

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/reportability 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. 91-14833 Filed 6-19-91; 8:45 am]

BILLING CODE 6560-50-F