

for storage, treatment, or disposal of hazardous waste must file a notification form with EPA (or an authorized State). The information requested includes the location and general description of hazardous waste activity. EPA uses the information for a variety of inspection, enforcement, and tracking purposes.

**Burden Statement:** The public reporting burden for this collection is estimated to average 3.1 hours per response and includes all aspects of the information collection including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Respondents:** Owners and operators of facilities that generate, transport, or handle hazardous waste.

**Estimated Number of Respondents:** 35,000.

**Estimated Number of Responses Per Respondent:** 1.

**Estimated Total Annual Burden on Respondents:** 108,500 hours.

**Frequency of Collection:** On occasion.

Send comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223Y), 401 M Street, SW., Washington, DC 20460.

and

Jonathan Gledhill, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20503.

Dated: July 1, 1993.

David Schwarz,

Acting Director, Regulatory Management Division.

[FR Doc. 93-16556 Filed 7-12-93; 8:45 am]

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[FRL-4678-6]

**Workshop on Exposure Factors Handbook**

**AGENCY:** U.S. Environmental Protection Agency.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a workshop sponsored by the U.S. Environmental Protection Agency's (EPA's) Risk Assessment Forum to develop recommendations for potential revisions and additions to EPA's 1990 *Exposure Factors Handbook* (Handbook) (EPA/600/8-89/043).

**DATES:** The workshop will begin on Wednesday, July 21, 1993, at 8:30 a.m.

and end on Thursday, July 22, 1993, at 5 p.m. Member of the public may attend as observers.

**ADDRESSES:** The meeting will be held at the Omni Georgetown Hotel, 2121 P Street, NW., Washington, DC.

Eastern Research Group, Inc., an EPA contractor, is providing logistical support for the workshop. To attend the workshop as an observer, call Eastern Research Group at 617/674-7374 or contact Mara Evans, Eastern Research Group, Inc., 110 Hartwell Avenue, Lexington, Massachusetts 02173, Tel: 617/674-7316 by Friday, July 16, 1993. Space is limited.

**FOR FURTHER INFORMATION CONTACT:**

Clare Stine, U.S. Environmental Protection Agency, Risk Assessment Forum (RD-672), 401 M Street, SW., Washington, DC 20460, Tel: (202) 260-6743.

**SUPPLEMENTARY INFORMATION:** The revised *Exposure Factors Handbook* is intended to serve as a support document to EPA's *Exposure Assessment Guidelines* (57 FR 22888; May 29, 1992) by providing data on factors that may be needed to calculate human exposure to toxic chemicals. The Guidelines were developed to promote consistency across exposure assessment activities carried out by various EPA offices. The Handbook provides a common data base that all Agency programs can use to derive values for exposure assessment factors.

This workshop will focus on developing recommendations on improving the 1990 *Exposure Factors Handbook*, and will seek consensus on recommendations for potential revisions and additions, including identification of new exposure factors and data sources.

To obtain a single copy of the 1990 Handbook, interested parties should contact the ORD Publications Office, CERL, U.S. Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268, Tel: 513/569-7562. Please provide you name, mailing address, and EPA document number EPA/600/8-89/043.

Dated: July 7, 1993.

Carl Garber,

Acting Assistant Administrator for Research and Development

[FR Doc. 93-16545 Filed 7-12-93; 8:45 am]

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[OPPTS-80016; FRL-4053-5]

**TSCA Section 8(e); Notice of Clarification and Solicitation of Public Comment**

**AGENCY:** Environmental Protection Agency (EPA)

RECEIVED

**ACTION:** Notice of clarification; solicitation of public comment. AUG 17 1993 TSCA NCIC

**SUMMARY:** This Notice solicits public comment on certain refinements to EPA's policy concerning the mandatory reporting of information under section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq. Specifically, comments are sought on EPA's section 8(e) policy refinements concerning mandatory reporting of information on the release of chemical substances to, and the detection of chemical substances in, environmental media. Comments are also sought on specific refinements made to EPA's policy concerning the reporting deadline for written "substantial risk" information and the circumstances under which certain information need not be reported to EPA under section 8(e) of TSCA. Finally, this notice reaffirms the Agency's position concerning claims of confidentiality for information contained in a notice of substantial risk under section 8(e).

**DATES:** Written comments on the reporting guidance set forth in this Notice must be submitted in triplicate and received by EPA no later than September 13, 1993.

**ADDRESSES:** All comments must be transmitted in triplicate to: TSCA Document Receipt Office (TS-790), TSCA Section 8(e) Public Docket (Docket No. OPPTS-80016), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

**FOR FURTHER INFORMATION CONTACT:** Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

TSCA section 8(e) states, "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

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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" [15 U.S.C. 2607(e)]. The broad scope and nature of TSCA section 8(e) makes it one of the most important health and safety data reporting provisions under TSCA. The statutory language of section 8(e) and the section 8(e) interpretive documents issued to date require the exercise of a certain degree of judgment in determining the section 8(e) reportability of information.

The section 8(e) reporting requirements became effective on January 1, 1977, the effective date of TSCA. Although section 8(e) is self-implementing, EPA issued a proposed policy statement on September 9, 1977 (42 FR 45362), and sought public comment with regard to the Agency's interpretation and implementation of section 8(e). Following receipt and consideration of numerous public comments, on March 16, 1978 (43 FR 11110), EPA issued a final TSCA section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk," hereinafter cited as the "1978 Policy Statement"). The 1978 Policy Statement describes the types of information that EPA considers reportable under section 8(e) and describes the procedures for reporting such information to EPA. On May 29, 1987 (52 FR 20083), EPA amended the 1978 Policy Statement to reflect a change in the address to which written section 8(e) notices must be transmitted. In June 1991, the Agency issued a TSCA Section 8(e) Reporting Guide, which is available from the source listed under **FOR FURTHER INFORMATION CONTACT** in this document.

## II. TSCA Section 8(e) CAP

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

In reviewing existing section 8(e) guidance as the result of questions raised by companies considering participating in the Section 8(e) CAP, EPA determined that Parts V(b)(1) and V(c) of the 1978 Policy Statement needed some refinement. On June 20, 1991 (56 FR 28458), EPA announced that the Agency was suspending the

applicability of Parts V(b)(1) and V(c) of EPA's 1978 Policy Statement which outlined the reportability of data on "widespread and previously unsuspected distribution in environmental media" and "emergency incidents of environmental contamination," respectively. The regulated community was informed that EPA would modify the section 8(e) policy to provide greater specificity regarding the types of environmental release, environmental detection, and environmental contamination information that should be submitted under section 8(e). In the interim, the regulated community was directed by EPA to focus on the statutory language of section 8(e) as the standard by which to determine the reportability of such information for purposes of the Section 8(e) CAP as well as ongoing compliance with section 8(e).

On September 30, 1991 (56 FR 49478), EPA announced an extension of the section 8(e) CAP reporting deadline for information relating to the release of chemicals to and the detection of chemicals in environmental media until such time as the Agency develops final refined section 8(e) reporting guidance on this point. This Notice addresses only the reportability of information concerning non-emergency situations on "widespread and previously unsuspected distribution in environmental media." The Agency has determined that any refined and/or amended guidance concerning the reportability of information on "emergency incidents of environmental contamination" (EIECs) under section 8(e) should be developed as part of the Agency's over-all policy concerning Federal chemical emergency/accident prevention, reporting, response, and/or remediation. EPA is deferring publication of any refined and/or amended guidance concerning the section 8(e) reportability of information on EIECs until issues associated with chemical emergency reporting policy are more fully defined and evaluated. The regulated community is again directed to focus on the statutory language of section 8(e) as the standard by which to determine the reportability of information on EIECs until that time.

EPA is in the process of resolving enforcement and compliance issues concerning reporting of section 8(e) "environmental" information under "Phase 2" of the CAP, and under section 8(e) more generally. After EPA considers the comments received in response to this notice, the Agency will issue in the **Federal Register** final refined guidance for reporting information concerning non-emergency situations regarding

environmental contamination. The notice will include discussion of compliance and enforcement issues associated with the refined guidance.

## III. Section 8(e) Policy Refinement

As section 8(e) is interpreted in Parts V(b)(1) and V(c) of the 1978 Policy Statement, EPA requires the reporting of certain substantial risk information concerning the release of chemical substances to, and the detection of chemical substances in, any environmental media. In order to enhance TSCA section 8(e) implementation, EPA is herein proposing refinements to the guidance presented in Part V(b)(1) of the 1978 Policy Statement. EPA is offering all interested parties the opportunity to submit written comments relating to the specific types of chemical release and detection information that should be reported under section 8(e) of TSCA.

Additionally, since EPA issued its 1978 Policy Statement, there have been numerous Federal laws passed and/or amended, and a large number of Federal regulations promulgated that are designed to gather chemical-related information, including information relating to the release of chemicals to and the detection of chemicals in the environment. Moreover, there may be other circumstances under which information may be considered known to the Administrator under TSCA section 8(e); several are listed in Part VII of the 1978 Policy Statement and other circumstances are identified herein. Therefore, comments are also being solicited on the circumstances under which EPA should consider itself to be adequately informed about substantial risk information, thereby falling outside of the mandatory reporting requirements of section 8(e).

Also, concerning Part IV of the 1978 Policy Statement, EPA intends to change the current 15-working day reporting deadline for the submission of written reports containing substantial risk information to 30 calendar days. Note that this slightly longer reporting deadline would apply only to written reports; oral reports regarding emergency incidents of environmental contamination will continue to be required to be made immediately (i.e., "as soon as [one obtains] knowledge of the incident," see Part IV of the 1978 Policy Statement). EPA believes the change from 15 working days to 30 calendar days would significantly relieve the burden on persons subject to section 8(e) reporting without substantially affecting EPA's ability to appropriately evaluate and respond in a

timely manner to the reported information.

With regard to follow-up reporting to oral reports concerning EIECs, EPA intends to eliminate the requirement in Part IV of the 1978 Policy Statement that a written report describing simply that an EIEC has occurred (i.e., the EIEC event itself) be submitted to the Agency. EPA believes that oral notification made to an appropriate Agency contact, as listed in Part IX of the 1978 Policy Statement, is generally sufficient notification for purposes of TSCA section 8(e). However, if health or environmental effects as described in Parts V(a) and V(b) of the 1978 Policy Statement are observed in conjunction with or subsequent to the release or detection, and the released or detected chemical substance or mixture is strongly implicated as being the cause of those effects, a written report would need to be submitted to EPA within 30 calendar days (the current requirement is 15-working days; see the preceding paragraph describing the intended reporting deadline change).

Finally, EPA is correcting the address and certain 24-hour emergency telephone numbers under Part IX of the 1978 Policy Statement, which describes particular reporting requirements.

#### A. Widespread/Previously Unsuspected Distribution

Part V(b)(1) of the 1978 Policy Statement explains that "[w]idespread and previously unsuspected distribution in environmental media, as indicated in studies (excluding materials contained within appropriate disposal facilities)" must be reported under section 8(e). Since 1978, EPA has received numerous written section 8(e) submissions alerting the Agency to the fact that a chemical known or suspected to be capable of causing serious health and/or environmental effects has been detected in significant amounts in environmental media (e.g., soil, surface waters, groundwater, air, biota) as well as in products or process streams. In such cases, EPA believes that the discovery of significant human and/or environmental exposure, when combined with the knowledge that the chemical or mixture is known or suspected to be capable of causing serious adverse health effects (e.g., cancer, birth defects, neurotoxicity) or serious adverse environmental effects (e.g., significant nontrivial toxicity in aquatic species), is clearly reportable under section 8(e) of TSCA. It is the exposure element of risk that is unknown to the Administrator in these cases, as opposed to the hazard element.

EPA believes, however, that because the overall scope of Part V(b)(1) may be unclear, this portion of the 1978 Policy Statement has been generally of limited use to the regulated community for determining when the detection of a chemical substance or mixture in environmental media must be reported under section 8(e) of TSCA. For example, while the introduction to Part V states that a "substantial risk of injury to health or the environment" is a risk of considerable concern because of (a) the seriousness of the effect... and (b) the fact or probability of its occurrence," Part V(b)(1) does not mention the need to consider the substance's potential for harm to either human health or the environment; thus, the existing guidance could lead to over-reporting. Further, the title of Part V(b) ("Environmental effects") may be somewhat misleading in that Part V(b)(1) is intended to specifically address non-emergency reporting of information pertaining to environmental contamination (i.e., situations which do not require immediate action, but nevertheless reasonably support the conclusion of a substantial risk). Therefore, EPA is changing the title of Part V(b) to "Non-Emergency Situations of Chemical Contamination Involving Humans and/or the Environment, and Environmental Effects."

With regard to non-emergency environmental contamination information, EPA interprets section 8(e) to require reporting of information that provides evidence of widespread environmental distribution of a chemical substance or mixture, and which because of the extent, pattern, and amount of the contamination seriously threatens or may seriously threaten: (1) Humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation (e.g., neurotoxicological effects, reproductive/developmental effects), or (2) non-human organisms with large-scale or ecologically significant population destruction. Thus, the mere presence of a chemical substance in an environmental media, absent some other relevant information as noted above, would not trigger reporting under section 8(e). Similarly, EPA believes that information concerning the detection of chemical substances properly contained within appropriate disposal facilities is not reportable under section 8(e).

The decision-making process for section 8(e) reporting of non-emergency situations involving environmental contamination and/or detection should include consideration of the toxicity of the chemical substance(s) involved. The

greater or more serious the known or suspected toxicity of the detected chemical substance or mixture, the less heavily one should weigh the amount, extent, and pattern of the contamination by that chemical or mixture in determining whether to report the situation under section 8(e) of TSCA. Conversely, the greater the amount, extent, and pattern of the contamination, the less heavily one should weigh the known or suspected toxicity of the chemical(s).

EPA considered establishing chemical-specific quantities and/or concentrations to be used by members of the regulated community as benchmarks for determining TSCA section 8(e) reportability of non-emergency situations depending on the toxicity of the chemical(s) involved. EPA has presently rejected this approach because there is such a wide variety of possible exposure scenarios associated with a non-emergency chemical release or detection that no predetermined quantity or concentration of a chemical could accurately delineate whether or not a release or detection of that amount or concentration would reasonably support a conclusion of substantial risk of injury to health or the environment. A given quantity or concentration of a substance under one set of circumstances could pose a radically different risk than it would under other circumstances. Rather, EPA is providing general guidelines for persons to use for determining the reportability of non-emergency situations under TSCA section 8(e).

Under various authorities administered by EPA, the Agency has established benchmark amounts/concentrations for a limited number of chemical substances within TSCA jurisdiction. For example, under the Safe Drinking Water Act, EPA has established Maximum Contaminant Levels (MCLs) for certain chemicals. Under TSCA section 8(e), on the other hand, "substantial risk" reporting is affected by a consideration of the hazard(s) associated with the chemical substance, and the nature, pattern, and extent of the release. Therefore, EPA believes that under some circumstances, information concerning a non-emergency chemical release or detection in an amount less than the chemical's MCL could "reasonably support the conclusion of substantial risk," thus requiring reporting under TSCA section 8(e).

However, it has been suggested to EPA by persons subject to section 8(e) that information on releases of chemicals in amounts less than their

MCLs, or other objective reporting standards if developed by EPA, should never be considered for reporting under section 8(e) because EPA has already established an objective threshold. As indicated above, EPA has at this time rejected this approach. Comment is specifically solicited on the subject of section 8(e) reporting of releases or detections of chemicals in amounts or concentrations below values established by EPA under other environmental protection authorities.

It should be noted that Part V(b)(1) of the 1978 Policy Statement pertains specifically and solely to the fact that a non-emergency situation involving the release or detection of a chemical substance or mixture has been discovered. In other words, information regarding a non-emergency chemical release or detection event, in and of itself, regardless of whether effects were observed associated with that particular release or detection, may be reportable under Part V(b)(1) of the 1978 Policy Statement. If health or environmental effects as described under Part V (i.e., Part V introduction, Part V(a), and Part V(b)) of the 1978 Policy Statement are observed in conjunction with or subsequent to the non-emergency release or detection, and the released or detected chemical substance or mixture is strongly implicated as being the cause of those effects, a written report must be submitted to the Agency within 30 calendar days, regardless of the quantity or concentration of the substance involved; this written reporting requirement remains unchanged (with the exception of the change in the reporting deadline from 15 working days to 30 calendar days for written information discussed above in this Unit).

The term "widespread" contamination in the context of a non-emergency situation would include, for example, presence in a product that is distributed commercially, multiple (e.g., 3 or more) reports of contamination (even in a single environmental medium) involving different sites inside and/or outside the boundaries of a facility, or presence in more than one environmental medium (e.g., discovery of a chemical in both soil and groundwater). For instance, a situation involving a toxic chemical contamination that has or could spread beyond the boundaries of a plant site via groundwater, surface water, and/or air is of greater concern than a situation involving similar soil contamination in which, because of the soil type or other circumstances, there is little or no likelihood that the chemical will migrate. There are also non-emergency

situations in which a significant chemical contamination is discovered inside physical structures within the plant site boundaries, which, when combined with other pertinent information (e.g., potential for exposure, toxicity of the chemical), can trigger section 8(e) reporting; examples include but are not limited to: (1) The detection of significant amounts of a toxic chemical substance in workplace air and/or on surfaces within a facility in which the chemical is typically handled in a closed system, and (2) the detection of significant levels of a toxic by-product not already generally known to be associated with a given chemical process, or known to be associated with the chemical process but found at levels significantly above those previously believed to be associated with that process.

#### *B. Information That Need Not Be Reported*

Part VII of the 1978 Policy Statement lists the circumstances under which information need not be reported to EPA pursuant to section 8(e). Specifically, Part VII of the 1978 Policy Statement indicates that information need not be reported to the Agency under section 8(e) of TSCA if it:

- (a) Has been published by EPA in reports;
- (b) Has been submitted in writing to EPA pursuant to a mandatory reporting requirement 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 a notification of spills under section 311(b)(5) of the Federal Water Pollution Control Act.

Since 1978, there have been numerous Federal laws passed and/or amended and a large number of Federal regulations promulgated that are designed to gather chemical-related information. In recognition of the

increased mandatory reporting of information under various laws administered, delegated, or authorized by EPA, EPA intends to revise paragraph (b) above so that a section 8(e) obligation is satisfied if emergency information is reported immediately (i.e., as soon as the subject person has knowledge of the incident) and non-emergency information is reported within 30 calendar days on a mandatory basis to:

(1) EPA, under any Federal statute administered by EPA (including, but not limited to, the Toxic Substances Control Act; the Federal Water Pollution Control Act; the Clean Air Act; the Federal Insecticide, Fungicide and Rodenticide Act; the Safe Drinking Water Act; the Marine Protection, Research and Sanctuaries Act; the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; the Pollution Prevention Act; the Emergency Planning and Community Right-to-Know Act (EPCRA));

(2) A State, under any Federal statute administered by EPA and delegated to that State (e.g., National Pollutant Discharge Elimination System (NPDES) permit requirements) (see example 1 below); or

(3) A State, under an EPA-authorized State program, which has been established pursuant to a Federal statute administered by EPA (e.g., an EPA-authorized State Resource Conservation and Recovery Act (RCRA) program).

The reporting exemptions under Part VII(b) do not pertain to information reported solely to a State or locality under a State or local law or a program not delegated or authorized by EPA, such as information reported solely to State and local emergency response committees under EPCRA. EPA believes that EPA approval and/or oversight of delegated and authorized programs provides a nexus to the EPA Administrator which is lacking under programs not authorized by EPA or delegated by the Agency to States.

EPA considered adopting the position that a section 8(e) reporting obligation would be considered satisfied if the information was reported within the specific time frame applicable to the federal authority or program cited in paragraphs (1), (2), and (3) above to which the submitter was subject. In view of the fact that the statutory language of TSCA section 8(e) requires that substantial risk information be reported "immediately," the Agency rejected this position because the time frames for mandatory reporting under the numerous authorities and programs cited above vary greatly and in some cases can exceed 6 months. Therefore, EPA at this time intends no change in its position that for EIECs, the obligation

to report under section 8(e) is satisfied if the mandatory reporting takes place immediately (i.e., as soon as the subject person has knowledge of the incident) under a Federal statute administered or delegated by EPA, or under a provision of an EPA-authorized State program. For non-emergency information, the obligation to report under section 8(e) of TSCA would be satisfied if the information is reported on a mandatory basis within 30 calendar days. This 30 calendar-day reporting period is a change from the current 15 working-day reporting period; it follows from the change discussed earlier in this Unit regarding the reporting deadline under Part IV of the 1978 Policy Statement for any written report of substantial risk information submitted under section 8(e).

Information that is not required to be reported under one of the above authorities, even if provided along with information required to be reported under that authority, remains subject to reporting under section 8(e) of TSCA.

Since issuing the 1978 Policy Statement, EPA has determined that there are certain circumstances not addressed in the 1978 Policy Statement in which information need not be reported under section 8(e). EPA typically has adequate access to such information, and EPA believes that reporting under the circumstances would result in an undue burden to the regulated community and an information review/processing burden to EPA which would outweigh any potential public benefit that might be obtained by requiring reporting of such information under section 8(e). Accordingly, EPA intends to change Part VII of the 1978 Policy Statement to indicate that information need not be reported under section 8(e) of TSCA if the information is obtained solely from one of the following sources:

1. An official publication or official report published or made available to the general public by EPA or another Federal agency (see example 2 below).
2. A scientific publication to which an EPA Headquarters library subscribes (see example 3 below) or that is referenced in a database, including one which is computerized, to which an EPA Headquarters library subscribes.
3. A data base, including one which is computerized, to which an EPA Headquarters library subscribes (see example 4 below).
4. A major written news publication (i.e., newspaper, news magazine, trade press) with national circulation in the U.S.

5. A radio or television news report broadcast nationally in the U.S. (see example 5 below).

6. A national public scientific conference or meeting held within the U.S., provided that the information is captured accurately by way of a meeting transcript, abstract, or other such record, and is cited in a bibliographic/abstract computerized data base, publication, or report of the type cited in paragraphs 1, 2, 3, 4, or 5 above within 30 days of obtaining such information (see example 6 below).

Regarding paragraphs 2 and 3 above, general information concerning the data bases and publications to which the EPA Headquarters libraries subscribe will be available from the source listed under **FOR FURTHER INFORMATION CONTACT** in this document. Specifically regarding paragraphs 4 and 5 above, EPA anticipates that information will be obtained from news publications with less than national circulation, or radio or television news reports broadcast only on a local, State, or regional level. In such cases, the information must be reported under section 8(e) of TSCA unless the subject person has actual knowledge that EPA has been adequately informed of such information through that or another source.

EPA maintains its position under Part VII(c) of the 1978 Policy Statement that information need not be reported under section 8(e) of TSCA if the information corroborates well established, serious adverse effects that are already documented. The term "corroborates," in the context of this particular reporting exclusion, means that the information essentially duplicates and/or confirms an existing and well-documented understanding of a serious adverse effect of a particular chemical substance or mixture. EPA has correctly received, and expects to continue to receive, substantial risk reports that show adverse effects of a more serious degree or of a different kind than are already established. In other words, the Agency expects subject persons to immediately consider reporting information on serious toxic effects (including but not limited to cancer, developmental, reproductive toxicity, or neurotoxicity) if, for example: such effects are substantially more serious in terms of the severity of the effects or the number of animals affected; occur within a significantly shorter time frame following exposure; occur via a different route of exposure; occur at a significantly lower dose or concentration; or occur in a different species, strain, or sex. Examples 7 through 10 below serve to illustrate the

distinctions created by this particular reporting exclusion.

The following examples illustrate certain of the types of factors that persons should consider in determining the applicability of the exclusions described above:

*Example 1.* While filing a mandatory report with the State pursuant to its NPDES permit, Company A also notifies the State in writing that a recently conducted clinical study showed that a statistically or biologically significant number of male factory workers exposed to the effluent are sterile. Despite the fact that the company notifies the State, such reporting is not mandatory under the NPDES program and the company must consider the need to submit a timely written report to EPA under section 8(e) of TSCA.

*Example 2.* Company A receives a public copy of an official report from the U.S. Department of Housing and Urban Development (HUD). In reading the report, the company learns that one of the chemicals the company distributes in commerce has been strongly implicated as being the cause of chromosomal damage in humans. Company A determines that the information contained in the report is of the type that would be required for submission to EPA. However, Company A correctly decides that it need not report the information under section 8(e). Per Part VII(a)(1) of the section 8(e) Policy Statement as refined herein, because the information was obtained from an "official publication ... made available to the general public by ... another Federal agency" it would not be reportable under section 8(e).

*Example 3.* Company A conducts a 9-day inhalation study of Chemical X in rats and finds that the chemical causes paralysis. Company A decides that these toxicological findings on one of its imported chemicals should be published in the open scientific literature and sends a draft manuscript to a scientific journal to which an EPA Headquarters library subscribes. Upon publication, Company B, who is also an importer of Chemical X, reads the article pertaining to the 9-day inhalation study of Chemical X and determines correctly that although the neurotoxicologic findings in rats are of the type required for submission to EPA under TSCA section 8(e), no section 8(e) notice from Company B is required. As the result of its chemical screening activities, EPA discovers the published article concerning Company A's 9-day study. After investigating further, EPA determines that Company A should have reported their findings under section 8(e) of TSCA immediately upon

obtaining the information; although the study was ultimately published, Company A did not obtain the information from a scientific journal.

**Example 4.** Company A processes chemical X and has no toxicological information on the chemical. As Company A is searching a large commercial computerized data base to which EPA subscribes for available toxicological information on chemical X, it discovers an abstract that states that Chemical X produced blindness in rats following oral administration. Although this toxicologic effect is clearly of the type required for submission under section 8(e) of TSCA, Company A decides correctly that formal section 8(e) filing of the obtained toxicological information is not needed because the computerized data base from which the information was obtained is one to which an EPA Headquarters library subscribes.

**Example 5.** The Director of Toxicology from Company A is at home watching the national nightly news on the television. During the broadcast, she learns that a very large release of Chemical X just occurred at a chemical manufacturing site in a nearby State. Despite the fact that she knows that her company is also a major manufacturer of Chemical X, no report under TSCA section 8(e) is required because the information was obtained from a news report broadcast nationally.

**Example 6.** During a national public scientific meeting presentation on Chemical X showing that Chemical X caused a significant level of birth defects in rats, the Director of Toxicology for Company A learns from the speaker that the oral administration of Chemical Y (an intermediate in a manufacturing process at Company A) also caused a significant level of birth defects in rats. In checking the content of the printed presentation abstract, which was distributed publicly by the meeting sponsors prior to the meeting and has been cited in a computerized data base to which an EPA Headquarters library subscribes, the Director discovers that the printed abstract accurately and adequately describes only the toxicologic findings for Chemical X and not for Chemical Y. Under these circumstances, Company A decides correctly to report the findings for Chemical Y to EPA under section 8(e) of TSCA.

**Example 7.** Company A manufactures chemical X and tests the chemical in a chronic feeding study in mice. It is already well established and well documented publicly that chemical X can cause a significant number of malignant skin tumors in mice as the

result of chronic dermal application. In the chronic feeding study, the company finds that chemical X causes a significant number of benign and malignant pancreatic tumors. Considering that the findings from the chronic feeding study differ in a major way from the already available information from the chronic dermal application study, the pancreatic cancer findings must immediately be considered for reporting to EPA under section 8(e) of TSCA.

**Example 8.** Company A manufactures chemical X and tests the chemical in a chronic skin-painting study in rats. It is already well-documented publicly that chemical X can cause malignant skin tumors at the application site in mice as the result of chronic dermal application. The company finds that chemical X causes a significant number of malignant skin tumors at the site of application in rats. In view of the fact that it is not well-known or well-established that chemical X can cause cancer in rats following dermal application, Company A must immediately consider the need to report its findings under section 8(e).

**Example 9.** During the conduct of a 28-day dermal application study in rats, Company A finds that exposure to one of its products, Chemical X, results in hind-limb paralysis. By way of an article published previously in a scientific journal to which an EPA Headquarters library subscribes, the company is also aware that acute oral exposure to Chemical X results in frank neurotoxicologic effects in rats. Considering the fact that the route of exposure in Company A's study was different than the one used in the published study, Company A must immediately consider the need to report its findings to EPA under section 8(e) of TSCA.

**Example 10.** During the conduct of a chronic dermal application study in rats, Company A finds that exposure to Chemical X results in a significant number of animals with malignant bone tumors after only 12 to 18 months of exposure. By way of a formally published abstract contained in a data base to which an EPA Headquarters library subscribes, the company is also aware that the same type of tumors had been found in rats exposed dermally to the same doses of Chemical X but only after two years of dermal exposure. Considering the fact that in Company A's study, the time to onset of the bone tumors differs significantly from that cited in the previously conducted study, Company A should immediately consider the need to submit the 12 to 18

month findings under section 8(e) of TSCA.

#### IV. Confidentiality Claims

EPA considers information contained in a notice of substantial risk under TSCA section 8(e) to be health and safety information generally covered by the term "health and safety study," as defined at TSCA section 3(6). Under TSCA section 14(b), such information can be withheld from the public as confidential if it "discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture [discloses] the portion of the mixture comprised by any of the chemical substances in that mixture."

TSCA section 3(6) defines a "health and safety study" to mean "any study of any effect of a chemical substance or mixture on health or the environment or on both, including the underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act."

In the legislative history of the Toxic Substances Control Act, the Conference Committee stated that "[i]t is intended that the term (health and safety studies) be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data that bears on the effects of a chemical substance on health or the environment would be included." H.R. Rep. No. 94-1679, 94th Cong., 2nd Sess. 58 (1976) (Conference Report) (emphasis added). EPA believes that TSCA section 8(e) information, such as information or underlying data from designed controlled studies or reports concerning undesigned uncontrolled circumstances, is information that "bears on the effects of a chemical substance on health or the environment." Likewise, incident information, exposure studies, and their underlying data are considered to be information relating to the effects of a chemical substance or mixture on health and/or the environment.

Therefore, to the extent that information contained in a section 8(e) substantial risk report falls within the meaning of the term "health and safety study" under TSCA, it is subject to the same non-disclosure restrictions afforded TSCA "Confidential Business Information" (TSCA CBI), as provided by TSCA section 14(b) and its interpreting regulations.

EPA considers chemical identity to be part of, or underlying data to, a health and safety study. See, for example, 40 CFR 716.3 and 40 CFR 720.3(k). As such, chemical identity will be afforded CBI protection by the Agency and therefore protected from public disclosure only under the circumstances provided under TSCA section 14 and the interpreting regulations.

In September 1990, EPA initiated a CBI review program to ensure that CBI claims are made in conformance with TSCA section 14. To date, EPA has challenged numerous CBI claims contained in section 8(e) notices and other filings, and in most cases the filing has been amended by the data submitter. EPA urges persons submitting data under TSCA section 8(e) to observe the limitations imposed on CBI claims by section 14 and the applicable regulations at 40 CFR part 2, subpart B, in order to save both Agency and submitter resources.

#### V. Refined Policy Text

For the reasons set forth in this notice, EPA is soliciting comment on refinements to the 1978 Policy Statement, which would be amended to read as follows:

#### Statement of Interpretation of, and Enforcement Policy Concerning, Section 8(e) of the Toxic Substances Control Act

1. In Part II, by revising the note at the end of the Part to read as follows:

Note. — Irrespective of a business organization's decision to establish and publicize 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 30 calendar days.

2. In Part IV, by revising the first paragraph to read as follows:

*Requirement that a Person "Immediately Inform" the Administrator.*

With the exception of certain 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 30th calendar day after the date the person obtained such information. Supplementary information generated after a section 8(e) notification has been filed should be submitted in writing within 30 calendar days after the date such supplementary information is obtained. Reports must be made as required under Part IX. For emergency incidents of environmental contamination, a person must report the

incident by telephone to the appropriate contact as directed in Part IX as soon as the person has knowledge of the incident. The report should contain as much of the information required by Part IX as is possible.

3. In Part V, by revising paragraph (b)(1) and adding the phrase "Environmental effects." to the beginning of each paragraph in (b)(2) through (b)(5) to read as follows:

(a) \* \* \*

(b) *Non-Emergency Situations of Chemical Contamination Involving Humans and/or the Environment, and Environmental Effects* —(1) Non-emergency situations of chemical contamination involving humans and/or the environment. Information that pertains to widespread chemical contamination that is not an "emergency" situation under Part V(c) below, but which because of the extent, pattern and/or amount of the contamination seriously threatens or may seriously threaten (i) humans with cancer, birth defects, mutation, death, or serious or prolonged incapacitation (e.g., serious neurotoxicological effects, reproductive/developmental effects), or (ii) non-human organisms with large-scale or ecologically significant population destruction, is subject to reporting. The mere presence of a chemical substance in an environmental media, absent some other relevant information as noted above, would not trigger reporting under section 8(e). The known or suspected toxicity of the detected chemical substance(s) should be considered in conjunction with the extent, pattern, and amount of the contamination in determining whether to report such non-emergency information. The greater or more serious the toxicity of the subject chemical or mixture, the less heavily one should weigh the amount, extent, and/or pattern of the contamination. Conversely, the greater the amount, extent, and/or pattern of the contamination, the less heavily one should weigh the toxicity of the chemical(s) in determining the section 8(e)-reportability of that release or detection. Information concerning the detection of chemical substances contained within appropriate disposal facilities should not be reported under this Part.

- (2) Environmental effects. \* \* \*
- (3) Environmental effects. \* \* \*
- (4) Environmental effects. \* \* \*
- (5) Environmental effects. \* \* \*

4. By revising Part VII to read as follows:

*VII. Information Which Need Not Be Reported*

"Substantial risk" information need not be reported if it:

(a) Is obtained from one of the following sources:

1. An official publication or official report published or made available to the general public by EPA or another Federal agency.
2. A scientific publication to which an EPA Headquarters library subscribes or that is referenced in a data base, including one which is computerized, to which an EPA Headquarters library subscribes.
3. A data base, including one which is computerized, to which an EPA Headquarters library subscribes.

Note: Specifically regarding paragraphs (2) and (3) above, general information concerning the data bases and publications to which the EPA Headquarters libraries subscribe is available from the Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M. St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

4. A major written news publication (i.e., newspaper, news magazine, trade press) with national circulation in the U.S.

5. A radio or television news report broadcast nationally in the U.S.

Note: Specifically regarding paragraphs (4) and (5) above, EPA anticipates that information will be obtained from news publications with less than national circulation, or radio or television news reports broadcast only on a local, State, or regional level. In such cases, the information must be reported under section 8(e) of TSCA unless the subject person has actual knowledge that EPA has been adequately informed of such information through that or another source.

6. A national public scientific conference or meeting held within the U.S., provided that the information is captured accurately by way of a meeting transcript, abstract, or other such record, and has been cited in a bibliographic/abstract computerized data base, publication, or report of the type cited in paragraphs (1), (2), (3), (4), or (5) above within 30 days of obtaining such information.

(b) Corroborates (i.e., substantially duplicates or confirms) in terms of, for example, route of exposure, dose, species, strain, sex, time to onset, and severity, a well-recognized/well-established serious adverse effect for the subject chemical(s), unless such information concerns effects observed in association with emergency incidents of environmental contamination as described in Part V(c).

(c) Is information that is reported to EPA within 30 calendar days for non-

emergency information, or immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information, pursuant to a mandatory reporting requirement of any statutory authority that is administered by EPA (including, but not limited to, the Toxic Substances Control Act; the Federal Water Pollution Control Act; the Clean Air Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Resource Conservation and Recovery Act; the Pollution Prevention Act; the Emergency Planning and Community Right-to-Know Act).

(d) Is information that is reported to a State within 30 calendar days for non-emergency information, or immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information, pursuant to a mandatory reporting requirement under any Federal statute administered by EPA and delegated to that State (e.g., National Pollutant Discharge Elimination System (NPDES) permit requirements), or

(e) Is information that is reported to a State within 30 calendar days for non-emergency information, or immediately (i.e., as soon as the subject person has knowledge of the incident) for emergency information, pursuant to a mandatory reporting provision of an EPA-authorized State program established under a Federal statute administered by EPA.

5. By revising Part IX to read as follows:

**IX. Reporting Requirements**

Notices shall be delivered to the TSCA Document Receipt Office (TS-790), (Attn: Section 8(e) Coordinator), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 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 distribution establishment with which the person is associated.

(d) Identify the chemical substance or mixture (including, if known, the CAS Registry Number).

(e) Summarize the adverse effects or risk being reported, describing the

nature and the extent of the effects or 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/she has knowledge of the incident (see below for appropriate telephone contacts). The report should contain as much of the information required by instructions (c) through (f) above as possible. Twenty-four hour emergency telephone numbers are:

Region I (Maine, Rhode Island, Connecticut, Vermont, Massachusetts, New Hampshire), (617) 223-7285.

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) 347-4062.

Region V (Wisconsin, Illinois, Indiana, Michigan, Ohio, Minnesota), (312) 353-2318.

Region VI (New Mexico, Texas, Oklahoma, Arkansas, Louisiana), (214) 655-2222.

Region VII (Nebraska, Iowa, Missouri, Kansas), (913) 236-3778.

Region VIII (Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota), (303) 293-1788.

Region IX (California, Nevada, Arizona, Hawaii, Guam), (415) 744-2000.

Region X (Washington, Oregon, Idaho, Alaska), (206) 442-1263.

**VI. Conclusion**

EPA will consider public comments submitted in response to this Notice and will publish in the Federal Register refined guidance pertaining to the types of non-emergency chemical release and detection information that must be reported under section 8(e), the time frames for reporting section 8(e) information, and the types of information that need not be reported under section 8(e). Comments are also sought on any change in public reporting burden which would result from the revisions and clarifications to the 1978 Policy Statement as described herein. The refinements contained in this Notice will not be effective until after EPA issues them in final form.

EPA intends to publish the refined TSCA section 8(e) reporting policy in the Code of Federal Regulations.

Dated: July 2, 1993.

Victor J. Kimm,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.  
[FR Doc. 93-16547 Filed 7-12-93; 8:45 am]

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**FEDERAL COMMUNICATIONS COMMISSION**

**Applications For Consolidated Hearing**

1. The Commission has before it the following applications for a renewal of license for television station (WHSB-TV) and a new commercial television station.

Applicant, city, and state	File No.	MM Docket No.
A. Trinity Christian Center of Santa Ana, Inc., d/b/a Trinity Broadcasting Network, Monro, GA.	BRCT-911129KR	93-156
B. Glendale Broadcasting Company, Monro, GA.	BPCT-920228KE	.....

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding headings at 51 FR 19347, May 29, 1986. The letter shown before each applicant's name, above, is used below to signify whether the issue in question applies to that particular applicant.

**Issue Heading and Applicant(s)**

Section 73.610-B  
FAA-B  
Comparative-A & B  
Ultimate-A & B

3. If there is any non-standardized issue(s) in this proceeding, the full text of the issue and the applicant(s) to which it applies are set forth in an Appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text may also be purchased from the Commission's duplicating contractor, Down Town Copy Center.