ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 68

[FRL–5881–9]

Accidental Release Prevention Requirements; Interpretations

AGENCY: Environmental Protection Agency.

ACTION: Interpretations.

SUMMARY: The Environmental Protection Agency is announcing clarifying interpretations of the accident prevention regulations authorized by section 112(r) of the Clean Air Act (CAA). First, the Agency is clarifying the method for calculating whether a quantity of a regulated substance in a listed solution exceeds its regulatory threshold under these rules. Second, the Agency is clarifying that certain reports and studies required by the accident prevention rules do not need to be reported under section 8(e) of the Toxic Substances Control Act (TSCA) or under the rules implementing TSCA section 8(d). The interpretations announced today clarify the Agency's existing policy and should help regulated entities understand their compliance obligations under these regulations.

EFFECTIVE DATE: August 25, 1997.

ADDRESSES: The docket for this notice is A–97–28. This notice pertains to previous final rules under dockets A–91–73 and A–91–74.

FOR FURTHER INFORMATION CONTACT: Regarding CAA section 112(r) and part 68, Vanessa Rodriguez, Chemical Engineer, Chemical Emergency Preparedness and Prevention Office, Environmental Protection Agency (5101), 401 M St., S.W., Washington, DC 20460, (202) 260–7913. Regarding TSCA section 8(d), David R. Williams, Associate Branch Chief, 401 M St. S.W., Washington DC 20460, (202) 260–3468. Regarding TSCA section 8(e), Richard H. Hefter, Jr., TSCA Section 8(e) Coordinator, High Production Volume Chemicals Branch, Office of Pollution Prevention and Toxics (7403), 401 M St. S.W., Washington, DC 20460, (202) 260–3470.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially affected by this action are those stationary sources that have more than a threshold quantity of a regulated substance in a process. Regulated categories and entities include:

Category	Examples of regulated entities
Chemical Manufacturers.	Industrial organics & inorganics, paints, pharmaceuticals, adhesives, sealants, fibers.
Petrochemical	Refineries, industrial gases, plastics & resins, synthetic rubber.
Other Manufacturing.	Electronics, semiconductors, paper, fabricated metals, industrial machinery, furniture, textiles.
Agriculture	Fertilizers, pesticides.
Public Sources.	Drinking and waste water treatment works.
Utilities	Electric and Gas Utilities.
Others	Food and cold storage, propane retail, warehousing and wholesalers.
Federal Sources.	Military and energy installations.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table also could be affected. To determine whether a stationary source is affected by this action, carefully examine the provisions of part 68 and related notices. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

I. Introduction and Background

The Clean Air Act (CAA), section 112(r), contains requirements for the prevention of accidental releases. The goal of the accidental release provisions is to prevent accidental releases and minimize the consequences of releases by focusing on those chemicals and operations that pose the greatest risk. The CAA requires EPA to develop a list of regulated substances that, in the event of an accidental release, are known to cause or may be reasonably expected to cause death, injury, or serious adverse effects to human health and the environment. At the time EPA promulgates its list of regulated substances, EPA also must establish threshold quantities for each regulated substance. Stationary sources that have more than a threshold quantity of a regulated substance are subject to accident prevention regulations promulgated under CAA section 112(r)(7).

On January 31, 1994, EPA promulgated the list of regulated substances and thresholds that identify stationary sources subject to the accidental release prevention regulations (59 FR 4478) (the ''List Rule''). EPA subsequently promulgated a rule requiring owners and operators of these stationary sources to develop programs addressing accidental releases and to make publicly available risk management plans (''RMPs'') summarizing these programs. (61 FR 31668, June 20, 1996) (the ''RMP Rule''). On April 15, 1996, EPA proposed amendments to the List Rule (61 FR 16598) and on June 20, 1996, stayed certain provisions of the list and threshold regulations affected by the proposed amendments (61 FR 31730). On May 22, 1997, EPA proposed additional amendments to the List Rule (62 FR 27992). For further information on these regulations, section 112(r), and related statutory provisions, see these notices. These rules can be found in 40 CFR part 68, ''Chemical Accident Prevention Provisions,'' and collectively are referred to as the accidental release prevention regulations.

II. Interpretations

In conducting outreach to affected stakeholders concerning the implementation of the accidental release prevention regulations, EPA has attempted to clarify informally various interpretive issues concerning both the List Rule and the RMP Rule. Furthermore, interpretive issues have been raised by various litigants that have petitioned for judicial review of the List Rule and the RMP Rule. EPA has used a number of mechanisms to communicate interpretations to all stakeholders, such as having staff participate in conferences and seminars sponsored by stakeholders and maintaining both files of questions and answers on its website and a hotline for addressing public inquiries. Question and answer files can be found at http://www.epa.gov/swercepp/ under Publications; the hotline can be reached at (800) 424–9346. Publication in the **Federal Register** allows EPA to give wider notice to the public of interpretations of the accidental release prevention regulations that have national application or nationwide scope and effect. Also, publication of these interpretations was part of the settlement agreement of General Electric Company's petition for review of the List Rule; notice of this settlement was published in the **Federal Register** on May 22, 1997 (62 FR 27992).

The interpretations discussed below clarify how to determine whether a threshold quantity for a regulated substance contained in a listed solution has been exceeded and discuss the relationship between offsite consequence analyses required by the RMP Rule and certain provisions of the Toxic Substances Control Act (TSCA).

These interpretations are clarifications of existing regulations and statutory provisions rather than revisions to the accidental release prevention regulations and are consistent with the working interpretations EPA has been using in its outreach efforts.

A. Threshold Quantities for Listed Solutions

In the regulations addressing the procedures for determining whether a threshold quantity of a regulated toxic substance has been exceeded, EPA set out rules for how to calculate the quantity of a regulated substance contained in a mixture (40 CFR 68.115). In general, the rule requires the owner or operator of a stationary source (the ''source'') to count towards a threshold the quantity of a regulated substance contained in a mixture if the regulated substance exceeds one percent (1%) of the weight of the mixture. However, if the partial pressure of the regulated substance in a mixture is less than 10 millimeters of mercury (mm Hg), then the source does not need to count the regulated substance in that mixture towards the threshold quantity (40 CFR 68.115(b)(1)). For example, if chemical A, a regulated substance, is present in a mixture at 5% by weight, but the partial pressure of that substance in the mixture is 7 millimeters of mercury (mm Hg), then the source does not need to count the regulated substance in that mixture towards the threshold quantity.

For certain chemicals commonly handled in solution with water, EPA established minimum concentrations for mixtures with water (40 CFR 68.130, Tables 1 and 2). These chemicals and their minimum concentrations are ammonia (20% or greater), hydrogen chloride / hydrochloric acid (37% or greater), hydrogen fluoride / hydrofluoric acid (50% or greater), and nitric acid (80% or greater). EPA also included separate listings for anhydrous forms of ammonia and hydrogen chloride.

Some confusion has arisen over whether the one percent default mixture rule would apply to mixtures containing aqueous solutions of ammonia, hydrochloric acid, hydrofluoric acid, or nitric acid. When EPA included minimum concentrations for these chemicals on the tables listing regulated substances, EPA intended to supersede the 1% general default rule for mixtures containing regulated toxic substances and to provide a simpler method for threshold determination than the partial pressure method. As EPA stated in the preamble to the List Rule, ''[t]hese chemicals, in mixtures or solutions with concentrations below the specified cut-off, will not have to be considered in determining whether a threshold quantity is present'' (59 FR 4478, 4488, January 31, 1994). Therefore, EPA wishes to clarify that the one percent mixture rule established in 40 CFR 68.115(b)(1) does not apply to aqueous solutions or mixtures containing ammonia, hydrochloric acid, hydrofluoric acid or nitric acid for purposes of determining whether more than a threshold quantity is present at a stationary source. For such mixtures, the quantity of regulated substance in the mixture must be considered only if the concentration of the regulated substance in the total mixture equals or exceeds the specified minimum concentration in the list rule.

Another question that has been asked about how to calculate the quantity of a regulated substance for a listed solution concerns whether the source must include the entire weight of the solution towards the threshold. For example, some have asked whether a 50,000 pound solution that is 28 percent (28%) ammonia (14,000 pounds of ammonia contained in solution) would exceed the threshold for aqueous ammonia, which is 20,000 pounds. Some have read the specific listing of these solutions to mean that the entire solution is the regulated substance, thus requiring threshold calculations to be based on the entire solution.

In providing concentration cutoffs for specific chemicals, EPA did not intend to treat the entire listed solution as a regulated substance. Rather, EPA intended simply to establish an alternative method for calculating minimum concentrations for substances that themselves are listed. The Agency's intent can be inferred from the location of the discussion of the concentration cut-offs in the ''threshold determination'' section of the List Rule preamble rather than in the discussion of the listing for toxic chemicals (compare 59 FR 4481–85 with 59 FR 4488). Furthermore, the citation in Tables 1 and 2 to the Chemical Abstract Service (CAS) number refers to the regulated substance contained in the solution rather than the entire solution. However, the Agency has not been consistent in expressing this interpretation since promulgation of the List Rule. For example, in the ''Risk Management Plan Rule: Summary and Response to Comments'' (''RMP/RTC'') EPA stated, ''[i]f the regulated substance is listed as a solution * * *, then the entire weight of the solution is used'' (page 28–104). This incorrect expression of EPA's interpretation appears to be isolated and was not in the context of the development of the List Rule. The action announced today reaffirms the Agency's position taken in the List Rule context: the threshold quantities for solutions at and above the concentrations stated in the List Rule apply only to the quantity of the regulated toxic substance (listed in Tables 1 and 2 of 40 CFR 68.130) in the solution and do not include the water content of the solution. Thus, in the ammonia solution example discussed above, the threshold for aqueous ammonia would not be exceeded because the ammonia content of the 50,000 pound solution would be 14,000 pounds (28% of 50,000), while the relevant threshold would be 20,000 pounds of ammonia.

B. Relationship to Certain TSCA Reporting Requirements

Among the comments received on both the List Rule and the RMP Rule were questions that asked about whether either TSCA section 8(e) or the rules implementing TSCA section 8(d) require reporting under TSCA of either the RMP or the hazard assessment required by the RMP Rule. When EPA promulgated the RMP Rule, EPA replied in the RMP/RTC that it did not interpret the TSCA provisions to require submission of copies or listing of either RMPs or the hazard assessments required by the RMP Rule (RMP/RTC, page 33–56). EPA believes that an expanded discussion of the relationship between the RMP Rule and the TSCA requirements is appropriate and that wider dissemination of this interpretation by this notice is useful to regulated entities.

Under TSCA section 8(d), current and prospective producers, importers, and processors are required to submit a broad range of unpublished health and safety studies conducted on the chemical substances and mixtures listed at 40 CFR 716.120. Chemicals are periodically added to section 716.120 by rulemaking. The requirements become effective on the date specified in the final rule and prospective reporting obligations terminate no later than 10 years after the effective date or upon removal of the chemical substance or mixture from section 716.120. Such health and safety studies include but are not limited to: epidemiological or clinical studies; studies of occupational exposure; *in vivo* and *in vitro* toxicological studies; and studies of environmental effects. Copies of such studies possessed at the time a person becomes subject to the reporting requirements must be submitted, and the following kinds of studies must be listed: studies ongoing as of the date a person becomes subject to the rule;

studies initiated after the date a person becomes subject to the rule; studies that are known to, but are not possessed by, a person as of the date that person becomes subject to the rule; and studies previously submitted to U.S. Government Agencies without confidentiality claims. It should be noted that EPA is in the process of substantially revising the TSCA section 8(d) reporting requirements at 40 CFR part 716 and plans to issue a **Federal Register** notice detailing these revisions in the near future. The revisions are not expected to affect the interpretations included in this notice.

TSCA section 8(e) states that ''any person who manufactures [including imports], processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.'' The type of information required to be submitted under section 8(e) covers a broad range of health and environmental effects studies, exposure studies, and certain emergency release events not otherwise covered by other EPA reporting requirements. The majority of the information submitted concerns controlled laboratory studies of the effects of chemicals on human health and the environment, such as animal bioassays and a wide range of other *in vivo* and *in vitro* studies. Incidents of environmental contamination or exposure studies based on actual releases may also be required to be submitted based on the toxicity of the chemicals and the likelihood that humans or the environment will be impacted. However, modeling studies including those based on theoretical exposure data (e.g., ''worst-case'' scenarios), are not considered reportable under section 8(e), nor are hazard or risk assessments based on reviews of existing data. However, data or studies underlying the assessments may have been reportable at the time they were obtained by the companies performing the assessments if the information was not otherwise known to EPA.

Hazard assessments required by the RMP Rule consist of an offsite consequence analysis component and a five-year accident history (40 CFR 68.20 through 68.42). For most sources affected by the RMP Rule, the offsite consequence analysis requires development of two types of release dispersion analyses, ''worst-case release scenario'' analyses under 40 CFR 68.25 and ''alternative release scenario'' analyses under 40 CFR 68.28. Under the worst-case release scenario, the RMP Rule provides most of the modeling parameters, while under the alternative release scenario, a source has more flexibility in selecting modeling parameters. The worst-case release scenario analysis does not require a probability estimate of the specified worst-case conditions actually occurring, although the rule provides some flexibility if the specified conditions have not occurred in a recent period. The alternative release scenario is supposed to represent a scenario that is more likely to occur than the worst case scenario and that will have offsite consequences, unless no alternative scenario would have offsite consequences.

The two types of scenarios required to be analyzed under the hazard assessment provisions of the RMP Rule are not unlike ''vulnerability analyses'' that some sources have conducted for Local Emergency Planning Committees under the Emergency Planning and Community Right-to-Know Act (EPCRA) in that these scenarios concern theoretical upset plant conditions rather than actual or likely exposure scenarios. The Agency has previously expressed the view that vulnerability analyses are not reportable under TSCA section 8(d).

The five-year accident history component of the hazard assessment is a compilation of data on historical accidents, which would include information on release conditions, impacts, and changes that may have resulted from investigation of the release (40 CFR 68.42). As a compilation of historical incidents, the five-year accident history does not supersede requirements for notification of accidental releases under various statutes and is distinct from the RMP Rule's requirements for accident investigations under 40 CFR 68.60 and 68.81. In particular, TSCA section 8(e), EPCRA section 304, and section 103 of the Comprehensive Emergency Response, Compensation and Liability Act (CERCLA) may require a release to be reported and follow-up notification submitted.

Having reviewed the requirements of the RMP Rule in light of the requirements of TSCA section 8(d) rules and TSCA section 8(e), it is apparent that a hazard assessment mandated by the RMP Rule (i.e., worst case and alternative case scenario analyses and five-year accident history) is not subject to the copy and list submission requirements of the Health and Safety Data Reporting Rule codified at 40 CFR part 716, which implements TSCA section 8(d), and it is apparent that a hazard assessment mandated by the RMP Rule is not subject to the reporting requirements of TSCA section 8(e). However, the foregoing does not affect the applicability of either TSCA section 8(e) or TSCA section 8(d) and regulations promulgated thereunder to any information or studies used to develop such hazard assessment. For example, it has been a longstanding EPA interpretation of TSCA section 8(e) that it requires some releases to be reported to EPA; while such a release may need to be compiled in the five-year accident history, the release would remain subject to TSCA section 8(e) reporting. Similarly, a study initiated by a source on its own as an outgrowth of the five-year accident history, such as a follow up study on known animal impacts from a specific accidental release, may be subject to the listing and/or submission requirements of the TSCA section 8(d) and the rules thereunder. Nevertheless, it should be clear that the preparation, compiling, and reporting of hazard assessments as mandated by the RMP Rule do not trigger the copy and list submission requirements of the part 716 implementing regulation for TSCA section 8(d) nor do they require reporting under TSCA section 8(e).

Dated: August 19, 1997.

Carol M. Browner,

Administrator.

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