992 S
8EHQ-0590-0993 S	8EHQ-0590-0995 S	8EHQ-0590-0997 S
8EHQ-0590-0998 S	8EHQ-0590-1001 S	8EHQ-0690-1004 S
8EHQ-0690-1005 S	8EHQ-0690-1006 S	8EHQ-0690-1010 S
8EHQ-0690-1011 S	8EHQ-0690-1012 S	8EHQ-0690-1013 S
8EHQ-0690-1014 S	8EHQ-0690-1016 S	8EHQ-0790-1022 S
8EHQ-0790-1023 S	8EHQ-0790-1025 S	8EHQ-0790-1026 S
8EHQ-0790-1028 S	8EHQ-0790-1029	8EHQ-0790-1031 S
8EHQ-0790-1036 S	8EHQ-0790-1037 S	8EHQ-0890-1039 S
8EHQ-0890-1042	8EHQ-0890-1044 S	8EHQ-0890-1048 S
8EHQ-0890-1049 S	8EHQ-0890-1050 S	8EHQ-0890-1052 S
8EHQ-0890-1054 S	8EHQ-0890-1056 S	8EHQ-0990-1058 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCT COMPOSITION/CHEMICAL IDENTITY

SUBMISSION #:	8EHQ-0990-1059 S *	8EHQ-0990-1060 S	8EHQ-0990-1062
	8EHQ-0990-1063	8EHQ-0990-1066 S	8EHQ-0990-1070 S
	8EHQ-0990-1071	8EHQ-0990-1073 S	8EHQ-0990-1075 S
	8EHQ-0990-1076 S	8EHQ-0990-1078	8EHQ-0990-1079 S
	8EHQ-0990-1083 S		

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-1277-0026 S	8EHQ-0378-0096 *	8EHQ-0378-0097 *
	8EHQ-0378-0104	8EHQ-0378-0105	8EHQ-0378-0109
	8EHQ-0378-0110	8EHQ-0378-0112 *	8EHQ-0378-0113
	8EHQ-0478-0115 *	8EHQ-0478-0117 *	8EHQ-0478-0118 P *
	8EHQ-0478-0123	8EHQ-0478-0138 P *	8EHQ-0578-0139
	8EHQ-0578-0146	8EHQ-0578-0148	8EHQ-0578-0152
	8EHQ-0578-0155 *	8EHQ-0578-0157 *	8EHQ-0578-0158 S *
	8EHQ-0578-0159 S *	8EHQ-0578-0162 S *	8EHQ-0578-0163
	8EHQ-0578-0164	8EHQ-0578-0165	8EHQ-0578-0166
	8EHQ-0578-0167 P	8EHQ-0578-0168	8EHQ-0578-0169 S *
	8EHQ-0678-0179 *	8EHQ-0678-0180 *	8EHQ-0678-0200 *
	8EHQ-0678-0202	8EHQ-0778-0209	8EHQ-0778-0217
	8EHQ-0778-0219 *	8EHQ-0778-0228 *	8EHQ-0878-0230
	8EHQ-0978-0239	8EHQ-1078-0245	8EHQ-0978-0246
	8EHQ-1078-0247	8EHQ-1078-0251	8EHQ-1078-0252
	8EHQ-1078-0253	8EHQ-1178-0256	8EHQ-1178-0261
	8EHQ-1278-0264	8EHQ-0179-0267	8EHQ-0179-0268 S
	8EHQ-0179-0270	8EHQ-0179-0271	8EHQ-0179-0272

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:

8EHQ-0279-0275	8EHQ-0479-0278	8EHQ-0379-0280
8EHQ-0479-0282 S	8EHQ-0579-0283	8EHQ-0579-0288
8EHQ-0679-0291	8EHQ-0779-0292	8EHQ-0779-0293
8EHQ-0779-0294	8EHQ-0779-0296	8EHQ-0779-0297
8EHQ-0583-0477 S	8EHQ-0583-0479 S	8EHQ-0683-0480
8EHQ-0683-0481	8EHQ-0683-0483 S	8EHQ-0783-0485 S *
8EHQ-0783-0487 S *	8EHQ-0883-0490	8EHQ-0983-0492 S
8EHQ-0983-0493 S *	8EHQ-1083-0494 *	8EHQ-1083-0495
8EHQ-1083-0496	8EHQ-1083-0497	8EHQ-1083-0498
8EHQ-1283-0500 S	8EHQ-1283-0501	8EHQ-1283-0502 P *
8EHQ-1283-0503	8EHQ-0184-0504	8EHQ-0284-0505
8EHQ-0384-0506 S	8EHQ-1083-0509	8EHQ-0484-0510
8EHQ-0484-0513	8EHQ-0584-0514	8EHQ-0584-0515 S
8EHQ-0584-0516 S	8EHQ-0584-0517	8EHQ-0584-0519
8EHQ-0684-0520	8EHQ-0784-0521 S	8EHQ-0784-0522
8EHQ-0884-0523	8EHQ-0884-0524	8EHQ-0884-0526
8EHQ-0884-0528	8EHQ-0984-0529	8EHQ-0984-0531 S *
8EHQ-1084-0532	8EHQ-1084-0533 S	8EHQ-1084-0534
8EHQ-1084-0535	8EHQ-0185-0542 S	8EHQ-0285-0544
8EHQ-0285-0545 S	8EHQ-0285-0546	8EHQ-0385-0547
8EHQ-0485-0548	8EHQ-0485-0549 S	8EHQ-0485-0550
8EHQ-0485-0551 *	8EHQ-0485-0552	8EHQ-0485-0553
8EHQ-0585-0554 S	8EHQ-0585-0555	8EHQ-0585-0556 S
8EHQ-0585-0557	8EHQ-0685-0558 S	8EHQ-0685-0559
8EHQ-0785-0561 S	8EHQ-0785-0562 S	8EHQ-0785-0563

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0885-0564	S		8EHQ-0885-0565	S		8EHQ-0985-0566	
	8EHQ-0985-0568	S		8EHQ-1085-0569			8EHQ-1085-0570	
	8EHQ-1085-0571	S		8EHQ-0585-0572			8EHQ-1185-0573	
	8EHQ-1185-0574			8EHQ-1185-0575			8EHQ-1185-0576	
	8EHQ-1285-0577			8EHQ-1285-0578			8EHQ-1285-0579	S
	8EHQ-1285-0580			8EHQ-1285-0581			8EHQ-0186-0582	S
	8EHQ-0685-0583	S		8EHQ-0186-0584			8EHQ-0186-0585	S
	8EHQ-0186-0586	S		8EHQ-0286-0588		*	8EHQ-0386-0589	S
	8EHQ-0386-0591			8EHQ-0386-0594	S		8EHQ-0486-0596	
	8EHQ-0486-0597			8EHQ-0486-0599			8EHQ-0486-0600	
	8EHQ-0586-0601			8EHQ-0586-0602	S		8EHQ-0686-0603	
	8EHQ-0786-0606	S		8EHQ-0786-0607	S		8EHQ-0786-0608	S
	8EHQ-0786-0609	S		8EHQ-0786-0613			8EHQ-0786-0614	
	8EHQ-0786-0615			8EHQ-0786-0616			8EHQ-0886-0621	
	8EHQ-0886-0622	S		8EHQ-0986-0623	S		8EHQ-0986-0624	S
	8EHQ-0986-0625	S		8EHQ-0986-0627			8EHQ-0986-0629	
	8EHQ-0986-0630			8EHQ-0986-0631	S		8EHQ-0986-0633	S
	8EHQ-0986-0634			8EHQ-1086-0635			8EHQ-1086-0636	S
	8EHQ-1086-0637			8EHQ-1086-0639	S		8EHQ-1086-0640	S *
	8EHQ-1086-0641			8EHQ-1086-0642			8EHQ-1186-0643	
	8EHQ-1186-0644			8EHQ-1286-0645			8EHQ-1286-0648	
	8EHQ-0187-0649	S		8EHQ-0287-0653			8EHQ-0287-0654	
	8EHQ-0287-0655	S		8EHQ-0287-0657	S		8EHQ-0287-0658	
	8EHQ-0387-0659			8EHQ-0487-0661	S		8EHQ-0487-0663	
	8EHQ-0487-0664	S		8EHQ-0487-0665	S	*	8EHQ-0487-0667	S *

PRODUCTION/USE/PROCESS

SUBMISSION #:								
	8EHQ-0487-0669	*	8EHQ-0487-0670	S		8EHQ-0487-0671		
	8EHQ-0587-0672	S	8EHQ-0587-0673			8EHQ-0587-0674	S	
	8EHQ-0587-0675	*	8EHQ-0587-0676			8EHQ-0687-0677		
	8EHQ-0587-0678		8EHQ-0687-0679			8EHQ-0687-0680		
	8EHQ-0687-0682		8EHQ-0687-0683			8EHQ-0787-0684	S	
	8EHQ-0787-0685		8EHQ-0787-0686	S		8EHQ-0887-0687		
	8EHQ-0887-0688		8EHQ-0887-0689		*	8EHQ-0887-0690		
	8EHQ-0887-0691	S	8EHQ-0987-0692			8EHQ-0987-0694		*
	8EHQ-1087-0695		8EHQ-1187-0698			8EHQ-1287-0699		
	8EHQ-1287-0700		8EHQ-1287-0701		*	8EHQ-1287-0704		
	8EHQ-1287-0706		8EHQ-1287-0709	S		8EHQ-1287-0710		
	8EHQ-0188-0714		8EHQ-0288-0715			8EHQ-0288-0716	S	
	8EHQ-0288-0717	S	8EHQ-0288-0719			8EHQ-0288-0720		
	8EHQ-0388-0721		8EHQ-0288-0722			8EHQ-0388-0723		
	8EHQ-0388-0724	S	8EHQ-0388-0725			8EHQ-0488-0729	S	
	8EHQ-0588-0730		8EHQ-0588-0731	S		8EHQ-0588-0732		
	8EHQ-0588-0733		8EHQ-0688-0734	S		8EHQ-0688-0735		
	8EHQ-0688-0738		8EHQ-0688-0739			8EHQ-0688-0740	S	
	8EHQ-0788-0742	*	8EHQ-0788-0744	S		8EHQ-0788-0745	S	
	8EHQ-0888-0746		8EHQ-0888-0747			8EHQ-0988-0748		
	8EHQ-0988-0749	S	8EHQ-0988-0750	S		8EHQ-0988-0751	S	
	8EHQ-0988-0752	S	8EHQ-0988-0753	S		8EHQ-0988-0754		
	8EHQ-1088-0755		8EHQ-1088-0756			8EHQ-1088-0757		
	8EHQ-1088-0758	S	8EHQ-1088-0759			8EHQ-1088-0760	S	
	8EHQ-1088-0763	S	8EHQ-1188-0765	S		8EHQ-1188-0766	S	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-1188-0767 S	8EHQ-1188-0768 S	8EHQ-1188-0770 S
	8EHQ-1188-0771 S	8EHQ-1288-0775	8EHQ-1288-0776
	8EHQ-1288-0778	8EHQ-0189-0779	8EHQ-0189-0781 S
	8EHQ-0289-0782 S	8EHQ-0289-0783 S	8EHQ-0289-0784
	8EHQ-0289-0785 S	8EHQ-0389-0787 S	8EHQ-0389-0788 S
	8EHQ-0389-0789	8EHQ-0389-0790 S	8EHQ-0389-0791 S
	8EHQ-0489-0792	8EHQ-0489-0793	8EHQ-0489-0794 S
	8EHQ-0589-0798 S	8EHQ-0589-0799	8EHQ-0589-0800
	8EHQ-0689-0802	8EHQ-0689-0804	8EHQ-0789-0805 S
	8EHQ-0789-0806 S	8EHQ-0789-0807 S	8EHQ-0789-0808 S
	8EHQ-0889-0810 S	8EHQ-0889-0811 S	8EHQ-0889-0813
	8EHQ-0889-0814	8EHQ-0886-0815	8EHQ-0889-0816 S
	8EHQ-0889-0817	8EHQ-0889-0818 S	8EHQ-0889-0819 S
	8EHQ-0889-0820	8EHQ-0989-0821 S	8EHQ-0989-0823
	8EHQ-0989-0824 S	8EHQ-0989-0825 S	8EHQ-0989-0826 S
	8EHQ-0989-0827 S	8EHQ-0989-0828 S	8EHQ-1089-0829
	8EHQ-1089-0831	8EHQ-1089-0832	8EHQ-1089-0833 S
	8EHQ-1089-0834 S	8EHQ-1089-0835 S	8EHQ-1089-0836
	8EHQ-1089-0838 S	8EHQ-1189-0839	8EHQ-1189-0840 S
	8EHQ-1189-0841	8EHQ-1189-0842 S	8EHQ-1189-0843 S
	8EHQ-1189-0845	8EHQ-1189-0847	8EHQ-1189-0848 S
	8EHQ-1289-0849 S	8EHQ-1289-0850	8EHQ-1289-0851 S
	8EHQ-1289-0852 S	8EHQ-1289-0853 S	8EHQ-1289-0854 S
	8EHQ-1289-0856	8EHQ-1289-0857 S	8EHQ-1289-0858 S
	8EHQ-0190-0861 S	8EHQ-0190-0862 S	8EHQ-0190-0863

PRODUCTION/USE/PROCESS

SUBMISSION #:	8EHQ-0190-0864	8EHQ-0190-0865 S	8EHQ-0190-0866 S
	8EHQ-0190-0867 *	8EHQ-0190-0868 S	8EHQ-0190-0869 S
	8EHQ-0190-0870 S	8EHQ-0190-0871 S	8EHQ-0290-0872 S
	8EHQ-0290-0874 S	8EHQ-0290-0875 S	8EHQ-0290-0877
	8EHQ-0290-0879 S	8EHQ-0290-0881 S	8EHQ-0290-0882
	8EHQ-0290-0883 S	8EHQ-0290-0885	8EHQ-0290-0886
	8EHQ-0290-0887 S	8EHQ-0290-0888 S	8EHQ-0290-0889 S
	8EHQ-0290-0890 S	8EHQ-0290-0891 S	8EHQ-0290-0894
	8EHQ-0390-0898	8EHQ-0390-0899 *	8EHQ-0390-0900
	8EHQ-0390-0901	8EHQ-0390-0902	8EHQ-0390-0903 S
	8EHQ-0390-0907 S	8EHQ-0390-0913 S	8EHQ-0390-0914 S
	8EHQ-0390-0915	8EHQ-0390-0916 S *	8EHQ-0490-0917
	8EHQ-0490-0918 S	8EHQ-0490-0919 S	8EHQ-0490-0924
	8EHQ-0490-0925 S	8EHQ-0490-0926 S	8EHQ-0490-0928 S
	8EHQ-0490-0930 S	8EHQ-0490-0931 S	8EHQ-0490-0932
	8EHQ-0490-0933	8EHQ-0490-0934 S	8EHQ-0490-0935 S
	8EHQ-0490-0936	8EHQ-0490-0937	8EHQ-0490-0938
	8EHQ-0490-0939	8EHQ-0490-0940	8EHQ-0490-0941
	8EHQ-0490-0943	8EHQ-0490-0944	8EHQ-0490-0945
	8EHQ-0490-0950	8EHQ-0490-0951	8EHQ-0490-0954 S
	8EHQ-0490-0955 S	8EHQ-0490-0956 S	8EHQ-0490-0957 S
	8EHQ-0490-0958 S	8EHQ-0490-0959 S	8EHQ-0490-0960
	8EHQ-0490-0962	8EHQ-0590-0964	8EHQ-0590-0968
	8EHQ-0590-0971	8EHQ-0590-0972	8EHQ-0590-0974
	8EHQ-0590-0975	8EHQ-0590-0976	8EHQ-0590-0981

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

PRODUCTION/USE/PROCESS

SUBMISSION #:			
8EHQ-0590-0983	8EHQ-0590-0985 *	8EHQ-0590-0992 S	
8EHQ-0590-0994 *	8EHQ-0590-0995 S	8EHQ-0590-0996	
8EHQ-0590-0997 S	8EHQ-0590-0998 S	8EHQ-0690-0999 *	
8EHQ-0590-1001 S	8EHQ-0690-1002	8EHQ-0690-1003	
8EHQ-0690-1004 S	8EHQ-0690-1005 S	8EHQ-0690-1006 S	
8EHQ-0690-1010 S	8EHQ-0690-1011 S	8EHQ-0690-1012 S	
8EHQ-0690-1013 S	8EHQ-0690-1014 S	8EHQ-0690-1015	
8EHQ-0690-1016 S	8EHQ-0690-1018	8EHQ-0690-1019	
8EHQ-0790-1021	8EHQ-0790-1023 S	8EHQ-0790-1024	
8EHQ-0790-1025 S	8EHQ-0790-1026 S	8EHQ-0790-1027	
8EHQ-0790-1028 S	8EHQ-0790-1029	8EHQ-0790-1031 S	
8EHQ-0790-1033	8EHQ-0790-1034	8EHQ-0790-1036 S	
8EHQ-0790-1037 S	8EHQ-0890-1039 S	8EHQ-0890-1040	
8EHQ-0890-1041	8EHQ-0890-1042	8EHQ-0890-1043	
8EHQ-0890-1044 S	8EHQ-0890-1045	8EHQ-0890-1046	
8EHQ-0890-1047	8EHQ-0890-1048 S	8EHQ-0890-1049 S	
8EHQ-0890-1050 S	8EHQ-0890-1052 S	8EHQ-0890-1053	
8EHQ-0890-1054 S	8EHQ-0890-1055 S	8EHQ-0890-1056 S	
8EHQ-0990-1058 S	8EHQ-0990-1060 S	8EHQ-0990-1061	
8EHQ-0990-1062	8EHQ-0990-1063	8EHQ-0990-1065	
8EHQ-0990-1066 S	8EHQ-0990-1069	8EHQ-0990-1070 S	
8EHQ-0990-1071	8EHQ-0990-1072	8EHQ-0990-1073 S	
8EHQ-0990-1074	8EHQ-0990-1075 S	8EHQ-0990-1076 S	
8EHQ-0990-1078	8EHQ-0990-1079 S	8EHQ-0990-1080 S	
8EHQ-0990-1081	8EHQ-0990-1083 S		

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

REPORTING RATIONALE

SUBMISSION #:	8EHQ-1078-0249	8EHQ-0880-0358 *	8EHQ-0783-0485 S *
	8EHQ-1083-0494 *	8EHQ-0384-0508 P *	8EHQ-0587-0672 S
	8EHQ-1287-0706	8EHQ-0488-0729 S	8EHQ-1188-0772
	8EHQ-0889-0813	8EHQ-0886-0815	8EHQ-0490-0933

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-1077-0007	8EHQ-1277-0027	8EHQ-0278-0049
	8EHQ-0378-0095 *	8EHQ-0378-0101 *	8EHQ-0378-0103 *
	8EHQ-0478-0122 *	8EHQ-0478-0129	8EHQ-0478-0130 *
	8EHQ-0578-0160 S *	8EHQ-0678-0185 *	8EHQ-0678-0206 *
	8EHQ-0678-0208	8EHQ-0778-0209	8EHQ-0778-0211
	8EHQ-0978-0244	8EHQ-1078-0245	8EHQ-1078-0247
	8EHQ-1078-0248	8EHQ-1078-0252	8EHQ-0179-0267
	8EHQ-0179-0269 S	8EHQ-0779-0293	8EHQ-0680-0346
	8EHQ-1180-0373 S	8EHQ-1180-0374 S	8EHQ-1180-0375 S
	8EHQ-0181-0379	8EHQ-0281-0384	8EHQ-0381-0386
	8EHQ-0381-0388 S	8EHQ-0381-0394 S	8EHQ-0581-0399
	8EHQ-0781-0405 S	8EHQ-1081-0414	8EHQ-1281-0421 S
	8EHQ-1281-0424	8EHQ-0382-0440 S	8EHQ-0382-0441
	8EHQ-0682-0450	8EHQ-0882-0452	8EHQ-1182-0462
	8EHQ-1182-0464	8EHQ-0483-0475	8EHQ-0783-0485 S *
	8EHQ-1083-0499	8EHQ-0284-0505	8EHQ-0884-0527
	8EHQ-0884-0528	8EHQ-1084-0532	8EHQ-1084-0534
	8EHQ-0185-0543	8EHQ-0285-0544	8EHQ-0385-0547
	8EHQ-0485-0548	8EHQ-0585-0555	8EHQ-0785-0560

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:			
8EHQ-0785-0562 S	8EHQ-1085-0570	8EHQ-0585-0572	
8EHQ-1285-0577	8EHQ-0186-0587	8EHQ-0986-0623 S	
8EHQ-0986-0626 S	8EHQ-0886-0628	8EHQ-0986-0633 S	
8EHQ-0287-0653	8EHQ-0287-0658	8EHQ-0487-0664 S	
8EHQ-0487-0666 S	8EHQ-0587-0672 S	8EHQ-0587-0676	
8EHQ-0687-0682	8EHQ-1087-0695	8EHQ-1287-0706	
8EHQ-0288-0716 S	8EHQ-0288-0717 S	8EHQ-0388-0721	
8EHQ-0388-0726 *	8EHQ-0488-0727	8EHQ-0488-0729 S	
8EHQ-0588-0731 S	8EHQ-0688-0738	8EHQ-0888-0746	
8EHQ-0988-0748	8EHQ-0988-0749 S	8EHQ-0988-0750 S	
8EHQ-0988-0751 S	8EHQ-1088-0758 S	8EHQ-1088-0760 S	
8EHQ-1088-0764 S	8EHQ-1188-0765 S	8EHQ-1188-0766 S	
8EHQ-1188-0767 S	8EHQ-1188-0770 S	8EHQ-1188-0771 S	
8EHQ-1288-0778	8EHQ-0289-0783 S	8EHQ-0289-0785 S	
8EHQ-0389-0786 S	8EHQ-0389-0790 S	8EHQ-0489-0792	
8EHQ-0489-0794 S	8EHQ-0789-0807 S	8EHQ-0889-0810 S	
8EHQ-0889-0811 S	8EHQ-0889-0813	8EHQ-0889-0816 S	
8EHQ-0889-0820	8EHQ-0989-0823	8EHQ-0989-0824 S	
8EHQ-0989-0825 S	8EHQ-0989-0827 S	8EHQ-0989-0828 S	
8EHQ-1089-0829	8EHQ-1089-0835 S	8EHQ-1189-0842 S	
8EHQ-1189-0844	8EHQ-1289-0849 S	8EHQ-1289-0851 S	
8EHQ-1289-0852 S	8EHQ-1289-0855	8EHQ-1289-0858 S	
8EHQ-0190-0861 S	8EHQ-0190-0862 S	8EHQ-0190-0865 S	
8EHQ-0190-0868 S	8EHQ-0190-0869 S	8EHQ-0190-0870 S	
8EHQ-0190-0871 S	8EHQ-0290-0872 S	8EHQ-0290-0874 S	

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:		
8EHQ-0290-0875 S	8EHQ-0290-0877	8EHQ-0290-0878
8EHQ-0290-0879 S	8EHQ-0290-0881 S	8EHQ-0290-0883 S
8EHQ-0290-0884	8EHQ-0290-0887 S	8EHQ-0290-0888 S
8EHQ-0290-0889 S	8EHQ-0290-0890 S	8EHQ-0290-0891 S
8EHQ-0290-0892	8EHQ-0390-0895 S	8EHQ-0390-0896 S
8EHQ-0390-0897 S	8EHQ-0390-0904	8EHQ-0390-0907 S
8EHQ-0390-0910 S	8EHQ-0390-0911 S	8EHQ-0390-0912 S
8EHQ-0490-0918 S	8EHQ-0490-0922 S	8EHQ-0490-0923 S
8EHQ-0490-0925 S	8EHQ-0490-0927 S	8EHQ-0490-0928 S
8EHQ-0490-0930 S	8EHQ-0490-0931 S	8EHQ-0490-0932
8EHQ-0490-0935 S	8EHQ-0490-0937	8EHQ-0490-0938
8EHQ-0490-0939	8EHQ-0490-0940	8EHQ-0490-0941
8EHQ-0490-0942	8EHQ-0490-0943	8EHQ-0490-0944
8EHQ-0490-0945	8EHQ-0490-0946	8EHQ-0490-0947
8EHQ-0490-0948	8EHQ-0490-0949	8EHQ-0490-0950
8EHQ-0490-0951	8EHQ-0490-0955 S	8EHQ-0490-0956 S
8EHQ-0490-0961 S	8EHQ-0590-0965	8EHQ-0590-0966
8EHQ-0590-0967	8EHQ-0590-0968	8EHQ-0590-0969
8EHQ-0590-0970	8EHQ-0590-0971	8EHQ-0590-0972
8EHQ-0590-0973	8EHQ-0590-0974	8EHQ-0590-0975
8EHQ-0590-0976	8EHQ-0590-0977	8EHQ-0590-0978
8EHQ-0590-0979	8EHQ-0590-0980	8EHQ-0590-0981
8EHQ-0590-0982	8EHQ-0590-0983	8EHQ-0590-0984
8EHQ-0590-0986 S	8EHQ-0590-0987 S	8EHQ-0590-0988 S
8EHQ-0590-0989 S	8EHQ-0590-0990	8EHQ-0590-0992 S

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

REPRODUCTIVE TOXICITY/TERATO. (ANIMAL)

SUBMISSION #:	8EHQ-0590-0995 S	8EHQ-0590-0997 S	8EHQ-0590-0998 S
	8EHQ-0690-0999 *	8EHQ-0690-1000 S	8EHQ-0690-1002
	8EHQ-0690-1003	8EHQ-0690-1006 S	8EHQ-0690-1008
	8EHQ-0690-1010 S	8EHQ-0690-1011 S	8EHQ-0690-1012 S
	8EHQ-0690-1013 S	8EHQ-0690-1014 S	8EHQ-0790-1024
	8EHQ-0790-1025 S	8EHQ-0790-1026 S	8EHQ-0790-1030
	8EHQ-0790-1037 S	8EHQ-0890-1042	8EHQ-0890-1043
	8EHQ-0890-1046	8EHQ-0890-1055 S	8EHQ-0990-1063
	8EHQ-0990-1064	8EHQ-0990-1073 S	8EHQ-0990-1075 S

REPRODUCTIVE TOXICITY/TERATO. (HUMAN)

SUBMISSION #:	8EHQ-0877-0003	8EHQ-1277-0021	8EHQ-0278-0056
	8EHQ-0478-0123	8EHQ-0478-0128	8EHQ-0578-0146
	8EHQ-0678-0192 S	8EHQ-1078-0245	8EHQ-1080-0367
	8EHQ-0382-0440 S	8EHQ-0286-0588 *	8EHQ-0288-0722
	8EHQ-0989-0821 S		

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:	8EHQ-1277-0023	8EHQ-1277-0024	8EHQ-0178-0068 *
	8EHQ-0178-0069	8EHQ-0578-0157 *	8EHQ-0678-0178
	8EHQ-0678-0184 *	8EHQ-0678-0185 *	8EHQ-0279-0274
	8EHQ-0679-0291	8EHQ-0779-0293	8EHQ-1279-0325
	8EHQ-0680-0346	8EHQ-1080-0366	8EHQ-0780-0369
	8EHQ-0181-0377	8EHQ-0281-0384	8EHQ-0381-0392
	8EHQ-1081-0419	8EHQ-1281-0425 S	8EHQ-0382-0438 S

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #:

8EHQ-0582-0445			8EHQ-0682-0446	S		8EHQ-1182-0462	
8EHQ-0483-0476	S		8EHQ-0583-0478	S		8EHQ-0683-0483	S
8EHQ-0683-0484	S		8EHQ-0783-0485	S	*	8EHQ-1083-0495	
8EHQ-1083-0498			8EHQ-0284-0505			8EHQ-0684-0520	
8EHQ-1084-0532			8EHQ-1084-0534			8EHQ-0385-0547	
8EHQ-0485-0549	S		8EHQ-0485-0550			8EHQ-0585-0556	S
8EHQ-0785-0561	S		8EHQ-0785-0562	S		8EHQ-1085-0571	S
8EHQ-0186-0585	S		8EHQ-0386-0590			8EHQ-0386-0591	
8EHQ-0486-0597			8EHQ-0686-0603			8EHQ-0686-0605	S
8EHQ-0786-0608	S		8EHQ-0986-0627			8EHQ-0986-0633	S
8EHQ-1086-0637			8EHQ-0287-0653			8EHQ-0487-0664	S
8EHQ-0587-0674	S		8EHQ-0687-0680			8EHQ-0687-0683	
8EHQ-0787-0686	S		8EHQ-1287-0700			8EHQ-1287-0703	
8EHQ-1287-0705			8EHQ-0188-0714			8EHQ-0388-0724	S
8EHQ-0488-0727			8EHQ-0688-0734	S		8EHQ-1088-0757	
8EHQ-1288-0777			8EHQ-0389-0780			8EHQ-0189-0781	S
8EHQ-0289-0782	S		8EHQ-0389-0789			8EHQ-0689-0803	
8EHQ-0989-0826	S		8EHQ-1089-0837	S		8EHQ-1189-0845	
8EHQ-0290-0880			8EHQ-0290-0884			8EHQ-0390-0908	S
8EHQ-0490-0926	S		8EHQ-0490-0931	S		8EHQ-0490-0934	S
8EHQ-0690-0999		*	8EHQ-0690-1003			8EHQ-0690-1007	
8EHQ-0690-1019			8EHQ-0690-1020			8EHQ-0790-1022	S
8EHQ-0790-1027			8EHQ-0790-1028	S		8EHQ-0790-1033	
8EHQ-0790-1037	S		8EHQ-0890-1041			8EHQ-0890-1046	
8EHQ-0890-1055	S		8EHQ-0890-1056	S		8EHQ-0990-1061	

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

SUBACUTE TOXICITY (ANIMAL)

SUBMISSION #: 8EHQ-0990-1062	8EHQ-0990-1070 S	8EHQ-0990-1081

SUBCHRONIC TOXICITY (ANIMAL)

SUBMISSION #: 8EHQ-1177-0014	8EHQ-0178-0033	8EHQ-0578-0160 S *
8EHQ-0578-0161 S *	8EHQ-0678-0184 *	8EHQ-0678-0190 *
8EHQ-0778-0209	8EHQ-0878-0231 *	8EHQ-0279-0274
8EHQ-0279-0275	8EHQ-1079-0312	8EHQ-0680-0347
8EHQ-0780-0354	8EHQ-0980-0364	8EHQ-0281-0384
8EHQ-0682-0446 S	8EHQ-0683-0483 S	8EHQ-1083-0494 *
8EHQ-0184-0504	8EHQ-0384-0507	8EHQ-0884-0524
8EHQ-0984-0529	8EHQ-0785-0561 S	8EHQ-0785-0562 S
8EHQ-1185-0574	8EHQ-1185-0576	8EHQ-0186-0582 S
8EHQ-0186-0586 S	8EHQ-0386-0594 S	8EHQ-0486-0600
8EHQ-1086-0635	8EHQ-1286-0648	8EHQ-0487-0668
8EHQ-0587-0676	8EHQ-1287-0702	8EHQ-1287-0706
8EHQ-0488-0729 S	8EHQ-0788-0744 S	8EHQ-0888-0747
8EHQ-0988-0748	8EHQ-1088-0756	8EHQ-1088-0760 S
8EHQ-1088-0763 S	8EHQ-0489-0793	8EHQ-0889-0817
8EHQ-1089-0836	8EHQ-1189-0840 S	8EHQ-1189-0843 S
8EHQ-1189-0846	8EHQ-1289-0855	8EHQ-0190-0866 S
8EHQ-0290-0881 S	8EHQ-0490-0930 S	8EHQ-0490-0931 S
8EHQ-0490-0932	8EHQ-0490-0936	8EHQ-0690-1002
8EHQ-0890-1049 S	8EHQ-0990-1063	8EHQ-0990-1074

TSCA 8(C) ALLEGATION

APPENDIX (D): STATUS REPORTS BY INFORMATION TYPE

SUBMISSION #:								
8EHQ-0378-0097		*	8EHQ-0478-0118	P	*	8EHQ-0478-0129		
8EHQ-0478-0135			8EHQ-1084-0532			8EHQ-0386-0589	S	
8EHQ-0786-0612			8EHQ-0886-0622	S		8EHQ-0986-0632		
8EHQ-0887-0690			8EHQ-0987-0694		*	8EHQ-0889-0818	S	
8EHQ-0989-0821	S		8EHQ-0390-0905	S	*	8EHQ-0490-0929	S	*
8EHQ-0590-0991	S		8EHQ-0990-1071			8EHQ-0990-1078		

THURSDAY, MARCH 16, 1978
PART V

federal register

ENVIRONMENTAL PROTECTION AGENCY

TOXIC SUBSTANCES CONTROL ACT

Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 849-2]

TOXIC SUBSTANCES CONTROL ACT

Notification of Substantial Risk Under Section 8(e)

AGENCY: Environmental Protection Agency.

ACTION: Statement of interpretation and enforcement policy.

SUMMARY: This action states EPA's interpretation of, and enforcement policy concerning, section 8(e) of the Toxic Substances Control Act (TSCA) (90 Stat. 2029, 15 U.S.C. 2607). The provisions of that section went into effect on January 1, 1977.

Section 8(e) states 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."

DATES: The policy expressed in this document is in effect as of the date of publication.

FOR FURTHER INFORMATION CONTACT:

Frank D. Kover, Assessment Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-755-2110.

SUPPLEMENTARY INFORMATION: On September 9, 1977, the Agency proposed guidance (42 FR 45362) on its interpretation of and policy concerning the provisions of section 8(e). Although the proposed "guidance" was an interpretive rule and statement of policy exempt from the notice and public comment provisions of the Administrative Procedure Act (5 U.S.C. 553), the Agency solicited comments on several issues to make more informed decisions. On October 11, the comment period was extended from October 15 to October 31, 1977 (42 FR 54857). On November 4, 1977, a supplemental notice to the proposed guidance was published (42 FR 57744), deleting the November 15 date for reporting certain information obtained before 1977 and stating that a new date would be established in the final guidance.

In developing this policy statement, two meetings have been held (February 1, 1977, and October 26, 1977) with selected representatives of industry and environmental and other interested groups. Comments submitted pursuant to the February 1 meeting were addressed in the preamble to the September 9 proposal. Over 100 written comments have been submitted pursuant to the September 9 proposal from trade associations, businesses, environmental groups, labor unions, State and Federal agencies, and other interested parties. Appendix B describes significant issues raised in these comments and the Agency's response to them.

The major modifications to the September 9 proposal are summarized in points 1 through 7 below.

(1) Pursuant to some question over the definition and nature of "guidance," this document is now described more accurately as a "policy statement." It is exempt from the notice and public comment provisions of the Administrative Procedure Act, as well as provisions concerning delayed effective dates.

(2) Many commenters expressed the view that to apply these requirements to officers and employees of a business organization would result in ill-considered, premature reports and would unfairly subject employees to conflicting responsibilities as individual respondents and as corporate agents. Other commenters expressed support for the view that certain employees have a responsibility to report pertinent information, and felt that the phrase "capable of appreciating pertinent information" appropriately described those employees.

The September 9 proposal would have applied section 8(e) requirements to commercial establishments as well as to employees capable of appreciating pertinent information, but stipulated enforcement priorities intended to encourage corporate processing and centralized reporting of such information (42 FR 45363). The intent was to ensure that pertinent information obtained by employees is promptly and appropriately considered, while minimizing duplicative or ill-considered submissions.

The Agency now feels that these objectives would best be served by allowing commercial establishments—under certain conditions designed to ensure full disclosure—to assume exclusive responsibility for reporting to EPA any substantial-risk information obtained by individual officers or employees. Accordingly, this policy statement stipulates that individual officers and employees will have fully discharged their section 8(e) obligations once they have notified the designated responsible company supervisor or official of pertinent information, *provided*, that the employing company or firm has established, internally publicizes, and affirmatively implements procedures governing such notifications. These procedures, at a minimum, must: (1) Specify the information that must be reported; (2) indicate how the notifications are to be prepared and submitted; (3) note the Federal penalties for failing to report; and (4) provide a mechanism for promptly notifying officers and employees who have submitted reports of the company's disposition of those reports, including whether or not they were submitted to EPA (and if not, informing employees of their right to report to EPA, as protected by TSCA section 23). EPA believes these four criteria will ensure prompt and appropriate processing of pertinent information.

Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that substantial-risk information is reported to EPA.

(3) The September 9 proposal stated, in Part III, that a person obtains information when he is aware that it "may suggest" substantial risk. Numerous commenters questioned the Administrator's authority to compel the reporting of information which "may suggest" substantial risk. The Administrator agrees that section 8(e) addresses information that "reasonably supports the conclusion" of substantial risk and has deleted the "may suggest" provision, but emphasizes that "reasonably supports the conclusion" of substantial risk is not identical to a conclusive demonstration of substantial risk. The former typically occurs, and must be reported, at an earlier stage. Part VI in this policy statement provides Agency interpretation of the types of information that "reasonably support" such a conclusion.

(4) Numerous commenters requested clarification of different aspects of Part V of the September 9 proposal ("Information Which Reasonably Supports a Conclusion of Substantial Risk"), particularly concerning environmental effects, and suggested different interpretations of what constitutes a "substantial risk". The Agency continues to focus in this policy statement on the effects set forth in the September 9 proposal, but clarifies that the substantiality of a risk is a function of both the seriousness of the effect and the probability of its occurrence (see Part V).

(5) Numerous commenters maintained that section 8(e) only applies prospectively to information obtained after January 1, 1977. The Agency disagrees, as explained in the preamble to the September 9 proposal. This policy statement continues to apply section 8(e) to information obtained before 1977 of which a person has

been aware since January 1, 1977. In response to requests for clarification, the statement defines what constitutes such awareness. In this manner, EPA intends to limit the need for searches of historical records and files.

(6) This policy statement now provides that any information published in scientific literature, in any language, is exempt if it is referred to in abstracts published by specified abstracting services.

(7) This policy statement describes in a new Part X how to submit claims of confidentiality.

Accordingly, the Administrator's interpretation of and policy towards section 8(e) is set forth below.

Dated: February 24, 1978.

DOUGLAS COSTLE
Administrator.

I. DEFINITIONS

The definitions set forth in TSCA section 3 apply to these requirements. In addition, the following definitions are provided for purposes of this policy statement:

The term "manufacture or process 'for commercial purposes' " means to manufacture or process: (1) For distribution in commerce, including for test marketing purposes, (2) for use as a catalyst or an intermediate, (3) for the exclusive use by the manufacturer or processor, or (4) for product research and development.

The term "person" includes any natural person, corporation, firm, company, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

The term "substantial-risk information" means information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.

II. PERSONS SUBJECT TO THE REQUIREMENT

Persons subject to section 8(e) requirements include both natural persons and business entities engaged in manufacturing, processing, or distributing in commerce a chemical substance or mixture. In the case of business entities, the president, chief executive officer, and any other officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA. The business organization is considered to have obtained any information which any officer or employee capable of appreciating the significance of that information has obtained. It is therefore incumbent upon business organizations to establish procedures for expeditiously processing pertinent information in order to comply with the schedule set forth in Part IV.

Those officers and employees of business organizations who are capable of appreciating the significance of pertinent information are also subject to these reporting requirements. An employing organization may relieve its individual officers and employees of any responsibility for reporting substantial-risk information directly to EPA by establishing, internally publicizing, and affirmatively implementing procedures for employee submission and corporate processing of pertinent information. These procedures, at a minimum, must: (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). An employee of any company that has established and publicized such procedures, who has internally submitted pertinent information in accordance with them, shall have discharged his section 8(e) obligation. Establishment of such procedures notwithstanding, all officials responsible and having authority for the organization's execution of its section 8(e) obligations retain personal liability for ensuring that the appropriate substantial-risk information is reported to EPA.

Business organizations that do not establish such procedures cannot relieve their individual officers and employees of the responsiblity for ensuring that substantial-risk information they obtain is reported to EPA. While officers and employees of such organizations may also elect to submit substantial-risk information to their superiors for corporate processing and reporting, rather than to EPA directly, they have not discharged their individual section 8(e) obligation until EPA has received the information.

NOTE.—Irrespective of a business organization's decision to establish and publicize the procedures described above, it is responsible for becoming cognizant of any substantial-risk information obtained by its officers and employees, and for ensuring that such information is reported to EPA within 15 working days.

III. WHEN A PERSON WILL BE REGARDED AS HAVING OBTAINED INFORMATION

A person obtains substantial-risk information at the time he first comes into possession of or knows of such information.

NOTE.—This includes information of which a prudent person similarly situated could reasonably be expected to possess or have knowledge.

An establishment obtains information at the time any officer or employee capable of appreciating the significance of such information obtains it.

IV. REQUIREMENT THAT A PERSON "IMMEDIATELY INFORM" THE ADMINISTRATOR

With the exception of information on emergency incidents of environmental contamination [see Part V(c)] a person has "immediately informed" the Administrator if information is received by EPA not later than the 15th working day after the date the person obtained such information. Supplementary information generated after a section 8(e) notification should, if appropriate, be immediately reported. For emergency incidents of environmental contamination, a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see Part IX for appropriate telephone contacts). The report should contain as much of the information required by Part IX as possible. A written report in accordance with Part IX (a) through (f) is to be submitted within 15 days.

Information currently in the possession of a person who is subject to reporting must be reported within 60 days of publication of this policy statement.

V. WHAT CONSTITUTES SUBSTANTIAL RISKS

A "substantial risk of injury to health or the environment" is a risk of considerable concern because of (a) the seriousness of the effect [see Subparts (a), (b), and (c) below for an illustrative list of effects of concern], 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".) These two criteria are differentially weighted for different types of effects. The human health effects listed in Subpart (a) below, for example, are so serious that relatively little weight is given to exposure; the mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure. In contrast, the remaining effects listed in Subparts (b) and (c) below 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 pertinent factors).

Note that: (1) The effects outlined below should not be reported if the re-

spondent has actual knowledge that the Administrator is already informed of them.

(ii) Information respecting these effects can be obtained either directly, by observation of their occurrence, or inferred from designed studies as discussed in Part VI.

The Agency considers effects for which substantial-risk information must be reported to include the following:

(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.

(c) *Emergency incidents of environmental contamination*—Any environmental contamination by a chemical substance or mixture to which any of the above adverse effects has been ascribed and which because of the pattern, extent, and amount of contamination (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.

VI. Nature and Sources of Information Which "Reasonably Supports the Conclusion" of Substantial Risk

Information attributing any of the effects described in Part V above to a chemical substance or mixture is to be reported if it is one of the types listed below and if it is not exempt from the reporting requirement by reason of Part VII of this policy statement. A person is not to delay reporting until he obtains conclusive information that a substantial risk exists, but is to immediately report any evidence which "reasonably supports" that conclusion. Such evidence will generally not be conclusive as to the substantiality of the risk; it should, however, reliably ascribe the effect to the chemical.

Information from the following sources concerning the effects described in Part V will often "reasonably support" a conclusion of substantial risk. Consideration of corroborative information before reporting can only occur where it is indicated below.

(1) *Designed, controlled studies.* In assessing the quality of information, the respondent is to consider whether it contains reliable evidence ascribing the effect to the chemical. Not only should final results from such studies be reported, but also preliminary results from incomplete studies where appropriate. Designed, controlled studies include:

(i) In vivo experiments and tests.

(ii) In vitro experiments and tests. Consideration may be given to the existence of corroborative information, if necessary to reasonably support the conclusion that a chemical presents a substantial risk.

(iii) Epidemiological studies.

(iv) Environmental monitoring studies.

(2) *Reports concerning and studies of undesigned, uncontrolled circumstances.* It is anticipated here that reportable effects will generally occur in a pattern, where a significant common feature is exposure to the chemical. However, a single instance of cancer, birth defects, mutation, death, or serious incapacitation in a human would be reportable if one (or a few) chemical(s) was strongly implicated. In addition, it is possible that effects less serious than those described in Part V(a) may be preliminary manifestations of the more serious effects and, together with another triggering piece of information, constitute reportable information; an example would be a group of exposed workers experiencing dizziness together with preliminary experimental results demonstrating neurological dysfunctions.

Reports and studies of undesigned circumstances include:

(i) Medical and health surveys.

(ii) Clinical studies.

(iii) Reports concerning and evidence of effects in consumers, workers, or the environment.

VII. Information Which Need Not Be Reported

Information need not be reported if it:

(a) Has been published by EPA in reports;

(b) Has been submitted in writing to EPA pursuant to mandatory reporting requirements under TSCA or any other authority administered by EPA (including the Federal Insecticide, Fungicide and Rodenticide Act, the Clean Air Act, the Federal Water Pollution Control Act, the Marine Protection, Research, and Sanctuaries Act, the Safe Drinking Water Act, and the Resource Conservation and Recovery Act), provided that the information: (1) Encompasses that required by Part IX (c) through (f); and (2) is from now on submitted within the time constraints set forth in Part IV and identified as a section 8(e) notice in accordance with Part IX(b);

(c) Has been published in the scientific literature and referenced by the following abstract services: (1) Agricola, (2) Biological Abstracts, (3) Chemical Abstracts, (4) Dissertation Abstracts, (5) Index Medicus, (6) National Technical Information Service.

(d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced as described in (c) above, unless such information concerns emergency incidents of environmental contamination as described in Part V(c), or

(e) Is contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act.

VIII. Information First Received by a Person Prior to the Effective Date of TSCA

Any substantial risk information possessed by a person prior to January 1, 1977, of which he is aware after that date shall be reported within 60 days of publication of this policy statement. The Agency considers that a person is "aware" of:

(a) Any information reviewed after January 1, 1977, including not only written reports, memoranda and other documents examined after January 1, 1977, but also information referred to in discussions and conferences in which the person participated after January 1, 1977;

(b) Any information the contents of which a person has been alerted to by date received after January 1, 1977, including any information concerning a chemical for which the person is presently assessing health and environmental effects;

(c) Any other information of which the person has actual knowledge.

IX. Reporting Requirements

Notices shall be delivered to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. (****)

A notice should:

(a) Be sent by certified mail, or in any other way permitting verification of its receipt by the Agency,

(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.

For emergency incidents of environmental contamination (see Part V(c)), a person shall report the incident to the Administrator by telephone as soon as he has knowledge of the incident (see below for appropriate telephone contacts). The report should contain as much of the information required by instructions (b) through (f) above as possible. A written report, in accordance with instructions (a) through (f) above, is to be submitted within 15 days. Twenty-four hour emergency telephone numbers are:

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6254.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

X. Confidentiality Claims

(a) Any person submitting a notice to EPA under section 8(e) of TSCA may assert a business confidentiality claim covering all or part of the information contained in the notice. Any information covered by a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2 (41 FR 36902, September 1, 1976).

(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 section IX of this policy statement.

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

XI. Failure To Report Information

Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under section 8(e). Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Pursuant to section 17, the Government may seek judicial relief to compel submittal of section 8(e) information and to otherwise restrain any violation of section 8(e).

Appendix A.—Quick Reference Summary for Emergency Incidents of Environmental Contamination

A. What should be reported as an emergency incident

An emergency incident of environmental contamination is "any environmental contamination by a chemical substance or mixture . . . which, because of the pattern, extent and amount of contamination, (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". (See Part V(c) for complete description.)

B. What need not be reported as an emergency incident

Information contained in notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act (FWPCA). (For a complete list of exemptions to reporting, see Part VII.)

C. When and where to report emergency incidents

Emergency incidents of environmental contamination are to be reported immediately by telephone to the appropriate EPA Regional 24-hour telephone emergency line listed below.

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), 617-223-7265.
Region II (New York, New Jersey, Puerto Rico, Virgin Islands), 201-548-8730.
Region III (Pennsylvania, West Virginia, Virginia, Maryland, Delaware, District of Columbia), 215-597-9898.
Region IV (Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida), 404-881-4062.
Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), 312-353-2318.
Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), 214-749-3840.
Region VII (Nebraska, Iowa, Missouri, Kansas), 816-374-3778.
Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), 303-837-3880.
Region IX (California, Nevada, Arizona, Hawaii, Guam), 415-556-6254.
Region X (Washington, Oregon, Idaho, Alaska), 206-442-1200.

In addition, a written report, in accordance with instructions (a) through (f) of Part IX, is to be submitted within 15 days to the Document Control Officer, Chemical Information Division, Office of Toxic Substances (WH-557), 401 M Street SW., Washington, D.C. 20460.

Appendix B—Significant Comments and Responses

A. Persons subject to these requirements

Comment 1: Employees cannot be held subject to these requirements, since: (a) They only have a partial role in the manufacture, processing, or distribution of chemicals, (b) in other sections of TSCA, the term "person who manufactures, processes, or distributes" chemicals clearly refers to business organizations; "persons" should be consistently defined, and (c) the application of criminal penalties mandates a strict interpretation of this word.

(****) See NOTE on last page of Appendix C

Response: The Agency considers that different sections of TSCA, having different purposes, are appropriately directed to different respondents. In the case of section 8(e), officers and employees who are capable of appreciating the significance of information have a legitimate responsibility to be alert to and report substantial-risk information. The guidance has been modified so that natural persons and business entities can fulfill their section 8(e) obligations in different ways. Most officers and employees can discharge their section 8(e) obligations by submitting pertinent information to corporate superiors, provided that the company has established the risk-evaluation procedures characterized in Part II. In the case of a business organization, its president, chief executive officer, and other officials responsible and having authority for the business organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 2: Even if employees can be held subject to these requirements, they should not be. To do so would force employees and employers into conflicting positions, inviting internal corporate dissension and over- reporting. Further, individuals often do not have the overview necessary to reach considered, well-supported decisions. Corporate reporting by designated officials will provide EPA with more reliable data.

Response: The Agency considers that employees have a legitimate role in risk reporting; it is imperative that risk information obtained by employees be appropriately considered. Officers and employees can fulfill their role in the reporting of substantial-risk information, without the disadvantages described above, by reporting information to superiors for corporate consideration, and, having done so, will have discharged their obligation to EPA. This is contingent upon the establishment by the business organization of certain procedures for risk-evaluation, thereby assuring the appropriate consideration of such reports. Those officers responsible and having authority for the organization's execution of its section 8(e) obligations must ensure that the organization reports substantial-risk information to EPA.

Comment 3: Clarify which employees are covered, and the extent of their obligation. Are employees "capable of appreciating pertinent information" by virtue of rank, or knowledge? Are rank and file employees subject to these requirements, or just supervisory and managerial personnel, company toxicologists, etc.? Is an employee absolved of further responsibility if he reports to his supervisor?

Response: The Agency considers that the phrase "capable of appreciating the significance of pertinent information" appropriately describes those officers and employees who have a responsibility to be alert to and report substantial-risk information, including not only relatively senior corporate officers but also many corporate employees. The policy statement modifies the September 9 proposal, in response to the concerns expressed in Comments 2 and 3, to permit most officers and employees to discharge their obligation by submitting information to corporate superiors, subject to the conditions described in Part II.

Comment 4: Consultants and independent labs should not be subject to these requirements.

Response: Contractors and independent labs are not responsible for reporting information they have obtained directly to EPA; rather, their client manufacturers, processors and distributors are responsible for reporting such information.

B. THE "OBTAINING" OF INFORMATION

Comment 5: The "may suggest" criterion in Part III of the proposal serves to compel further examination of information that by itself is not subject to section 8(e) requirements. The statutory language calling for "reasonable support" does not support this. Further, risk assessment often requires anywhere from months to several years of study after preliminary results "suggest" risk, far exceeding the 15-day compliance period.

Response: The Agency does not intend to compel under section 8(e) examination of information that by itself is not subject to section 8(e) requirements and has deleted the "may suggest" provision, providing its interpretation of what constitutes evidence that "reasonably supports the conclusion" of substantial risk in a new Part VI.

Comment 6: Section 8(e) obligations are incurred upon obtaining conclusory substantial-risk information.

Response: The Agency disagrees, and considers that "reasonable support" of a conclusion of substantial risk is not identical to the conclusion itself. The former typically occurs, and must be reported, at an earlier stage.

Comment 7: The statement, in Part III of the proposal that a person has obtained information if he ". . . should know of the existence of such information not in his possession but which would be delivered to him on request," tends to compel an active search for substantial-risk information rather than the reporting of substantial-risk information a person "obtains." This is of particular concern to importers with limited access to information possessed by their suppliers.

Response: The Agency considers that section 8(e) applies to information which a person possesses or of which he knows. It is not intended to compel searches for information or extraordinary efforts to acquire information. The Agency further considers, however, that "known" information includes information which a prudent person similarly situated could reasonably be expected to know. Negligence or intentional avoidance of information does not absolve a person of his section 8(e) obligation. Part III has been modified to express these intentions.

Comment 8: Circumstances can exist when coming "into possession" of risk information does not correspond to an understanding of the implications of the information; "obtains" should be defined in terms of possession of information and awareness of its import.

Response: The "obtaining" of information occurs via persons who are "capable of appreciating the significance of pertinent information." There will likely be circumstances in which the evaluation of information clarifies its full import; the establishment of corporate procedures for processing risk-information prescribed in Part II will expedite this.

C. TIME ALLOWED FOR COMPLIANCE

Comment 9: Fifteen calendar days is insufficient to determine whether information which "may suggest" substantial risk should be reported; it is even insufficient to accommodate normal procedural time constraints (corporate processing, mailing, holidays, etc.).

Response: The Agency has changed the compliance period to 15 business days. It is imperative that procedures be established to expedite the reporting of substantial-risk information, not that reporting conform to existing procedures.

Comment 10: Allow from 30 to 90 days for the second phase of reporting; alternatively, do not prescribe a time limit for additional reporting.

Response: Having deleted the "may suggest" criterion, the Agency sees no need to provide a second phase to the reporting period. Supplemental information that is generated after a section 8(e) notification should, if appropriate, be immediately reported.

Comment 11: Allow from 90 to 120 days to report pre-1977 information; this period should commence: (a) upon final publication, (b) January 1, 1978, (c) following the inventory reporting period since many of the same corporate personnel will be implementing both requirements.

Response: The policy statement prescribes a 60 day reporting period, commencing immediately upon publication. Section 8(e) has been in effect since January 1, 1977; postponement in reporting substantial-risk information is not warranted.

D. EFFECTS AND INFORMATION THAT MUST BE REPORTED

Comment 12: The reporting of "any instance" of cancer, birth defects, etc., in humans is too broad and such information will be of little use; chemical workers, like the general population, develop cancers and other ailments of uncertain etiology.

Response: This policy statement clarifies that the reporting of single occurrences of human cancer or other serious effects will depend upon evidence strongly implicating one (or a few) chemical(s).

Comment 13: Dermal ailments and nausea are poorly chosen examples of precursor symptoms. Deleting these examples will avoid unduly emphasizing them when other symptoms may be more important, yet will not eliminate the obligation to report them if they are suspected precursors.

Response: The Agency agrees.

Comment 14: How are reportable data distinguished from routine tests including range tests such as LD_{50}'s?

Response: This policy statement directs the reporting of specified effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemical; unknown effects occurring during such a range test may have to be reported if they are those of concern to the Agency and if the information meets the criteria set forth in Parts V and VI.

Comment 15: The most widespread "in vitro" test is the Ames test, which is subject to considerable debate. Clarify the circumstances under which positive results of in vitro tests must be reported.

Response: Part VI clarifies that the reporting of in vitro tests will depend upon the existence of corroborative information if necessary to reasonably support the conclusion of substantial risk.

Comment 16: The description of "extreme persistence" as a substantial risk is an example of the need to redefine Part V(c) ("Environmental Effects"). Persistence and bioaccumulation should be considered risks only when coupled with toxicity and significant exposure.

Response: Part V now clarifies those effects for which reporting depends upon a significant exposure potential. Persistence by itself is no longer itemized as a reportable effect but rather is considered to be a component of exposure potential; it may also underlie the measurements described in Part V(b)(1). Laboratory indicators of pronounced bioaccumulation are to be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

Comment 17: The n-octanol/water partition coefficient addresses a physico-chemical property, not biological effects, and is not alone an indicator of substantial risk; further, the values stated for the coefficient and the bioaccumulation factor in fish do not correspond.

Response: The Agency acknowledges the numerical error and has amended the values to correspond. This policy statement now directs the reporting of an experimental measurement of bioaccumulation when coupled with an adverse effect and potential for widespread exposure.

Comment 18: The requirement that information which "links" an effect to a chemical be reported is too broad and contradicts the statutory language of "reasonably supports".

Response: The Agency has provided in a new Part VI its interpretation of "reasonably supports".

Comment 19: A determination that information "reasonably supports the conclusion" of substantial risk cannot be made independently of considerations of use since the method and manner of using a chemical may influence the occurrence of an effect; in particular, the criteria should reflect a distinction between normal and abnormal uses of chemicals.

Response: The Agency considers that the appropriate components of a "substantial risk" with respect to a chemical are (a) the seriousness of the effect, and (b) total exposure potential. The method and manner of using a chemical is one of several factors determining its exposure potential. As described in Part V, the importance of exposure potential as a component of "substantial risk" depends upon the kind of effect of concern. Thus, the effects described in Part V(a) are so serious that relatively little weight is given to exposure; the effects described in Parts V (b) and (c) involve a significant exposure or exposure potential.

The Agency further considers that a definition of "normal" use for a particular chemical will often depend upon a knowledge of the risks associated with the chemical.

E. INFORMATION THAT NEED NOT BE REPORTED

Comment 20: Information published in scientific literature in languages other than English should be exempted if published in summary form by abstracting services. Can the accuracy of English language abstracts and commercial translations of foreign literature be assumed?

Response: This policy statement now provides that information published in scientific literature, whether in English or another language, is exempt from reporting if published in summary form by certain specified abstract services.

Comment 21: Information exchange systems with other Federal agencies should be immediately established so that respondents need not report to EPA information already reported to other Agencies, and vice versa. Such duplicative reports are unduly burdensome.

Response: EPA is coordinating this program with other agencies now. When this coordination is successfully completed, the policy statement will be amended to exempt from the reporting requirement information that has been submitted to other specified agencies. In the meantime, substantial-risk information must be reported directly to EPA; such a report does not discharge any reporting obligation to other agencies.

F. INFORMATION FIRST RECEIVED PRIOR TO THE EFFECTIVE DATE OF TSCA

Comment 22: The tense of the verb "obtains" reveals that section 8(e) was intended to be applied prospectively to information newly acquired after January 1, 1977. Utilize section 8(d) or other rules to acquire information obtained before then.

Response: As discussed in the preamble to the September 9 proposal, the Agency considers section 8(e) to apply to risk information possessed by or known to a person before, on, or after January 1, 1977. Concerning information first obtained before 1977, this policy statement continues to require reporting of information received if a person has been aware of it since January 1, 1977, for the reasons discussed in the September 9 preamble.

Comment 23: The term "aware" is too vague to be of any help in responding to these requirements. Since many corporate employees are potentially subject to these requirements, and given uncertainty over the extent to which they ought to be aware of pre-1977 information, this provision tends to compel the very file search it was intended to avoid. The term "aware" should be further defined, possibly in terms of actual knowledge.

Response: The Agency in Part VIII of this policy statement now defines the pre-1977 information of which a person is considered to be aware.

G. CONFIDENTIAL INFORMATION

Comment 24: EPA should delay guidance until procedures are published governing the treatment of confidential submissions.

Comment 25: EPA should treat all submissions as confidential until the information is verified.

Comment 26: EPA should automatically publish section 8(e) notices.

Response to Comments 24 through 26: EPA has included a new Part X which describes how to submit a claim of confidentiality and states that any or all of the information submitted may be claimed as confidential. Such information will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 CFR Part 2.

H. MISCELLANEOUS

Comment 27: What is the statutory basis or need for guidance? What is its exact status under the Administrative Procedure Act?

Response: This policy statement sets forth EPA's interpretation of and policy concerning TSCA section 8(e). As an interpretive rule and statement of policy it is not subject to the comment period and delayed effective date provisions of the Administrative Procedure Act (5 U.S.C. 553). Although TSCA does not mandate a policy statement, the Agency of necessity must develop the criteria which will govern enforcement activities. Trade associations and businesses were among those who previously expressed interest in such a statement to guide their compliance.

Comment 28: Clarify whether these requirements apply to chemicals previously but no longer manufactured, processed, or distributed in commerce by a person.

Response: Information obtained before 1977 must be reported if the person has been aware of it since January 1, 1977, as prescribed by Part VIII. Concerning chemicals which a person has discontinued manufacturing, processing, or distributing since January 1, 1977, information obtained before the time of discontinuation is subject to these requirements. It is expected that the acquisition of information after that time will be minimal; however, should additional information be acquired, it may trigger the reporting described in Part VIII.

Comment 29: Clarify the meaning of "substantial risk" relative to other risks addressed by TSCA.

Response: A substantial risk is defined in Part V(a) of this policy statement as a risk of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence. As opposed to other risks addressed by TSCA, economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is "substantial".

Comment 30: To what extent are "users" of chemicals subject to these requirements?

Response: The Agency considers that many industrial uses of chemicals actually fall within the scope of "processing" chemicals. A manufacturer, processor, or distributor who obtains substantial-risk information concerning chemicals he handles should be alert to the possibility he may have to report it.

Comment 31: Are chemicals manufactured, processed and distributed in commerce in small quantities solely for purposes of research and development subject to these requirements?

Response: In general, the Agency considers that much manufacturing, processing, and distribution in commerce of chemicals in small quantities solely for purposes of research and development is conducted for "commercial purposes". Such purposes would include the sale and distribution of such materials, as well as their use by the manufacturer or processor in activities (for example, product research and development and studies assessing the feasibility and safety of using chemicals) preceding his or a client's commercial use of such materials or others on a larger scale.

As described in Part V, the Agency considers that "substantial risks" depend in part upon an exposure potential. Thus, the occurrence of the effects described in Part V(a) presuppose exposure to the chemical and must be reported; reporting of the other effects will depend upon a potential for significant levels of exposure.

Comment 32: Are raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide subject to TSCA?

Response: The Administrator considers that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA.

In order to be considered a pesticide, a substance must be intended for use as a pesticide. Raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide are not themselves regulated under FIFRA (unless they happen to be pesticides themselves) and, therefore, are subject to TSCA. The pesti-

cide regulations at 40 CFR 162.4 are consistent with this view.

Comment 33: Are intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device subject to TSCA?

Response: The Administrator considers that intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA. The definitions of the FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components. Therefore, they are subject to regulation under the FFDCA. Any such substance is excluded from regulation under TSCA insofar as it is actually manufactured, processed, or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic, or device.

Comment 34: Employees should have the option to submit reports anonymously.

Response: EPA considers that any person may report information to EPA under TSCA. Those who are required to do so under section 8(e) are persons who manufacture, process, or distribute in commerce chemical substances or mixtures, including not only business entities but also such employees as described in Part II. In order to establish that such persons have discharged their obligations, and in order to encourage responsible review of the quality of information and the substantiality of risks, EPA believes that notifiers should identify themselves. Section 23 will adequately protect employees from discrimination pursuant to notifications they have made under section 8(e).

[FR Doc. 78-7064 Filed 3-15-78; 8:45 am]

NOTE

According to technical amendments published by EPA in the May 29, 1987 FEDERAL REGISTER (52 FR 20083), TSCA Section 8(e) submissions are to be addressed to the Agency as follows:

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

federal register

Friday,
February 1, 1991

APPENDIX D
(CAP Notice)

Part II

Environmental Protection Agency

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-80015; FRL-3844-4]

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice, pursuant to sections 15 and 16 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, announces the opportunity to register for EPA's TSCA Section 8(e) Compliance Audit Program. This Notice also contains the text of an Agreement for the TSCA Section 8(e) Compliance Audit Program ("CAP Agreement"). The TSCA Section 8(e) Compliance Audit Program and the registration provisions and CAP Agreement conditions are described below.

DATES: The Registration period for the TSCA Section 8(e) Compliance Audit Program commences February 1, 1991, and closes May 2, 1991. Persons interested in registering for the voluntary TSCA Section 8(e) Compliance Audit Program must request a CAP Agreement and submit a signed CAP Agreement to EPA no later than May 2, 1991.

ADDRESSES: Copies of the CAP Agreement may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

Section 8(e) of TSCA states that "any person who manufactures, [imports,] 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 [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information."

"Substantial risk information" reportable to EPA under section 8(e) of TSCA refers to new information that reasonably supports a conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. (The term new information refers to information (including preliminary data) about which EPA has not already been adequately informed.) Such information need not and most typically does not establish conclusively that such a risk exists. In other words, reasonable support for a conclusion is not synonymous with the conclusion itself and usually precedes the conclusion.

In deciding whether new information reasonably supports a conclusion of substantial risk, one must consider (1) The seriousness of the adverse effect, and (2) the fact or probability of the effect's occurrence. These two criteria should be weighed differently depending upon the seriousness of the effect and the extent of the exposure; i.e., the more serious the effect, the less heavily one should weigh the actual or potential exposure, and vice versa.

In some cases, e.g., the observance of certain types of serious toxicologic effects in animals or humans, exposure to the chemical substance(s) or mixtures is presupposed and will constitute sufficient evidence of exposure for a determination to be made to submit the new-found toxicological data. Such serious effects include, but are not limited to, (1) Birth defects and/or serious developmental effects (including those observed in the presence of maternal toxicity), and (2) cancer (as evidenced by benign and/or malignant tumors).

Any decision-making process for determining section 8(e)-reportability should focus primarily on whether new toxicologic or exposure data offer reasonable support for a conclusion of substantial risk and should not focus to any great extent, if at all, on whether the information is conclusive regarding the risk. Therefore, a decision to report pursuant to section 8(e) should not involve (1) Exhaustive health or environmental assessments, or (2) any evaluation of the economic or social benefits of the use(s) of the subject chemical(s).

In reviewing recent enforcement cases, EPA has found that some companies may be misinterpreting TSCA section 8(e) and EPA's "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk," ("Section 8(e) Policy Statement," March 16, 1978, 43 FR 11110). Some companies obtaining information on certain serious health effects appear to be further evaluating and wrongly discounting the significance of the information on the basis of a "weight-of-the-evidence" risk assessment. It is EPA's position, however, that if certain serious health effects are discovered, the information should be considered for immediate reporting under section 8(e) without further evaluation. The following are examples of information that should be considered immediately for reporting under section 8(e) of TSCA.

1. New information concerning statistically or biologically significant increases in benign and/or malignant tumors in an animal study; a "weight-of-the-evidence" risk assessment should not be used to discount the findings.

2. Statistically or biologically significant increases in teratologic or other serious reproductive effects observed in animals; the level of maternal toxicity observed in the study should not be used to discount the findings.

3. Serious toxic effects (e.g., cancer, birth defects, and neurotoxicity) observed in tests of chemical substances or mixtures at the research and development stage; such findings should not be discounted because the company believes that there is no exposure to the chemical(s).

Up-to-date information on hazard and exposure is vital in supporting EPA efforts to protect human health and the environment from risks from toxic chemicals. EPA has the responsibility under TSCA to perform needed risk assessments on chemicals. Section 8(e) is a very important part of TSCA's section 8 information reporting and recordkeeping provisions that enable EPA to obtain and disseminate information needed to set priorities and perform risk assessments that may be national in scope. Companies that do not report vital information are undermining the effectiveness of the early warning system intended under section 8(e).

In the past year, some companies have alleged that EPA has changed its interpretation of TSCA section 8(e) thereby creating vulnerability that was not previously contemplated for reporting. These same entities have said that EPA's TSCA Sections 8, 12, and 13 Enforcement Response Policy contains significant disincentives (namely very high monetary penalties) to dissuade auditing of past studies and reporting them to EPA.

EPA has not changed its interpretation of TSCA section 8(e). EPA's implementation of the TSCA section 8(e) program is based on sound guidance

that is and has been consistent with the statutory language and intent of section 8(e), as well as EPA's Section 8(e) Policy Statement. Nevertheless, to achieve the Agency's goal of obtaining any outstanding section 8(e) data, EPA has developed this one-time voluntary compliance program designed to strongly encourage companies to voluntarily audit their files for studies reportable under section 8(e). This program is known as the TSCA Section 8(e) Compliance Audit Program.

The TSCA Section 8(e) Compliance Audit Program has been developed to encourage industry reporting by setting forth guidelines that identify in advance EPA's enforcement response and allow companies to assess liability prior to electing to participate. Companies that do not participate in the TSCA Section 8(e) Compliance Audit Program should be aware that EPA intends to actively pursue violations of the TSCA section 8(e) reporting requirement.

II. Text of the Registration/CAP Agreement

The text of the Registration and CAP Agreement for the TSCA Section 8(e) Compliance Audit Program:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticides and Toxic Substances

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program

The United States Environmental Protection Agency ("EPA") and the Regulatee, the Parties herein, wishing to register for and enter into this Agreement for a Toxic Substances Control Act ("TSCA") Section 8(e) Compliance Audit Program ("CAP Agreement") and having consented to the terms of this CAP Agreement do therefore agree to fully comply with the terms of this CAP Agreement.

I. Registration Requirements

A. The Regulatee agrees to conduct a TSCA Section 8(e) Compliance Audit Program to determine its compliance status with TSCA section 8(e).

B. To register for the TSCA Section 8(e) Compliance Audit Program, the Regulatee must, no later than May 2, 1991, sign and return this CAP Agreement by certified mail-return receipt requested to: Michael F. Wood, Director, Compliance Division (EN-342), Office of Compliance Monitoring, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

C. After EPA receives this signed CAP Agreement from the Regulatee, EPA will sign this CAP Agreement and enter the following identification number (_____) to the copy of this CAP Agreement which will be returned to the Regulatee. The Final Report and all other documents submitted pursuant to Unit II.C of this CAP Agreement must display the identification number established by this paragraph.

D. The TSCA Section 8(e) Compliance Audit Program shall commence no later than May 2, 1991.

E. The TSCA Section 8(e) Compliance Audit Program shall terminate within 180 days of May 2, 1991. Thus, all submissions under this TSCA Section 8(e) Compliance Audit Program must be delivered to EPA no later than October 29, 1991.

II. Terms of Agreement

EPA and the Regulatee mutually initiated this TSCA Section 8(e) Compliance Audit Program in response to a February 1, 1991, **Federal Register** notice announcing the opportunity to participate in the TSCA Section 8(e) Compliance Audit Program. As part of this CAP Agreement, EPA and the Regulatee agree to the following:

A. General Provisions

1. This CAP Agreement and the Consent Agreement and Consent Order in this matter shall be a complete settlement of all civil and administrative claims and causes of action which arose or could have arisen under TSCA section 8(e) in connection with any study or report submitted pursuant to the terms of this CAP Agreement. Pursuant to TSCA, EPA will consider ability to pay/effect on ability to continue to do business claims during the course of development of the Consent Agreement and Consent Order in this matter. The Regulatee will be responsible for submitting adequate documentation of such claims to EPA at the time of submission of the Final Report required by this CAP Agreement.

2. For purposes of this CAP Agreement and any subsequent proceeding, without trial or any adjudication of the facts, the Regulatee admits that EPA has jurisdiction over the subject matter of the terms of this CAP Agreement and any study or report submitted pursuant to this CAP Agreement.

3. The Regulatee waives its right to request a judicial or administrative hearing on any issue of law or fact that has arisen or may arise during the conduct of the TSCA Section 8(e) Compliance Audit Program conducted pursuant to the terms of this CAP Agreement, or that may arise in any subsequent proceeding involving the Consent Agreement and Consent Order resulting from and entered into pursuant to the terms of this CAP Agreement, including but not limited to the Regulatee's right under TSCA section 16(a)(2)(A) to request a hearing.

4. The Parties agree that any study or report submitted by the Regulatee under this TSCA Section 8(e) Compliance Audit Program and pursuant to the terms of this CAP Agreement constitute a violation of TSCA sections 8(e) and 15(3)(B), for which a civil penalty will be assessed against the Regulatee. Any study or report submitted under TSCA section 8(e) prior to the date of commencement of the TSCA Section 8(e) Compliance Audit Program is not subject to the terms of this CAP Agreement or the TSCA Section 8(e) Compliance Audit Program.

5. EPA reserves its rights under TSCA section 16 to take appropriate enforcement action if EPA determines later that the Regulatee was required to submit under TSCA section 8(e) a study or report determined by the Regulatee to be not reportable and therefore not submitted under the TSCA Section 8(e) Compliance Audit Program. In such event, the terms of the EPA TSCA Sections 8, 12, and 13 Enforcement Response Policy will apply to such proceeding.

6. EPA reserves its rights to challenge the categorization of studies or reports submitted under this TSCA Section 8(e) Compliance Audit Program pursuant to the requirements of Unit II.B.2.a and b of this CAP Agreement.

7. EPA agrees that any submissions made pursuant to the terms of this CAP Agreement and the TSCA Section 8(e) Compliance Audit Program will be viewed by EPA as "prior such violations" under TSCA section 16(a)(2)(B) for future violations of TSCA section 8(e) only.

8. The Final Report submitted pursuant to Unit II.C.4 of this CAP Agreement shall be the controlling document for purposes of determining what was submitted under the TSCA Section 8(e) Compliance Audit Program and this CAP Agreement.

9. Any submission made by the Regulatee to EPA that does not meet all of the requirements of the TSCA Section 8(e) Compliance Audit Program and this CAP Agreement is subject to the EPA TSCA Sections 8, 12, and 13 Enforcement Response Policy.

B. TSCA Section 8(e) Compliance Audit Program and Civil Penalties

1. In conducting the TSCA Section 8(e) Compliance Audit Program, the Regulatee shall use EPA's March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of

Substantial Risk" (43 FR 11110) ("TSCA Section 8(e) Policy Statement") to determine whether the reviewed study or report is:

a. *Not reportable under TSCA Section 8(e)*: The Regulatee will not submit the study or report.

b. *Reportable under TSCA Section 8(e)*: The Regulatee will submit the study or report.

Upon Registration for the TSCA Section 8(e) Compliance Audit Program, the Regulatee will receive a copy of the TSCA Section 8(e) Policy Statement, the publication numbers of publicly available and previously published volumes of Section 8(e) "Status Reports" available through the National Technical Information Service, copies of Question and Answer documents developed in response to specific questions involving section 8(e), and a document entitled "Substantiating Claims of Confidentiality."

2. The Regulatee agrees to pay the following stipulated civil penalties for all studies or reports submitted under this TSCA Section 8(e) Compliance Audit Program as TSCA section 8(e) data:

a. $15,000 per study for any submitted study or report involving effects in humans.

b. $6,000 per study for any other submitted study or report submitted as TSCA section 8(e) data.

As a matter of policy under this TSCA Section 8(e) Compliance Audit Program, EPA agrees to a $1,000,000 cap on the total civil penalty for the Regulatee.

3. The Regulatee shall be exempt from any additional late and/or nonreporting TSCA section 8(e) civil liability which arose or could have arisen for any study or report submitted under this TSCA Section 8(e) Compliance Audit Program.

4. Upon termination of the TSCA Section 8(e) Compliance Audit Program, the Regulatee shall provide EPA with a Final Report certifying that the TSCA Section 8(e) Compliance Audit Program has been completed. Such Final Report shall be signed and certified by the appropriate corporate official with authority to settle claims on behalf of the Regulatee. Such Final Report shall also comply with the requirements of Unit II.C.4 of this CAP Agreement.

5. Following termination of the audit, EPA will present the Regulatee with a Consent Agreement and Consent Order summarizing the results of the TSCA Section 8(e) Compliance Audit Program and specifying the terms of payment of stipulated civil penalties. The Regulatee will have 30 calendar days from its receipt of an executed copy of the Consent Order to pay any stipulated civil penalties.

C. Information Submission and Final Report

1. All studies or reports submitted to EPA by the Regulatee under the terms of this CAP Agreement shall be identified pursuant to the categories established in Unit II.B.2.a and b of this CAP Agreement, and shall be sent to the following address: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Attn: Section 8(e) Coordinator (CAP Agreement).

2. The Regulatee shall submit one original and two full copies of all cover letters, studies, reports, substantiations of confidentiality claims, and, as appropriate, sanitized copies of cover letters, studies, reports, or substantiations of confidentiality claims.

3. In accordance with Part IX of the TSCA Section 8(e) Policy Statement, each study or report submitted to EPA by the Regulatee under the terms of this CAP Agreement shall be accompanied by a separate cover letter containing the following information:

a. Company name, address and telephone number.

b. The signature and printed name, title and telephone number of the person submitting the study or report.

c. A clear statement that the document, identified on the cover letter by the identification number established by Unit I.C of this CAP Agreement, is being submitted pursuant to the TSCA Section 8(e) Compliance Audit Program and this CAP Agreement.

d. The exact identity of each tested chemical or mixture or component of a tested mixture including the CAS Registry Number, if known.

e. The title of the accompanying study or report.

f. A full summary of the reportable adverse effect(s) or exposure(s) observed in the accompanying study or report. In addition, the cover letter should identify by EPA Document Control Number any previous TSCA section 8(e) submission(s) or premanufacture notification(s) (PMN(s)) submitted by the Regulatee on the subject chemical substance(s) or mixture or component(s) of such mixture.

4. Each study or report submitted to EPA by the Regulatee under the terms of this CAP Agreement shall be listed in a Final Report. Such Final Report shall list each submitted study or report by title pursuant to the categories established in Unit II.B.2.a and b of this CAP Agreement, and shall display the identification number established by Unit I.C of this CAP Agreement. Such Final Report shall certify that the TSCA Section 8(e) Compliance Audit has been completed and include the following statement: "I certify that the information contained in or accompanying this Final Report is true, accurate, and complete. As to any identified portion(s) of this Final Report for which I cannot personally verify its truth and accuracy, I certify as the company official having supervisory responsibility for the person(s) who, acting under my direct instructions, made the verification, that this information is true, accurate, and complete." The Final Report will be the controlling document as to what was or was not submitted under the terms of this CAP Agreement and shall be sent to the address specified in Unit I.B of this CAP Agreement.

D. Other Matters

1. Nothing in this CAP Agreement shall relieve the Regulatee from complying with all applicable TSCA regulations or other applicable environmental statutes.

2. This CAP Agreement shall be binding upon the Parties and in full effect pursuant to the requirements specified in Unit I. of this CAP Agreement.

3. The Regulatee's obligations under this CAP Agreement shall end when the Final Report required by Unit II.C.4 of this CAP Agreement has been submitted to EPA and stipulated civil penalties paid.

4. Failure to comply with the terms of this CAP Agreement permits EPA to proceed under TSCA section 16 to impose the civil penalties allowable under the existing EPA TSCA Sections 8, 12, and 13 Enforcement Response Policy for any study or report submitted pursuant to Unit II.C of this CAP Agreement.

5. All of the terms and conditions of this CAP Agreement together comprise one agreement, and each of the terms and conditions is in consideration for all of the other terms and conditions. In the event that this CAP Agreement (or one or more of its terms and conditions) is held invalid, or is not executed by all of the signatory parties in identical form, then the entire CAP Agreement shall be null and void.

6. The Regulatee may assert claims of confidentiality under TSCA section 14 for submissions under this CAP Agreement. The Regulatee must, at the time of submission, provide substantiation for all information claimed as confidential. The Regulatee agrees that the failure to assert a claim of confidentiality for studies, reports, or information submitted under the terms

of this CAP Agreement shall be interpreted by EPA as a waiver by the Regulatee of the right to assert a claim of confidentiality.

7. Submissions containing information claimed as TSCA Confidential Business Information (TSCA CBI) shall contain cover sheets bearing the typed or stamped legend "company confidential," "proprietary," or "trade secret." Information contained in the submission which is claimed as TSCA CBI must be clearly marked by boxing, circling, or underlining the specific text so claimed. All pages containing such information shall also be marked "CONFIDENTIAL." Care should be taken to ensure that these markings do not obscure the text of the submission. Submissions directed to EPA in this manner should be sent by certified mail-return receipt requested or in any other way which will permit verification by the Regulatee of its receipt by EPA.

8. If the Regulatee chooses to assert a confidentiality claim, the Regulatee shall provide two sets of each such submission: one set shall have the TSCA CBI material marked in the manner contemplated under 40 CFR 2.203(b) and Unit II.D.7 of this CAP Agreement; the second set shall have the TSCA CBI material excised. The Regulatee is advised that the second, "sanitized" set will be available for public review without further notice to the Regulatee and therefore care should be exercised in the creation of this set. Each sanitized and unsanitized submission must comply with Unit II.C.2 of this CAP Agreement and thus will consist of one original and two copies.

9. The Regulatee is advised to review carefully the confidentiality claim procedures at 40 CFR 2.201. Specific information concerning TSCA section 8(e) confidentiality claims is contained at Part X of the TSCA Section 8(e) Policy Statement.

10. The Regulatee agrees that if the specific chemical identity is claimed as confidential in a submission, a generic nonconfidential chemical identity will be included on the sanitized version of the submission. Guidance for developing appropriate generic chemical identities may be obtained by consulting the TSCA Chemical Substance Inventory: 1985 Edition, or by contacting the Office of Toxic Substances' Chemical Inventory Section at (202) 382-3527.

11. The Regulatee agrees that confidentiality claims will be honored by EPA only if each claim is accompanied by responses to the questions in the document provided with this CAP Agreement entitled "Substantiating Claims of Confidentiality." The Regulatee shall provide an original and two copies of these responses in accordance with Unit II.C.2 of this CAP Agreement. The Regulatee shall also, in the event the Regulatee desires information in these responses to be considered TSCA CBI, provide a sanitized original and two copies in accordance with Unit II.C.2 and Unit II.D.8 of this CAP Agreement.

12. The Regulatee agrees that failure to adhere to each requirement pertaining to TSCA CBI may result in forfeiture of the CBI protection for the submission and its subsequent availability in its entirety for public review.

WE AGREE TO THIS:

For Regulatee:

[Signing official]

[Title]

[Company name]

[Signing official]

[Title]

[Company name]

For EPA:

Michael F. Wood,

Director, Compliance Division, Office of Compliance Monitoring.

Michael J. Walker,

Associate Enforcement Counsel for Pesticides and Toxic Substances.

III. Conclusions

EPA has announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program. Any further information regarding this Audit Program or the CAP Agreement may be obtained from the contact person noted above.

Dated: January 25, 1991.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 91-2299 Filed 1-31-91; 8:45 am]

BILLING CODE 6560-50-F

federal register

Friday
April 26, 1991

APPENDIX D
(CAP Modifications)

Part VI

Environmental Protection Agency

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-80015A; FRL-3891-8]

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice, pursuant to sections 15 and 16 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., announces modifications to EPA's TSCA Section 8(e) Compliance Audit Program and the Agreement for the TSCA Section 8(e) Compliance Audit Program ("CAP Agreement"). The modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement include extension of the registration and termination dates, the opportunity to petition EPA for a case-by-case extension of the termination date, modifications to the CAP Agreement provisions regarding admission of a violation of TSCA section 8(e) and waiver of right to a hearing, and EPA's development of a TSCA section 8(e) reporting guide.

DATES: The Registration period for the TSCA Section 8(e) Compliance Audit Program closes on June 18, 1991. Persons interested in registering for the TSCA Section 8(e) Compliance Audit Program must request a CAP Agreement and submit a signed CAP Agreement to EPA no later than June 18, 1991.

ADDRESSES: Copies of the CAP Agreement may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 1, 1991 (56 FR 4128), EPA announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program. The TSCA Section 8(e) Compliance Audit Program is a one-time voluntary compliance audit program developed in order to achieve EPA's goal of obtaining any outstanding TSCA section 8(e) data. The TSCA Section 8(e) Compliance Audit Program has been initiated to foster compliance with the statutory obligations of TSCA section 8(e), and to obtain critical information about potential risks of chemical substances. In designing the TSCA Section 8(e) Compliance Audit Program EPA's objective was to provide, in the context of an enforcement initiative, positive incentives for companies to conduct audits of their data and to submit to the Agency the type of information required under section 8(e) of TSCA.

EPA recognizes that proper application of section 8(e) requires the exercise of scientific judgement. EPA is not interested in creating an atmosphere in which companies view a "data dump" strategy as the best course of action for meeting their obligations. The Agency hopes that cooperative consultation among EPA, data submitters, and other interested parties can lead to a more successful TSCA Section 8(e) Compliance Audit Program and ultimately a better understanding of the section 8(e) program. Based on written communications with the regulated industry, EPA has made the following modifications to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement that was published on February 1, 1991.

II. Modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement

A. Registration Requirements

The registration deadline/audit commencement date has been extended for 45 days to June 18, 1991. Thus, Units I.B and D of the CAP Agreement have been modified to read as follows:

> B. To register for the TSCA Section 8(e) Compliance Audit Program, the Regulatee must, no later June 18, 1991, sign and return this CAP Agreement by certified mail-return receipt requested to....
>
> D. The TSCA Section 8(e) Compliance Audit Program shall commence no later than June 18, 1991.

The audit termination date/deadline has been extended for approximately 90 days, to February 28, 1992. Procedures for case-by-case extensions have also been added. A Regulatee can petition EPA in writing no later than November 29, 1991, for an additional extension of the audit termination date (i.e., beyond February 28, 1992). Extension petitions must contain an adequate justification for the request, and will be favorably viewed if based on difficulties experienced by a Regulatee with the volume of information being reviewed and not because the Regulatee delayed initiation of the audit. Companies are urged to submit studies or reports as they are determined to be reportable, and extension petitions will be viewed with disfavor if a Regulatee has not submitted any information by the November 29, 1991, deadline for extension requests. In this way EPA encourages the phased receipt of information over time while recognizing the need for appropriate time extensions for Regulatees that have a large amount of records to review. Thus, Unit I.E of the CAP Agreement has been modified to read as follows:

> E. The TSCA Section 8(e) Compliance Audit Program shall terminate on February 28, 1992, and all submissions under this TSCA Section 8(e) Compliance Audit Program must be delivered to EPA no later than February 28, 1992. The Regulatee may petition EPA in writing at the address specified in Unit I.B of this CAP Agreement for an extension of the February 28, 1992, termination date. Extension requests must be received by EPA no later than November 29, 1991, and must contain an adequate justification for the extension.

No other modifications to the "registration requirements" portion of the CAP Agreement have been made.

B. Terms of Agreement--General Provisions

The provision of the CAP Agreement regarding an admission of violation or a "violation of TSCA" has been changed and Unit II.A.4 of the CAP Agreement has been modified to read as follows:

> 4. The Regulatee neither admits nor denies that the submission of studies or reports by the Regulatee under this TSCA Section 8(e) Compliance Audit Program and pursuant to the terms of this CAP Agreement constitutes admission of a violation of TSCA sections 8(e) and 15(3)(B), but agrees to pay a stipulated civil penalty for each study or report in accordance with Unit II.B.2 of this CAP Agreement. Any study or report submitted under TSCA section 8(e) prior to the date of commencement of the TSCA Section 8(e) Compliance Audit Program is not subject to the terms of this CAP Agreement or the TSCA Section 8(e) Compliance Audit Program.

The provision of the CAP Agreement regarding waiver of rights has been changed and Unit II.A.3 of the CAP Agreement has been modified to read as follows:

> 3. The Regulatee waives its right to request a judicial or administrative hearing, under TSCA section 16(a)(2)(A) or other provisions of law, on any issue of law or fact that has arisen or may arise regarding the application of TSCA section 8(e) to any study or report submitted pursuant to Unit II.B.1 of this CAP Agreement.

The provision of the CAP Agreement regarding "prior violations" has been

modified slightly to make it clear that submissions under the CAP Agreement will count as one "prior violation" of 8(e) only. Thus, Unit II.A.7 of the CAP Agreement has been modified to read as follows:

7. EPA agrees that any submissions made pursuant to the terms of this CAP Agreement and the TSCA Section 8(e) Compliance Audit Program will be viewed by EPA as one "prior such violation" under TSCA section 16(a)(2)(B) for future violations of TSCA section 8(e) only.

No other modifications to the "terms of agreement--general provisions" portion of the CAP Agreement have been made.

C. Terms of Agreement--TSCA Section 8(e) Compliance Audit Program and Civil Penalties

In order to facilitate participation in the TSCA Section 8(e) Compliance Audit Program as well as to improve section 8(e) compliance in general, EPA is preparing and plans to disseminate a section 8(e) reporting "guide" comprised primarily of approximately 150 existing TSCA section 8(e) submission "Status Reports" which contain useful reporting and implementation guidance. This guide will include two indices. The first index, which pertains to the 150 "Status Reports," will be arranged by toxicologic study type and other important subheadings related to reporting criteria. The second index will be cumulative and arranged by type of study for all initial submissions received under section 8(e) to date. An additional component of the guide will be a consolidated presentation of section 8(e) question and answer (Q&A) documents arranged under subheadings similar to the indices described above.

In response to a written request from the Chemical Manufacturers Association (CMA) for additional guidance in the areas of neurotoxic effects and environmental effects/releases, EPA agreed to perform an expedited review of a limited number of case histories to be submitted by CMA in early May. The Office of Pesticides and Toxic Substances (OPTS) is establishing a panel of EPA staff scientists to perform the expedited review of the case histories which are submitted. While the EPA panel can address endpoints of concern, CMA was asked to prioritize the submissions to focus attention on the key scientific questions, especially neurotoxicity/acute toxicity concerns. The EPA review will focus primarily on whether the case studies would be reportable under section 8(e). The rationale for EPA's conclusions and responses concerning the appropriateness of reporting will be provided as part of the section 8(e) reporting guide which has been described above. EPA will make every effort to complete the guide in early June and release it prior to the revised June 18, 1991, registration deadline/audit commencement date.

EPA requested that the environmental effects/release cases focus on areas that industry believes are problematic in terms of what is reportable under section 8(e). In order for EPA to respond more completely about the section 8(e) reportability of the provided environmental effects/release information cases, EPA also asked if the information is required to be submitted to another governmental authority and, if so, the identity of that authority and the timeframe for the reporting. The rationale for EPA's conclusions and responses concerning the appropriateness of reporting will be provided as part of the section 8(e) reporting guide described above. EPA will make every effort to complete the guide in early June and release it prior to the revised June 18, 1991, registration deadline/audit commencement date. However, if necessary because of a delay in completion of the guidance on the environmental effects/release information, reporting of this information under the TSCA Section 8(e) Compliance Audit Program will be put on a specific schedule which will be determined later based on when EPA completes and disseminates the guidance in this area.

Thus, to reflect the availability of the TSCA section 8(e) reporting guide, the second portion of the CAP Agreement language at Unit II.B.1 has been modified to read as follows:

....Upon Registration for the TSCA Section 8(e) Compliance Audit Program, the Regulatee will receive a copy of the TSCA Section 8(e) Policy Statement, the publication numbers of publicly available and previously published volumes of Section 8(e) "Status Reports" available through the National Technical Information Service, copies of Question and Answer documents developed in response to specific questions involving section 8(e), a document entitled "Substantiating Claims of Confidentiality," and the TSCA section 8(e) reporting guide.

EPA believes that the actions described above emphasize the Agency's strong commitment to making the TSCA Section 8(e) Compliance Audit Program a successful initiative. EPA hopes that providing the selected case histories and the section 8(e) reporting guide will enhance understanding of the TSCA section 8(e) program, and assist the regulated community as they participate in the TSCA Section 8(e) Compliance Audit Program.

III. Conclusions

EPA has announced modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement. Any further information regarding this Audit Program or the CAP Agreement may be obtained from the contact person noted above.

Dated: April 24, 1991.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 91-10065 Filed 4-26-91; 8:45 am]

BILLING CODE 6560-50-F

federal register

Thursday
June 20, 1991
(Encoded Version)

APPENDIX D
(CAP Modifications)

Part IV

Environmental Protection Agency

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-80015B; FRL-3932-1]

Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice, pursuant to sections 15 and 16 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., announces the availability of the TSCA section 8(e) reporting guide and modifications to EPA's TSCA Section 8(e) Compliance Audit Program and the Agreement for the TSCA Section 8(e) Compliance Audit Program ("CAP Agreement"). The modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement include the extension of the registration deadline until July 1, 1991, the addition of provisions for listing of certain types of previously reportable TSCA section 8(e) information now in EPA's possession, and modification of EPA's guidance for reporting information concerning "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination" under TSCA section 8(e).

DATES: The Registration period for the TSCA Section 8(e) Compliance Audit Program closes on July 1, 1991. All persons interested in registering for the TSCA Section 8(e) Compliance Audit Program must request a CAP Agreement and submit a signed CAP Agreement to EPA no later than July 1, 1991.

ADDRESSES: Copies of the modified CAP Agreement and the TSCA section 8(e) reporting guide may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

FOR FURTHER INFORMATION CONTACT: David Kling, Acting Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 1, 1991 (56 FR 4128), EPA announced the opportunity to register for the TSCA Section 8(e) Compliance Audit Program. The TSCA Section 8(e) Compliance Audit Program is a one-time voluntary compliance audit program developed to obtain outstanding TSCA section 8(e) data and foster compliance with the statutory obligations of TSCA section 8(e).

On April 26, 1991 (56 FR 19514), EPA modified the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement. The modifications included extension of the registration and termination dates, the opportunity to petition EPA for a case-by-case extension of the termination date, modifications to the CAP Agreement provisions regarding admission of a violation of TSCA section 8(e) and waiver of right to a hearing, and EPA's development of a TSCA section 8(e) reporting guide.

II. TSCA Section 8(e) Reporting Guide

Since the April 26, 1991 modifications were announced, EPA completed development of the TSCA section 8(e) reporting guide. The guide contains useful reporting and implementation guidance and includes two major indices. The first index, which references approximately 150 section 8(e) "Status Reports," is arranged by toxicologic study type with subheadings related to section 8(e) reporting criteria. The second index is cumulative and is arranged by type of study for all initial submissions received under section 8(e) from January 1, 1977, to October 1, 1990.

There are two major objectives for presenting the guide. First, the guide makes certain information pertaining to section 8(e) reporting more accessible to members of the regulated community and others. Second, the guide provides reference to both general and specific examples of submitted information as well as EPA's comments regarding such submissions. The examples are intended to help persons who are subject to section 8(e) understand better the types of information that should be submitted to EPA under this important mandatory chemical hazard/risk information reporting provision of TSCA.

Most of the guide is presented in a basic question and answer format reflecting primarily the most common questions asked about section 8(e) of TSCA. The guide also contains EPA's comments regarding the TSCA section 8(e)-applicability/reportablity of a number of toxicologic "case studies" provided to the Agency by the Chemical Manufacturers Association (CMA).

Copies of the TSCA section 8(e) reporting guide may be obtained from the TSCA Assistance Information Service, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

III. Modifications to the TSCA Section 8(e) Compliance Audit Program and the CAP Agreement

A. Registration Requirements

The registration deadline/audit commencement date has been extended for approximately two weeks to July 1, 1991. Thus, Units I.B and D of the CAP Agreement have been modified to read as follows:

> B. To register for the TSCA Section 8(e) Compliance Audit Program, the Regulatee must, no later than July 1, 1991, sign and return this CAP Agreement by certified mail-return receipt requested to....
>
> D. The TSCA Section 8(e) Compliance Audit Program shall commence no later than July 1, 1991.

No other modifications to the "Registration Requirements" portion of the CAP Agreement have been made.

B. Terms of Agreement--TSCA Section 8(e) Compliance Audit Program and Civil Penalties Concerning Late Reporters

EPA has received inquiries regarding instances of late reporting of section 8(e) information when such studies or reports were (1) received by the Office of Toxic Substances (OTS) on a "For Your Information" ("FYI") basis and included in the formal OTS "FYI" filing system, or (2) submitted to EPA pursuant to a mandatory reporting obligation under a statute administered by EPA. By late reporting, EPA is referring to information received beyond the 15 working days deadline as set forth in Part IV of EPA's March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110) ("TSCA Section 8(e) Policy Statement"). After evaluation of the issue, EPA has determined that a reduced penalty scheme is appropriate for instances of late reporting of section 8(e) information when the studies or reports were (1) submitted in writing to and received by EPA prior to June 18, 1991, pursuant to a mandatory reporting obligation under TSCA or another EPA-administered statute, or (2) received by OTS on an "FYI" basis and included in the formal OTS "FYI" filing system, prior to June 18, 1991. This approach meets EPA's TSCA Section 8(e) Compliance Audit Program goal of obtaining, in the context of an enforcement initiative, outstanding section 8(e) information. Instead of resubmitting copies of these types of studies or reports, the information may simply be listed under the TSCA Section 8(e) Compliance Audit Program and identified by cover letter. A $5,000 stipulated civil penalty will be assessed for each study or report listed. Thus, Unit II.B.1.c has been added to the CAP Agreement to read as follows:

> c. Data that would have been reportable under TSCA Section 8(e) when initially obtained by the Regulatee, and that subsequent to the section 8(e) reporting deadline (and before June 18, 1991), were (i) submitted in writing to and received by EPA pursuant to a mandatory reporting requirement under TSCA or another statute administered by EPA, or (ii) received by the Office of Toxic Substances (OTS) on a "For Your Information" ("FYI") basis and included in the formal OTS "FYI" filing system: The Regulatee will list the

study or report pursuant to Unit II.B.3 of this CAP Agreement. Only information that meets the requirements of Unit II.B.1.c is eligible for this listing provision.

Unit II.B.3 has been added to the CAP Agreement to read as follows:

3. The following provisions shall govern the list required to be submitted under Unit II.B.1.c of this CAP Agreement:

a. For each study or report listed, the listing must comply with the requirements of Unit II.C of this CAP Agreement, must describe the date of the submission and (i) the mandatory reporting requirement of TSCA or another EPA-administered statute under which the study or report was submitted, or (ii) the Office of Toxic Substances "FYI" filing system number for the submission. Within 360 days after submission of the list, EPA may request the Regulatee to submit any of the listed information in order to determine if the Regulatee correctly listed rather than submitted the study or report.

b. The Regulatee agrees to pay the following stipulated civil penalty for information listed under this audit as data that would have been reportable under TSCA Section 8(e) when initially obtained by the Regulatee, and that subsequent to the section 8(e) reporting deadline as specified in Part IV of the TSCA Section 8(e) Policy Statement (and before June 18, 1991), were (i) submitted in writing to and received by EPA pursuant to a mandatory reporting requirement under TSCA or another statute administered by EPA, or (ii) received by the Office of Toxic Substances (OTS) on an "FYI" basis and included in the formal OTS "FYI" filing system: $5,000 per study or report.

C. Additions to the TSCA Section 8(e) Reporting Guide

In response to a written request from the Chemical Manufacturers Association (CMA) for additional guidance on the section 8(e) reportability of certain types of health effects and environmental effects/release information, EPA agreed to perform an expedited review of a limited number of case studies submitted by CMA. The Office of Pesticides and Toxic Substances (OPTS) established a panel of EPA toxicologists, biologists, chemists, medical and public health experts, environmental scientists, TSCA policy staff, and legal and enforcement staff to perform an expedited review of the case studies which were submitted by CMA. EPA reviewed the case studies involving reportability of health effects information, and provides an analysis of the toxicologic significance and TSCA section 8(e)-reportability of the health effects case studies in the TSCA section 8(e) reporting guide described above and referenced in the CAP Agreement.

D. Reporting of Information Referenced in Parts V(b)(1) and V(c) of EPA's Section 8(e) Policy Statement

TSCA section 8(e) requires reporting of information which reasonably supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to the environment. EPA provided guidance on how persons could fulfill their section 8(e) reporting obligations in the TSCA Section 8(e) Policy Statement. However, in reviewing this guidance in connection with the TSCA Section 8(e) Compliance Audit Program, EPA has determined that Part V(b)(1) ("widespread and previously unsuspected distribution in environmental media") and Part V(c) ("emergency incidents of environmental contamination") of the TSCA Section 8(e) Policy Statement need additional clarification and that possible misinterpretation with regard to the guidance in these sections could lead to overreporting under the TSCA Section 8(e) Compliance Audit Program.

Therefore, EPA plans to initiate a review of the reporting of information on widespread environmental distribution and emergency incidents of environmental contamination under TSCA section 8(e) and other Federal statutes in order to determine what information of these types should continue to be considered for submittal under section 8(e). The review may involve discussions with other EPA program offices, EPA Regional offices, other Federal Agencies, State Governments, members of the regulated industry, environmental interest groups, and others. All interested persons will have the opportunity to comment on any proposed revisions to Parts V(b)(1) and V(c) of the TSCA Section 8(e) Policy Statement that result from this review.

In the *interim*, regulatees auditing their files for reportable environmental risk information under the TSCA Section 8(e) Compliance Audit Program should be guided by the statutory language of section 8(e) and Part V(b)(2) through (b)(5) of EPA's TSCA Section 8(e) Policy Statement. In assessing whether information or studies involving widespread and previous unsuspected environmental distribution, emergency incidents of environmental contamination, or other previously unknown situations involving significant environmental contamination should be submitted under the TSCA Section 8(e) Compliance Audit Program, or under section 8(e) in general, regulatees should make a reasonable judgement whether such information meets the statutory standards of TSCA section 8(e) instead of relying on Parts V(b)(1) or V(c) of the TSCA Section 8(e) Policy Statement. Even though EPA is suspending the applicability of Parts V(b)(1) and V(c) of the TSCA Section 8(e) Policy Statement, persons are still responsible under TSCA section 8(e) to report information that reasonably supports a conclusion of substantial risk of injury to the environment. This is a continuing statutory obligation. Thus, to reflect this change, Unit II.B.1 of the CAP Agreement has been modified to read as follows:

1. In conducting the TSCA Section 8(e) Compliance Audit Program, the Regulatee shall follow the statutory language of TSCA section 8(e) and EPA's guidance on section 8(e) in the March 16, 1978, "Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" (43 FR 11110) ("TSCA Section 8(e) Policy Statement"), with the exception of Parts V(b)(1) and V(c) of the TSCA Section 8(e) Policy Statement, to determine whether the reviewed study or report is:....

No other modifications to the "Terms of Agreement" provisions of the CAP Agreement have been made.

IV. Conclusion

EPA believes that the actions described above emphasize the Agency's strong commitment to making the TSCA Section 8(e) Compliance Audit Program a successful initiative. EPA believes that providing the section 8(e) reporting guide as well as the results of the Agency's review of several toxicologic case studies will enhance understanding of the TSCA section 8(e) program, and assist the regulated community as they participate in the TSCA Section 8(e) Compliance Audit Program. Any further information regarding this Compliance Audit Program or the CAP Agreement may be obtained from the contact person noted above.

Dated: June 18, 1991.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 91-????? Filed ??-??-91; 8:45 am]

BILLING CODE 6560-50-F

Support Information for Confidentiality Claims

Information submitted under specific reporting requirements of the Toxic Substances Control Act (TSCA) or in support of TSCA is subject to the provisions of Section 14 of TSCA and to EPA's Regulations on the Confidentiality of Business Information (see 40 CFR Part 2). You must comply with the following procedures to assert a claim of confidentiality for the information solicited in the attached letter. Failure to follow these procedures fully at the time you submit the information to EPA will be interpreted by the Agency as a waiver of your claim of confidentiality.

Asserting a Claim

Information claimed as confidential must be clearly marked by boxing, circling or underlining. All pages containing such information should also be stamped **"CONFIDENTIAL"**. Care should be taken to ensure that these markings do not obscure the submission's text.

Sanitized Copy

Two copies must be submitted of any documents containing information claimed as confidential. One copy should be complete, with the information being claimed as confidential marked in the manner described in the preceding paragraph. The other copy should have all of the information claimed as confidential excised. This version will be placed in EPA's Public Files.

Substantiating Claims of Confidentiality

Detailed written responses to the following questions must be provided at the time you submit information for any portion of the information you claim as confidential. Your responses should be as specific as possible, with examples as appropriate, and should provide substantiation arguments for all types of information (e.g., sales or production/importation volumes, chemical identity, company identity) you claim as confidential.

1. For what period of time do you assert this claim of confidentiality? If a claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why the information should remain confidential until such event or time.

2. Have there been any confidentiality determinations made by EPA, other Federal agencies, or courts in connection with this information? If so, please enclose copies.

3. Has any of the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming as confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves your company?

5. Does the information claimed as confidential appear or is it referred to in any of items listed below:

   - advertising or promotional materials for the chemical or the end product containing it;

   - safety data sheets or other similar materials for the chemical or the end product containing it;

   - professional or trade publications; or

   - any other media available to the public or to your competitors.

   If you answered yes to any of the above questions, you must indicate where the information appears and explain why it should nonetheless be treated as confidential.

6. Would disclosure of this information be likely to result in substantial harm to your competitive position? If so, you must specifically describe the alleged harmful effects and indicate why they should be considered to be substantial. Also, you must describe how disclosure of the information would cause the harm.

7. If the information in question is "health and safety data" pursuant to 40 CFR Part 2.306(3)(i), do you assert that disclosure of the information you are claiming as confidential would reveal:

   a) confidential process information;

   b) confidential proportions of a mixture; or

   c) information unrelated to the effects of the substance on human health or the environment?

   If your answer to any of the above questions is yes, you must explain how such information would be revealed.