

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.

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