

**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 I.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 I.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 I.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 I.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 I.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 I.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 I.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 I.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.

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