Chemical Name	CAS No.	Effective Date
• • • • •	•	•
1-Chloro-1,1-difluoroethane (HCFC-142b)	75-68-3	1/1/94
• • • • •	•	•
Chlorodifluoromethane (HCFC-22)	75-45-6	1/1/94
• • • • •	•	•
Chlorotetrafluoroethane	63938-10-3	1/1/94
1-Chloro-1,1,2,2-tetrafluoroethane (HCFC-124a)	354-25-6	1/1/94
2-Chloro-1,1,1,2-tetrafluoroethane (HCFC-124)	2837-89-0	1/1/94
• • • • •	•	•
1,1-Dichloro-1-fluoroethane (HCFC-141b)	1717-00-6	1/1/94
• • • • •	•	•
Dichlorotrifluoroethane	34077-87-7	1/1/94
Dichloro-1,1,2-trifluoroethane	90454-18-5	1/1/94
1,1-Dichloro-1,2,2-trifluoroethane (HCFC-123b)	812-04-4	1/1/94
1,2-Dichloro-1,1,2-trifluoroethane (HCFC-123a)	354-23-4	1/1/94
2,2-Dichloro-1,1,1-trifluoroethane (HCFC-123)	306-83-2	1/1/94
• • • • •	•	•

(b) * * *

CAS No.	Chemical Name	Effective Date
• • • • • • •		•
75-45-6	Chlorodifluoromethane (HCFC-22)	1/1/94
• • • • • • •		•
75-68-3	1-Chloro-1,1-difluoroethane (HCFC-142b)	1/1/94
• • • • • • •		•
306-83-2	2,2-Dichloro-1,1,1-trifluoroethane (HCFC-123)	1/1/94
• • • • • • •		•
354-23-4	1,2-Dichloro-1,1,2-trifluoroethane (HCFC-123a)	1/1/94
354-25-6	1-Chloro-1,1,2,2-tetrafluoroethane (HCFC-124a)	1/1/94
• • • • • • •		•
812-04-4	1,1-Dichloro-1,2,2-trifluoroethane (HCFC-123b)	1/1/94
• • • • • • •		•
1717-00-6	1,1-Dichloro-1-fluoroethane (HCFC-141b)	1/1/94
• • • • • • •		•
2837-89-0	2-Chloro-1,1,1,2-tetrafluoroethane (HCFC-124)	1/1/94
• • • • • • •		•
34077-87-7	Dichlorotrifluoroethane	1/1/94
63938-10-3	Chlorotetrafluoroethane	1/1/94
90454-18-5	Dichloro-1,1,2-trifluoroethane	1/1/94
• • • • • • •		•

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40 CFR Parts 372 and 721

[OPPTS-400069C; FRL-4738-8]

Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is adding 21 chemicals and 2 chemical categories to the list of toxic chemicals under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). All of these chemicals and chemical categories appear on the Resource Conservation and Recovery Act (RCRA) list of hazardous wastes at 40 CFR 261.33(f). The addition of these chemicals and chemical categories to the EPCRA section 313 list of toxic chemicals is based on their acute human health effects, carcinogenicity or other chronic human health effects, or their environmental effects, and on evidence that each is manufactured or imported in quantities of at least 10,000 pounds per year by at least one facility. EPA has found that the chemicals meet the criteria for addition to the list of toxic substances as established in EPCRA section 313(d)(2). EPCRA section 313 reporting for the newly listed chemicals

and chemical categories will be required beginning with activities during the 1994 calendar year. As such, the first reports for the added chemicals and chemical categories must be submitted to EPA and States by July 1, 1995. EPA is also promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 18 chemical substances that were proposed for addition to the EPCRA section 313 list but that are not being added today because no evidence was found that they are manufactured or imported in quantities of at least 10,000 pounds at any one facility. The SNURs will require persons to submit a significant new use notice to EPA at least 90 days before manufacturing, importing, or processing any of the 18 substances (listed herein) in amounts of 10,000 pounds or greater, per year, per facility, for any use.

DATES: The amendments to part 372 (the EPCRA section 313 rule) is effective January 1, 1994. In accordance with 40 CFR 23.5, the SNURs shall be promulgated for purposes of judicial review at 1 p.m. eastern time on December 15, 1993. The amendments to part 721 (the SNURs) become effective on January 14, 1994.

FOR FURTHER INFORMATION CONTACT: Maria J. Doa, Petitions Coordinator, Emergency Planning and Community Right-to-Know Information Hotline, Environmental Protection Agency, Mail Stop 7408, 401 M St., SW., Washington, DC 20460, Toll free: 800–535–0202.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

This rule is issued under section 313(d) and (e) of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11023 et seq., "EPCRA"). EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986.

B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using toxic chemicals to report their environmental releases of such chemicals annually. Beginning with the 1991 reporting year, such facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act (42 U.S.C. 13106 et seq.). Section 313 established an initial list of toxic chemicals that was composed of more than 300 chemicals and 20 chemical categories. Section 313(d) authorizes EPA to add or delete chemicals from the list, and sets forth criteria for these actions. Under section 313(e), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA issued a statement of petition policy and guidance in the **Federal Register** of February 4, 1987 (52 FR 3479) to provide guidance regarding the recommended content and format for petitions. On May 23, 1991 (56 FR 23703), EPA issued guidance regarding the recommended content of petitions to delete individual members of the section 313 metal compound categories.

II. Description of Petition

On March 4, 1992, EPA received a petition from Governor Mario M. Cuomo of New York and the Natural Resources Defense Council to add 80 chemicals and 2 chemical categories to the list of toxic chemicals under section 313 of EPCRA. All of the chemicals and chemical categories appear on the RCRA list of hazardous wastes under 40 CFR 261.33(f).

On September 8, 1992 (57 FR 41020), EPA partially granted the petition by proposing the addition of 68 chemicals and 2 chemical categories. It was the Agency's determination that these chemicals cause or can reasonably be anticipated to cause adverse acute or chronic human health effects or environmental effects as set forth in section 313(d)(2). The remaining 12 chemicals were not proposed for addition because it was EPA's belief that the available data did not indicate that they met the listing criteria of section 313(d)(2).

The proposed rule also included an alternative proposal to add only that subset of the 68 chemicals and 2 chemical categories that met the toxicity criteria for listing and also had evidence of production greater than a certain manufacturing threshold. As described in the proposal, the selection of the manufacturing threshold would be guided by the section 313(f) reporting thresholds, such that the addition of those chemicals produced in quantities less than the selected threshold would not be expected to result in the submission of EPCRA section 313 Form R reports to EPA and States. In conjunction with this alternative proposal, EPA proposed a SNUR under section 5(a)(2) of TSCA to gather information about any planned production greater than 25,000 pounds per facility of any of the petitioned chemicals that met the EPCRA section 313 toxicity criteria for listing and were on the TSCA Section 8(b) Inventory of Chemical Substances, but would not be added under the alternative proposal because they would not be expected to exceed the manufacturing volume threshold.

III. Summary of Final Rule

In this action, EPA is adding 21 chemicals and 2 chemical categories to the EPCRA section 313 list. EPA finds that each of these chemicals and chemical categories meets one or more of the toxicity criteria for listing found in EPCRA section 313(d)(2). Additionally, evidence exists that each of these chemicals can reasonably be anticipated to be manufactured or imported in quantities of at least 10,000 pounds (the EPCRA section 313 otherwise use reporting threshold) by at least one facility. Therefore, the Agency believes that the listing of these chemicals can reasonably be anticipated to generate EPCRA section 313 reports and that adding these chemicals to the list is appropriate.

The proposed rule contained summary information on EPA's review of these chemicals, including the toxicity evaluation. This background information will not be repeated here in the final rule. Based on an evaluation of the public comments received and a reanalysis of the available data cited in the proposed rule, EPA has determined that each of these 21 chemicals and 2 chemical categories meets one or more of the EPCRA section 313 listing criteria. Response to comments on specific chemicals appears in Unit III.G. of this preamble.

The following chemicals are found to meet the statutory criteria of section 313(d)(2)(A) for acute toxicity: bis(2-chloroethoxy)methane; formic acid; and methyl chlorocarbonate. The following chemicals and chemical categories are found to meet the statutory criteria of section 313(d)(2)(B) for cancer or other chronic human toxicity: acetophenone; amitrole; 1,4-dichloro-2-butene; dihydrosafrole; ethylenebisdithiocarbamic acid, salts and esters; ethylidene dichloride; formic acid; hexachlorophene; hydrogen sulfide; malononitrile; methacrylonitrile; methyl mercaptan; 2-methylpyridine; 5-nitro-o-toluidine; paraldehyde; pentachloroethane; pronamide; 1,1,1,2-tetrachloroethane; thiram; trypan blue; and warfarin and salts. The following chemicals are also found to meet the statutory criteria of section 313(d)(2)(C) for environmental toxicity: hexachlorophene; hydrogen sulfide; and thiram.

Upon reevaluation of the toxicity data, EPA has determined that two chemicals that were proposed for listing based on "may be sufficient" evidence of toxicity and evidence of production above the manufacturing level threshold

do not have sufficient evidence of toxicity to meet the statutory criteria of EPCRA section 313(d)(2) and thus are not listed in this final rule. These chemicals are p-chloro-m-cresol and p-toluidine. p-Chloro-m-cresol was rated toxic to man with a probable lethal dose of 50 to 500 milligrams per kilogram (mg/kg); however, because pertinent information, such as mode of exposure, was lacking, the significance of this study could not be determined. The animal LD_{50} (400 mg/kg) studies via other routes of exposure also demonstrated only moderate lethality concerns for this chemical. Because the toxicity data are limited, and the available data indicate that the chemical induces toxicity at relatively high dose levels, the Agency believes that the section 313(d)(2) listing criteria are not met. For p-toluidine, there is only limited evidence of carcinogenicity; increased incidence of hepatoma was seen in the male mice and in high dose female mice only when compared with pooled controls. p-Toluidine was not carcinogenic in male rats and is not mutagenic in a number of genotoxicity test systems. Therefore, the Agency believes that there is insufficient evidence for listing p-toluidine pursuant to section 313(d)(2).

For one other chemical, crotonaldehyde, that was proposed for listing based on "may be sufficient" evidence of environmental toxicity and evidence of production above the manufacturing level threshold, the Agency finds that the evidence of environmental toxicity is insufficient for listing pursuant to EPCRA section 313(d)(2)(C). However, upon reevaluation of the human health data, the Agency believes that there exists a concern for carcinogenicity for this chemical. Therefore, this chemical is not being added to the EPCRA section 313 list in this action, but will be proposed for listing pursuant to EPCRA section 313(d)(2)(B) in the Agency-initiated expansion rule to follow soon.

The Agency proposed to add nine polycyclic organic compounds to the EPCRA section 313 list, but is not finalizing the addition of any of these compounds in today's action. Eight of these compounds have been referred to the Agency's chemical list expansion project for inclusion in a category of specific polycyclic aromatic compounds, because they are similar in structure, origin, and type of adverse effect induced to the other constituents of this possible category. The remaining polycyclic organic compound, fluoranthene, was not referred to the possible category under the expansion project because it differs from the other constituents in type of adverse effect induced. However, it is not being added to the EPCRA section 313 list today because its production volume does not meet or exceed the 10,000 pound per facility threshold.

In response to a comment, the Agency has reevaluated one chemical, methyl ethyl ketone peroxide, that was found to be insufficient for listing in the initial review and therefore was not proposed for addition to the EPCRA section 313 list. As a result of this reevaluation, the Agency has identified a possible concern for corrosivity for this chemical and has referred it for consideration under the Agency's chemical list expansion effort.

In this action, EPA is also promulgating SNURs under section 5(a)(2) of TSCA for 18 chemical substances that were proposed for addition to the EPCRA section 313 list but that are not being added today because no evidence was found that they are manufactured or imported in quantities of at least 10,000 pounds at any one facility. The SNURs will require persons to submit a significant new use notice to EPA at least 90 days before manufacturing, importing, or processing any of the 18 substances in amounts of 10,000 pounds or greater, per year, per facility, for any use. The 18 substances are listed in Unit V.D. of this preamble.

IV. Summary of Public Comment

The public comment period for the proposed rule ended November 9, 1992. Sixty-five comments were received, including 34 from industry, 21 from environmental groups, and the remainder from other public interest groups, private citizens, labor groups, and government agencies and associations. In the **Federal Register** of September 10, 1993 (57 FR 47709), EPA published a notice of availability to allow the public an opportunity to comment on certain additional materials that were added to the docket after the close of the public comment period for the proposed rule. The public comment period for the notice of availability ended September 27, 1993. One comment was received during the public comment period. One additional letter was received requesting an extension of the public comment period on the notice of availability and providing brief comments. This letter will also be treated as a public comment on the notice of availability.

EPA received comments in the following major areas: petition response policy; use of a manufacturing level threshold in listing decisions; use of a production tracking mechanism; listing of categories; use of predictive techniques; general technical comments, and chemical-specific comments.

A. Petition Response Policy

Five industry commenters contended that this petition should have been rejected outright because the petitioners did not provide adequate information for this petition to be evaluated and did not follow the guidelines in EPA's statement of petition policy and guidance (52 FR 3479, February 4, 1987). Two of these commenters argued that acceptance of this petition creates a double standard between information required for listing and delisting petitions and establishes a "dangerous" precedent by EPA's assuming the burden of critically evaluating the petitioned chemicals. One of these commenters contended that, because the petitioners cited only chronic human toxicity as the basis for concern, EPA should have evaluated these chemicals solely for chronic human toxicity, not for all effects.

The Agency does not believe that this petition should have been rejected outright. The petitioners argued that, because the Agency had already listed these chemicals on RCRA using criteria similar to the section 313 toxicity criteria, these chemicals could reasonably be anticipated to cause the toxic effects cited in section 313(d)(2). While the Agency clearly would prefer that petitioners provide specific information relevant to all effects, the Agency believes that the information and rationale provided by the petitioners in this case were adequate for the purposes of initiating an Agency review of this petition. The Agency has, on occasion, made similar decisions with respect to evaluation of delisting petitions containing little specific information, such as the petition to delete decabromodiphenyl oxide (54 FR 46424, November 3, 1989) from section 313.

Three commenters contended that it was inappropriate to base an EPCRA section 313 listing decision solely on the RCRA status of the chemicals, because the two statutes have different purposes and different listing criteria. The Agency agrees. All chemicals included in the petition were evaluated for addition to the EPCRA section 313 list of toxic chemicals by applying the listing criteria established under section 313(d)(2). EPA's decision to add these chemicals to EPCRA section 313 was not based on their RCRA status. Furthermore, as stated in the proposal (57 FR 41021, September 8, 1992), the actions taken in this proceeding have no effect on any substance's status under RCRA or any other statute.

Seven commenters contended that it was inappropriate for EPA to use the *Draft Hazard Assessment Guidelines for Listing Chemicals on the Toxic Release Inventory* (Ref. 1) in the technical review of the petition. These commenters believed that EPA should finalize these draft guidelines prior to using them to make section 313 listing decisions, particularly since the guidelines have been presented for public comment, but this comment has not yet been incorporated. In response, EPA believes that it is appropriate to use these draft guidelines in listing and delisting decisions, because they are merely an embodiment of internal EPA practices that have been used in the review of petitions to add and delete chemicals from EPCRA section 313 since the inception of the program. These guidelines do not constitute a set of rules for additions and deletions, but merely an explanation of the process and general standards for evaluating chemicals against the section 313 listing criteria. The draft guidelines notwithstanding, EPA has evaluated every chemical subject to this rulemaking against the section 313 statutory criteria.

One commenter suggested that this petition should be considered in the context of the overall EPCRA section 313 chemical list expansion effort rather than in isolation. EPA has coordinated its response to this petition with its own, internally-initiated effort to identify toxic chemicals for addition to the EPCRA section 313 list. As a result of this effort, the Agency expects to propose a chemical list expansion rule in late 1993 or early 1994. However, the chemicals that are the subject of today's action were included in a governor's petition, and the Agency has now completed its review of the petition and the public comment. The Agency does not see any potential benefit to be gained by delaying today's action to coincide with the Agency-initiated expansion rule.

Two commenters recommended that EPA prioritize its listing decisions, using the Agency's limited resources to list first those chemicals that pose the greatest risk. However, the statutory criteria for listing chemicals under EPCRA section 313 focus on hazard, not risk. Only section 313(d)(2)(A) requires a risk-related factor, the potential for exposure in the form of chemical concentrations beyond the fenceline. The Agency has also used its discretion to consider exposure potential when evaluating chemicals that show moderate aquatic toxicity under section 313(d)(2)(C). Because of the focus of the statutory criteria, EPA believes that prioritization of chemicals for listing under section 313 should be based largely on hazard, not on risk. In this case, EPA received a petition and is required by section 313(e) to act in response to the petition.

Three commenters suggested that, prior to adding chemicals, EPA should subject them to a "policy screen" to determine, for example, if EPCRA is the most appropriate mechanism for collecting data about the chemicals, whether listing the chemical best serves the public right-to-know purposes of EPCRA, or whether listing will promote good environmental practices with respect to the chemical. One commenter contended that EPA needs to evaluate and articulate the usefulness of collecting this data for these chemicals. The Agency believes that EPCRA section 313 is an appropriate mechanism for collecting data on these chemicals, and that listing these chemicals will serve the purposes of EPCRA by providing the public with information about releases of these chemicals from facilities. EPA believes that EPCRA section 313 data have been extremely useful to the public, industry, and government, particularly in promoting good environmental practices with respect to toxic chemicals, and the Agency fully expects this to be true for these chemicals as well.

B. Manufacturing Volume Threshold

Twelve commenters, primarily from industry, expressed support for the use of a manufacturing volume threshold in EPCRA section 313 listing decisions. These commenters agreed with the Agency's position that the public's right-to-know is not served by listing chemicals for which few, if any, reports would be submitted. In contrast, 31 commenters, primarily environmental and public interest groups, labor groups, and private citizens, supported the proposal to add all 68 chemicals and 2 categories that were found to meet the toxicity criteria and opposed the proposal to employ a manufacturing volume threshold. These commenters stated that it is inappropriate to use production volume data to make listing determinations that should be based solely on toxicity.

Two commenters maintained that use of the manufacturing volume threshold is appropriate, because EPA has the option but is not required to list chemicals that meet the statutory criteria for listing. Two other commenters contended that the law and legislative history make it clear that, when responding to a governor's petition, EPA has a mandatory duty to add all chemicals that meet the toxicity criteria in section 313(d)(2). These latter commenters contend that the discretion cited by EPA in the proposal applies to Agency-initiated actions only. Four commenters state that the use of a manufacturing level threshold as a basis for listing is inappropriate, because the statute expressly lists the types of data to be considered in chemical listing decisions, and manufacturing data are not included in that list. Five commenters contended that choosing not to list certain toxic chemicals because they are not manufactured at levels that exceed a certain volume threshold is inconsistent with or contravenes the intent of the statute.

EPA reaffirms its belief, stated in the proposal, that "the use of a manufacturing volume threshold in responding to petitions under section 313(e) is appropriate and within the authority granted by EPCRA" (57 FR 41035, September 8, 1992). The detailed rationale for this belief is included in the proposal and is not reiterated here. However, in summary, the Agency believes that the discretion granted under section 313(d)(2) in the words "a chemical may be added" applies equally to Agency-initiated actions and to petition responses. Section 313(e), which governs the petition process, explicitly directs the Agency to, if appropriate, initiate a rulemaking "in accordance with subsection (d)(2)." Further, the Agency believes that the use of this threshold is not only a permissible and reasonable interpretation of the statute, but also "consistent with the section 313 list's purpose of generation of publicly available release data on listed chemicals and therefore a valid exercise of the Agency's discretion" (57 FR 41035). Finally, while the statute specifies generally accepted scientific principles, laboratory tests, and other studies as the permissible bases for making a toxicity determination under section 313(d)(2), EPCRA does not preclude the Agency from considering other information, such as production volume, when exercising its discretion when responding to a petition to list or not list a chemical that may meet the toxicity criteria.

Three commenters contended that EPA should not use a manufacturing volume threshold because available production data may be inaccurate or incomplete and therefore an inadequate basis for a decision. EPA acknowledged in the proposal that "information used to determine if a chemical is manufactured, imported or processed in quantities greater than an established manufacturing volume threshold...is limited" (57 FR 41038, September 2,

1992). In the proposal, EPA presented the production volume information it had obtained and specifically sought information from the commenters on production volumes. However, no additional information about production of any of these chemicals above either a 10,000 pound or a 25,000 pound threshold was provided by any commenter.

The Agency has conducted an extensive search of a number of different data sources to ensure that the best possible production information was used for the final decisions. While these data may be incomplete or inaccurate for some chemicals, EPA believes that, as the best available information, it constitutes a reasonable basis for these decisions.

EPA conducted, subsequent to the proposal, a search of a variety of data sources to attempt to identify production that was not identified at the proposal stage. The revised economic analysis (Ref. 2) provides information about the additional data sources that were examined and the results of the search for additional production data. One chemical (hexachlorophene) and one chemical category (warfarin and salts) were identified with manufacturing or import volumes in excess of the 10,000 pound threshold. (One chemical, trypan blue, had already been identified at the proposal stage as having a manufacturing or import volume above 10,000 pounds.) One additional chemical, paraldehyde, was identified with a known import volume of 5,000 pounds and is also known to form from acetaldehyde, a listed section 313 chemical, on standing. It is EPA's belief that this evidence of import and coincidental manufacture indicate that production of paraldehyde could reasonably be anticipated to exceed the 10,000 pound threshold.

Three commenters objected to the use of a manufacturing volume threshold because any confidential business information (CBI) used by EPA as a justification for a decision could not be released to the public or listed as a justification for rulemaking in the **Federal Register**. Therefore, the public would not be able to check or comment on EPA's judgments made using these data. In response, EPA has several options for using CBI data as a basis for a rulemaking. EPA can request a waiver from facilities to release certain information to the public. Alternatively, EPA can aggregate or otherwise mask facility-specific information in ways that provide the necessary information to the public without divulging CBI. Therefore, EPA does not believe that the possibility that CBI data will undermine the discretionary use of production volume in an EPCRA listing decision provides a sufficient reason to abandon the manufacturing volume threshold approach.

Ten public interest group commenters stated that adding chemicals for which no reports would be expected imposes no serious burden on the regulated community. Therefore the decision to refrain from adding chemicals that would not be expected to yield reports will provide no or only negligible burden relief to facilities. Two commenters argued that the fact that the regulated community has never petitioned EPA to remove from EPCRA section 313 the chemicals for which no reports have ever been received, indicates that the regulated community is not concerned about the negligible burden of having these chemicals on the list. Industry commenters contended that listing chemicals for which no reports would be expected imposes a burden on industry because subject facilities would still be required to determine whether they exceed thresholds for these chemicals. They also contend that facilities may be subject to an indirect burden from other regulatory requirements triggered by an EPCRA section 313 listing.

EPA believes that listing chemicals for which no reports would be expected would impose some additional burden on industry without producing any notable benefit. Some additional burden would be involved in examining a longer list of chemicals to determine which, if any, are manufactured, processed, or used at a subject facility. Some additional burden may also be imposed if the facility manufactures, processes, or uses a small quantity of any of these chemicals and therefore must perform threshold calculations to determine reporting obligations. EPA acknowledges that, for most facilities, the additional burden is likely to be minor. However, the Agency believes that even this minor additional burden would not be justified if there were clearly no reasonable basis for the Agency to expect submission of reports for these chemicals. EPA also believes that the absence of petitions to remove certain chemicals from the list does not necessarily indicate that the regulated community is not concerned with the burden associated with the presence on the list of those chemicals or other chemicals for which no reporting would be expected. Indeed, the general support for the use of a manufacturing volume threshold expressed by the regulated community in the public comment period suggests the contrary.

Eighteen commenters contended that listing these chemicals individually later because of production increases would be a cumbersome, costly, and inefficient process that would waste scarce EPA resources. EPA does not expect future individual listing to be particularly cumbersome, inefficient, or time-consuming. Hazard assessments have already been performed for these chemicals. Therefore, it would be relatively simple to add these chemicals in the future based on evidence of production or use volumes likely to generate reports. Thirteen commenters contended that such future listing may result in the loss of one, two, or more years' data between the time that production increased and the time that the reporting requirement would take effect. For the 18 chemicals subject to the significant new use rules being promulgated today, EPA does not expect any loss of data. The significant new use rules, which are also being promulgated in final form today, will require facilities to submit notification to the Agency of their intent to produce any of the subject chemicals in quantities of 10,000 pounds or more. Upon receipt of this notice, the Agency may require under TSCA authorities the submission of additional data about this production, including the data that would be required under EPCRA section 313. For chemicals that are not subject to the significant new use rules, EPA acknowledges that there may be a time lag for receipt of Form R reports under this approach. However, the number of lost reports would not be expected to be large unless one or more of these chemicals that are currently believed to be out of production entirely or produced in only very low quantities underwent a sudden and dramatic production increase. The production data the Agency has examined gives the Agency no reason to expect such sudden production increases for any of these chemicals. For example, many of these chemicals are canceled pesticides or drugs that are no longer approved for use in this country and do not appear to be produced for export. For chemicals such as these, it is reasonable to expect future production to remain constant or to decline.

Two commenters argued that, if a manufacturing level threshold is to be employed, it should be set at 10,000 pounds, rather than 25,000 pounds, since 10,000 pounds represents the lowest activity threshold for reporting under section 313. The Agency reaffirms that the purpose of a manufacturing volume threshold would be to ensure that chemicals are only added to EPCRA

section 313 if it is reasonable to expect submission of reports for those chemicals. In general, the Agency agrees with the commenters that the manufacturing volume threshold used in making decisions to add chemicals to the section 313 list should correspond to the lowest section 313 activity threshold for reporting, which is the 10,000 pound threshold for otherwise using a chemical. Accordingly, a manufacturing volume threshold of 10,000 pounds was adopted for this action. However, in certain cases, readily available and reliable production and use information may lead the Agency to conclude that no reports would be submitted for a chemical whose known production exceeds 10,000 pounds but is less than 25,000 pounds. In such cases, the Agency may use its discretion not to list that chemical.

Two commenters contended that failing to list toxic chemicals that currently are not produced or are produced in low quantities may cause businesses to switch their manufacturing, processing, or use from listed section 313 chemicals to chemicals that are not on the section 313 list. While such substitution may certainly occur, EPA does not believe it is likely for the majority of these chemicals, since many of them are canceled, restricted, or are research or medical chemicals used in small quantities for very specific purposes. For chemicals that are subject to the significant new use rules being promulgated today, EPA would receive notification of a facility's intent to manufacture any of these chemicals in quantities of at least 10,000 pounds. If evidence of production at or above the 10,000 pound threshold becomes available for any chemical, whether through notice under the significant new use rules or through other means, the Agency will examine that chemical for potential addition to the EPCRA section 313 list.

One commenter stated that some chemicals that are not produced in large quantities nationally are of particular interest in the commenter's local area. However, the commenter did not identify particular chemicals or provide any production information. Under EPA's approach, the manufacturing volume threshold applies on a per facility basis. Therefore, if a chemical is known to be produced at a facility in the commenter's area in a quantity that would be sufficient to generate a section 313 Form R report, that chemical would be listed under this action.

C. Production Tracking Mechanism

EPA recognized in the proposal that there may be future production of certain of these chemicals in excess of the manufacturing volume threshold. Therefore, the Agency stated its intention to promulgate a significant new use rule (SNUR) under TSCA section 5(a)(2) to identify such future production. The SNUR was proposed for 21 chemical substances and 1 chemical category that were on the TSCA section 8(b) Inventory of Chemical Substances and were believed to meet the EPCRA section 313(d)(2) toxicity criteria, but were not known to be in production at or above 25,000 pounds. The Agency requested comment on the suitability of the SNUR as a production tracking mechanism, as well as on the use of other regulatory mechanisms for obtaining production volume information.

Five commenters objected to the use of the SNUR because they believe it imposes excessively burdensome requirements and collects more information than is needed for the stated purpose. Four commenters stated that the burden reduction of not listing the chemicals would be outweighed by the additional burden of the SNUR, and therefore the Agency should simply make a listing decision rather than promulgate the SNUR. One commenter contended that using a SNUR to track future production for EPCRA purposes is not an appropriate use of a SNUR, which is supposed to be used for tracking new uses of a chemical substance for TSCA purposes. Four commenters contended that the Agency should consider a less burdensome tracking mechanism, such as a minimal notification requirement under TSCA section 8(a). Several commenters objected to the use of a SNUR because the SNUR could not track production of chemicals not covered by TSCA, such as drugs, drug intermediates, and pesticides. Two commenters stated that compliance with the SNUR requirements might not be as high as compliance with EPCRA section 313, since EPCRA section 313 has high visibility and can be enforced with citizen suits.

The Agency has closely considered these comments and has determined that a SNUR remains the most appropriate mechanism for monitoring these chemical substances and taking follow-up action, if appropriate. Therefore, the Agency is promulgating SNURs for 18 of the chemical substances for which a SNUR was proposed. Three chemicals (hexachlorophene, paraldehyde, and trypan blue) and one chemical category (warfarin and salts) that were included in the proposed SNUR are not included in today's final SNURs because they are being added to the EPCRA section 313 list today.

EPA disagrees that using a SNUR to track future production is an inappropriate use of TSCA section 5(a)(2). Indeed, as indicated in the TSCA Conference Report, Congress specifically contemplated such a use in drafting TSCA. "Thus a significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human or environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use." (H.R. Rep. 1679, 94th Cong., 2d Sess. 66 (1976)). In addition, there is no indication in TSCA or the legislative history that SNURs are to be used only for TSCA purposes. In fact, it was broadly acknowledged by Congress that TSCA is to be a "gap filler" in relation to other laws administered by EPA.

EPA disagrees that submission of a significant new use notice (SNUN) is an excessively burdensome requirement. The chemical substances for which EPA is issuing SNURs are known to, or can reasonably be anticipated to cause an adverse effect on humans or the environment. These chemical substances are currently produced below the section 313 reporting threshold for otherwise using a chemical substance of 10,000 pounds at any facility. Production volume increases above this level, and subsequent changes in exposures to these chemical substances, may present an unreasonable risk of injury to human health or the environment. The burden estimated for submission of SNUNs to the Agency is not unreasonable, since receipt of the notice will allow EPA to evaluate the new exposure scenarios, consider additional data submitted with the notice, and take action under TSCA section 5(e) or 5(f), if appropriate, to develop additional data or prevent an unreasonable risk. Following receipt of a SNUN, and subsequent evaluation of available data on the chemical substance, EPA may also determine to list the chemical under EPCRA section 313.

EPA's determination to issue SNURs for these chemical substances rather than list them under EPCRA section 313 is not based upon the relative burden of reporting for EPCRA section 313 versus reporting under a SNUR, but rather the appropriateness of each statutory

section for managing toxic chemical problems. The primary purpose of a SNUR is to ensure that the Agency is notified prior to any significant or new exposures to new or existing chemical substances. For example, a SNUR may be promulgated to obtain a notice prior to resumption of production of a chemical substance that has been phased out of commerce because of health concerns, or changes in worker exposure or pollution control measures for hazardous chemical substances which could effect exposure levels. Today's action is consistent with EPA's past use of TSCA section 5(a)(2). As noted in the preamble to the proposed rule, EPA believes that it is important to focus on those toxic chemicals that will yield data for the public. Because these chemicals are produced below the reporting threshold, adding the chemicals to the EPCRA section 313 list would not yield data for the public.

EPA considered the use of a TSCA section 8(a) reporting rule as an alternative to a SNUR. A section 8(a) rule would provide a means to acquire production volume and other exposure related data on these chemicals. However, section 8(a) is limited when compared to section 5(a)(2) in that it does not provide a mechanism for follow-up collection or generation of additional data, or for mitigation of possible unreasonable risks, except by subsequent rulemaking. Because these chemical substances are known to be hazardous, EPA considers the follow-up authorities contained in section 5 of TSCA to be appropriate. In addition, small businesses are exempt from reporting under TSCA section 8(a), and EPA believes it could miss increases in production by small businesses if it used section 8(a) rather than SNURs.

EPA disagrees with the commenters who argued that SNURs should not be used as a production tracking mechanism in this situation because they cannot be used for chemicals not covered by TSCA, such as drugs and pesticides. The fact that SNURs are inappropriate tracking mechanisms for certain of these chemicals does not argue against their use for other chemicals that are covered by TSCA. EPA has not identified any more suitable production tracking mechanism, and therefore believes that it is preferable to use the SNURs rather than another alternative or no tracking mechanism at all. It should be noted that pesticides and drugs that have other, non-pesticidal or non-drug uses may be included on the TSCA Inventory (e.g., DDT) and can be appropriate subjects of SNURs.

EPA agrees that EPCRA section 313 has high visibility, and can be enforced by citizen suits. However, under TSCA, penalties for violation can reach $25,000 per day per violation. Because SNUR violations are considered among the most egregious of possible TSCA violations, companies have a strong motivation to comply. In addition, EPA diligently monitors compliance with section 5(a)(2). Finally, TSCA section 20 also has authority for citizen suits to enforce TSCA rules. EPA, therefore, does not believe that there is any evidence or compelling reason to believe that compliance with EPCRA section 313 would be higher than for TSCA section 5(a)(2).

Unit V. of this preamble contains additional discussion on the SNURs being finalized today.

D. Addition of Categories

Two chemical categories (ethylenebisdithiocarbamic acid, salts and esters; warfarin and salts) were proposed for listing. Four commenters contended that EPCRA does not provide for the addition of a chemical category without individually evaluating and justifying each member of that category. The Agency believes that the statutory authority to add "a chemical" to the list may be reasonably interpreted to include the authority to add groups or categories of chemicals to the list, particularly in light of the fact that the original list adopted by Congress in section 313(c) of EPCRA included 20 chemical categories, mostly metal compounds, but also including categories of organic chemicals such as chlorophenols. The Agency believes it may satisfy the statutory criteria for adding a chemical category to the list by identifying the toxic effect of concern for at least one member of the category, and then showing why that effect may reasonably be expected to be caused by all other members of that category. The justification for the listing of the two categories in this action is given below in the chemical-specific portion of the response to comments section.

Four commenters objected to the listing of chemical categories because categories are difficult for EPA to administer and/or for the public and industry to understand. They also contend that industry compliance with reporting and supplier notification requirements is more difficult for categories because facilities are not provided with discrete chemical names and Chemical Abstract Service (CAS) registry numbers. Because the two categories being added to the section 313 list today each consist of chemicals that are similar chemically and in potential effect, EPA believes that these categories will not be difficult for the public or industry to understand or for the Agency to administer. The Agency will work with the public and the regulated community to develop, as appropriate, any interpretations and guidance the Agency determines are necessary to facilitate accurate reporting for these categories.

Several commenters stated that categories should only be used to group compounds that are similar chemically and in potential effects. As stated above, it is the Agency's belief that the two categories added to section 313 in this action are each composed of chemicals that are similar chemically and in potential effects.

The Agency proposed to add 9 polycyclic organic compounds to the section 313 list and requested comment on whether these chemicals should be listed as a category rather than individually. The Agency is not adding any of these polycyclic organic compounds to the EPCRA section 313 list in today's action. Eight of these compounds have been referred for consideration under the Agency-initiated chemical list expansion effort. In that expansion effort, the Agency is considering the addition of a delineated category of polycyclic aromatic compounds (PACs) to the EPCRA section 313 list. The eight polycyclic organic compounds are being referred for possible inclusion in that category because they are similar in structure, origin, and the type of adverse effect induced to the other constituents of the possible PAC category. Specific comments already received on the grouping of these compounds into a category will not be addressed in today's action, but will be referred for consideration in the final rule for the chemical list expansion effort.

One polycyclic organic compound (fluoranthene) that was included in the proposal is not being referred for consideration in the PAC category under the chemical list expansion effort because it is not similar to the other constituents in type of adverse effect induced. However, that chemical is not being added to the EPCRA section 313 list in this rule because it does not meet the manufacturing threshold.

E. Use of Predictive Techniques

The hazard assessments for several of the chemicals in the proposal included estimated aquatic toxicity values generated from quantitative structure activity relationship equations (QSARs) and other predictive techniques. Several commenters objected to the use of values generated by these predictive

techniques as evidence that a chemical meets the toxicity criteria of section 313. Some commenters stated that there is no basis in the statute or the legislative history for their use. Other commenters believed that such predictive techniques could be used, but not as a sufficient basis by themselves for listing a chemical on section 313. Some commenters questioned the technical accuracy of QSARs, since their predictive power varies, and comparison of QSAR data with actual aquatic toxicity results can show a significant margin of error in some cases. One commenter requested that the QSAR reference manual or other supporting documentation be added to the docket. This reference manual was added to the docket and its availability was announced in a **Federal Register** notice of availability published September 10, 1993 (58 FR 47709).

EPA believes that, where no or insufficient actual aquatic toxicity data exist upon which to base a decision, toxicity estimates generated by QSARs and other predictive techniques may constitute sufficient evidence that a chemical meets the section 313 listing criteria. EPA's authority to use such predictive techniques derives from section 313(d)(2) of the statute, which states that EPA shall base its listing determinations on, *inter alia*, "generally accepted scientific principles." EPA believes that the aquatic QSAR equations that are in widespread use and that show a high correlation between estimated and measured aquatic toxicity values can be considered to be generally accepted scientific principles (Ref. 3) and can form the basis of a listing determination. However, none of EPA's listing decisions for this final rule rely solely on aquatic toxicity values generated by QSARs or other predictive techniques. Several chemicals for which QSAR estimates were included in the proposal are being added to the list based upon other, sufficient evidence of toxicity. The remainder of the chemicals for which QSAR estimates were included in the proposal are not being added to the list in this action because their production does not exceed the manufacturing level threshold.

F. General Technical Comments

Five commenters contended that chemicals whose evidence of toxicity places them in the "may be sufficient" category of the *Draft Hazard Assessment Guidelines* (Ref. 1) should not be listed under EPCRA section 313 because they do not reach the level of significance specified in the statute. These commenters contended that the statutory listing criteria are more stringent than those used to develop the proposal. One commenter pointed out that, according to the *Draft Hazard Assessment Guidelines*, the Agency did not intend to automatically list all the "may be sufficient" chemicals; two commenters pointed out that these guidelines call for a two-step approach of initial screening followed by an in-depth hazard analysis, and that it did not appear that this in-depth hazard analysis was performed.

EPA agrees with the commenters that a determination of "sufficient" evidence is required to support the listing of a chemical under section 313. For each of the 14 chemicals that were classified as "may be sufficient" in the alternative proposal and that had evidence of production exceeding the manufacturing threshold, EPA has now conducted a detailed hazard assessment to determine whether there is sufficient evidence to establish that the chemical meets the statutory criteria for addition to the list (Ref. 4). To make this determination, EPA reviewed the readily available toxicity information on the chemicals for the effects cited in the proposed rule, environmental fate data where appropriate, and any public comment received. EPA's determination that a chemical is known to cause or can reasonably be anticipated to cause one of the adverse effects described in section 313(d)(2) is based on the significance of the effects induced by the chemical, the severity of the effects, the dose level causing the effect, and the quality and quantity of the available data. This included a consideration of the type of hazard data (e.g., data in animals versus human) and the confidence in this hazard data base (e.g., the sufficiency of the hazard data). Based on the results of these hazard assessments (Ref. 4), all of the chemicals being added to the EPCRA section 313 list in this action have sufficient evidence that they meet one or more of the statutory listing criteria under EPCRA section 313(d)(2). The basis for the listing decisions is presented in Unit III. of this preamble.

One commenter maintained that intraperitoneal (stomach cavity) injection has minimal relevance for evaluating potential human exposure from industrial situations and should not be used to support an EPCRA section 313 listing decision. The commenter contended that, if considered at all, intraperitoneal injection is a form of exposure that should be considered in establishing a section 313(d)(2)(A) finding of acute effects, not a section 313(d)(2)(B) finding of chronic effects.

EPA disagrees with the commenter. In making section 313 listing decisions, the Agency cannot ignore the possible significance of any existing data, including data from intraperitoneal injection studies. Although it is preferable to have toxicity data from the common routes of human exposure for risk assessment, EPA has taken the conservative approach for hazard identification under EPCRA section 313. This comment related to two chemicals (malononitrile and pentachloroethane) that are being added to the section 313 list today. For these chemicals, any data from intraperitoneal or other injection routes of exposure are supplemented by data from other, noninjection exposure routes. For example, in addition to chronic human and rat injection studies to support the neurotoxicity concerns of malononitrile, acute inhalation studies in rats and mice were also available which demonstrated acute neurotoxicity effects for this chemical (Ref. 4). For pentachloroethane, acute (dog) and chronic (dog and cat) inhalation studies showed numerous neurological effects (Ref. 4). The proposed rule contains information on EPA's review of these chemicals, including the toxicity evaluation. This background information will not be repeated here in the final rule. Based on EPA's reanalysis of the available information in the proposed rule for these two chemicals (Ref. 4), EPA has determined that malononitrile and pentachloroethane have sufficient evidence to meet the statutory listing criteria under EPCRA section 313(d)(2)(B).

One commenter objected to the use of data concerning effects of short duration (transient episodes) to support a finding of chronic neurotoxicity. The commenter contended that there is no correlation between transient acute impact and chronic neurotoxicity that is appropriate to industrial chemicals as a whole. The commenter contended that, if a chemical exhibits transient acute but not chronic effects, it should not be listed based on chronic neurotoxicity, unless additional data on chronic neurologic effects are also used in the determination to list the chemical.

EPA agrees with the commenter that if a chemical exhibits acute neurotoxic effects, it should be listed based on acute effects unless additional data on long-term neurotoxic effects are available (Ref. 4). This comment related to two of the chemicals that are being added to the section 313 list today. For these chemicals, any data from acute studies were previously supplemented by chronic neurotoxicity information. For example, in chronic toxicity studies, 2-methylpyridine produced numerous

neurological effects in rats. For pentachloroethane, numerous neurological effects were demonstrated in dogs and cats in chronic toxicity studies. The proposed rule contains information on EPA's review of these chemicals, including the toxicity evaluation. This background information will not be repeated here in the final rule. Based on comments received and EPA's reanalysis of the available information in the proposed rule for these two chemicals (Ref. 4), EPA has determined that 2-methylpyridine and pentachloroethane have sufficient evidence to meet the statutory listing criteria under EPCRA section 313(d)(2)(B) based on available neurotoxicity data for these chemicals.

One commenter stated its belief that EPA has taken the position that an EPA Group B2 classification as to human carcinogenicity satisfies the section 313(d)(2)(B) statutory criterion that a chemical "can reasonably be anticipated to cause in humans . . . cancer." The commenter notes that none of the cited references, however, contains human carcinogenicity data, and all references are to animal data. In response, EPA reaffirms its belief that Group B2 compounds satisfy the statutory criteria pursuant to EPCRA section 313(d)(2)(B). According to EPA guidelines, chemicals are classified as Group B2 compounds when there is sufficient evidence that the chemical causes cancer in animal studies and therefore is a probable human carcinogen. EPA reaffirms its belief that this evidence is sufficient to satisfy EPCRA section 313(d)(2)(B) findings that a chemical can reasonably be anticipated to cause cancer in humans (Ref. 4).

Three commenters stated that EPA should broaden the factors it considers when making a listing determination to include other factors related to potential exposure and risk, such as physical and chemical properties or persistence and bioaccumulation. EPA routinely considers the fate of the chemicals in the environment in its exposure analyses for chemicals meeting the acute toxicity criterion of EPCRA section 313(d)(2)(A), and has done so for this petition as well (Ref. 5).

Two commenters indicated that EPA should examine other data sources such as the National Response Center (NRC) and State and local agencies to determine frequency and circumstances of past releases, and should consider this data when making a listing decision under section 313. Upon examination of the data sources suggested by the commenters, EPA has concluded that these data bases cannot replace EPA's standard potential dose rate (PDR) analysis (described at 57 FR 22892, May 29, 1992) for chemical releases to air, water, and land on a routine basis. These data bases report accidental releases and, therefore, are not appropriate for use in conducting an analysis of ambient chemical concentrations and doses received by the general population based on routine releases. In addition, these data bases often yield little information on the route or circumstances of exposure (Ref. 5).

Several commenters stated that, for those chemicals that have sufficient evidence of acute toxicity, EPA cannot assume that there are sufficient releases of a chemical to reasonably anticipate that the substance will cause the acute effects beyond site boundaries as a result of continuous or frequent releases, as stipulated in section 313(d)(2)(A). Two commenters believe that, given the limits of available production information, EPA does not need to do exposure assessments to list chemicals. As stated in the proposal, EPA assumed for the purposes of the proposal that "there are sufficient releases for the Agency to reasonably anticipate that the chemical will cause 'significant acute human health effects' beyond the facility site boundaries" (57 FR 41022). This assumption was made for the purposes of the proposal because the time limitations imposed by the statute and limitations in currently available production volume information prevented the Agency from conducting detailed exposure assessments for each of the chemicals proposed for listing pursuant to section 313(d)(2)(A). However, the Agency agrees that, to list a chemical under section 313(d)(2)(A), the Agency must demonstrate why it believes that the chemical can reasonably be anticipated to cause acute effects at concentration levels reasonably likely to be found beyond the facility site boundaries due to continuous or frequently recurring releases.

To that end, the Agency has conducted exposure assessments (Refs. 5, 6, 7, and 8) for all chemicals for which the Agency is listing the chemical based solely on acute effects under section 313(d)(2)(A). These exposure assessments have been added to the docket, and their availability was announced in the **Federal Register** notice of availability published September 10, 1993 (58 FR 47709). Based on EPA's analysis of the available toxicity information for the 13 chemicals in the "may be sufficient" category (Ref. 4), 3 of the chemicals have sufficient evidence to meet the statutory listing criterion for acute toxicity under EPCRA section 313(d)(2)(A). Exposure and risk assessments (Ref. 9) showed a significant acute human health risk from fugitive releases of bis(2-chloroethoxy)methane and formic acid. For methyl chlorocarbonate, exposure and risk assessments (Ref. 9) showed a significant acute human health risk from fugitive and stack releases. Therefore, there is sufficient evidence for listing these chemicals pursuant to section 313(d)(2)(A).

During the public comment period following the publication of the notice of availability, one commenter raised a number of questions about the exposure assessment report (Ref. 5). The commenter contended that the basis for many of the estimated releases and exposures was not clear. The procedures EPA used to estimate the releases to water, land, and air, and releases from incineration, were provided in reference number 7 of the exposure report. The methods used in calculating the releases to the various media indicated how to use those estimated releases in calculating potential dose rates (PDRs) for each use application. PDRs based on generic air releases were estimated using the Point Plume model, reference number 1 in the exposure report, which provides short-term ambient air concentrations from releases from a single source.

The commenter stated that the exposure report (Ref. 5) did not provide an extrapolation from the examples given to nationwide exposures, and did not indicate how many people are expected to be exposed to the listed PDRs. EPCRA does not require an estimation of number of persons exposed to list a chemical under section 313(d)(2)(A) for acute effects. Regarding extrapolation to nationwide data, the hypothetical manufacturing and use release estimates were derived using site-specific information when possible and generic Standard Industrial Classification (SIC) code information, which assumes the plants are located anywhere in the U.S.; therefore, these results should be valid for any location in the country.

The commenter contends that the derivation of the PDRs for ingesting contaminated groundwater from landfill releases was not explained in the exposure report (Ref. 5), and that the assumed consumption of 2 liters per day is questionable at best. The derivation of the landfill PDR calculations was listed as reference number 11 of the exposure report. The drinking water ingestion estimate of 2 liters of water per day is based on EPA guidance; see the *Exposure Factors Handbook* (EPA/600/

8–89/043). This recommendation is based on several studies of drinking water consumption, showing that 2 liters of water per day is a reasonable default value for daily drinking water ingestion.

The same commenter objected to the use of acrylic acid and methyl ethyl ketone as surrogate chemicals to estimate the releases of formic acid in the release analysis (Ref. 8). The Agency agrees that actual monitoring data on formic acid emissions and releases would make a release estimate superior to an assessment based on data assumptions and modelling estimates. However, there do not appear to be any readily available monitoring data for formic acid emissions. The Agency believes that, in the absence of actual monitoring data and the associated modelling necessary to determine the actual releases of formic acid, use of section 313 data for surrogate chemicals is appropriate and reasonable. The following reasons describe the choice of acrylic acid and methyl ethyl ketone as surrogate chemicals for the estimation of releases of formic acid to the environment.

To estimate the possible releases of formic acid, the release analyses used the 1990 section 313 data for methyl ethyl ketone and acrylic acid at the Hoechst Celanese facility in Pampa, Texas, which also manufactures formic acid. Acrylic acid is very similar to formic acid for certain physical properties, such as water solubility and molecular weight. In addition, both acrylic acid and formic acid are organic acids. The release analysis also used such factors as the Agency's emission factors, the number of valves, flanges and tanks, and the type of chemical, such as organic liquid or crude oil. EPA understands that the type of equipment used has direct bearing on the environmental releases; however, detailed information about the actual equipment used was not available. Because the same basic reaction (oxidation of aldehydes) is used to form acrylic acid and formic acid, EPA believes it is reasonable to assume that the process equipment used would be similar for the production of both formic acid and acrylic acid. Therefore, if the through-put amount and the number of process tanks, valves, and flanges is the same for two different chemical processes, and the chemicals belong to the same class and have similar physical-chemical properties, then the releases of the two chemicals are expected to be in the same range.

EPA's release analysis (Ref. 8) took into account the physical property differences of formic acid and acrylic acid, as well as the throughput or production volume differences, and the different media of release. Methyl ethyl ketone (MEK) was selected to adjust the acrylic acid estimates because MEK's vapor pressure is more similar to formic acid's than is acrylic acid's vapor pressure. The Agency believes that the estimated releases for formic acid based on acrylic acid and methyl ethyl ketone are reasonable in light of the lack of actual monitoring data for formic acid.

G. Chemical-Specific Comments

The Agency received comments about a number of the specific chemicals included in the proposal. However, many of the chemicals proposed for addition are not included in this final rule because no evidence could be found that at least one facility manufactured or imported them at a level of at least 10,000 pounds. In those cases, the decision not to list the chemical was based entirely on production volume data, not on toxicity or other technical information. Therefore, the Agency will not respond in this rule to technical comments received on chemicals that did not meet the production volume threshold, other than to say that these comments were not relevant to the Agency's final listing decision.

1. *Hydrogen sulfide.* Several commenters contended that the data supporting the proposal to list hydrogen sulfide are inadequate to show that this chemical causes chronic health effects under section 313(d)(2)(B), and that the chemical should have been evaluated instead under section 313(d)(2)(A) for its potential acute effects. These commenters contended that some of the effects seen at the end of a 90–day inhalation study (inflammation, edema, cellular necrosis, hyperplasia, and exfoliation) are all acute effects that can be seen following single exposures to various pulmonary irritants. They contended that the fact that these respiratory effects were seen at the end of a 90–day inhalation study is not sufficient to consider them chronic effects. Instead, these effects were most likely acute respiratory effects that would have undergone biological repair as soon as exposures ceased, such that they would not have been evident if the animals were allowed a 2-week recovery period prior to sacrifice.

Based on EPA's reanalysis of the available data for this chemical (Ref. 4), EPA agrees with the commenters that the respiratory effects reported in humans are most likely due to its acute effects. EPA also agrees that the inflammation of the nasal mucosa observed in mice in the 90–day inhalation study was likely due to irritation of acute nature. However, the neurotoxic effects, such as insomnia, anxiety, perceptual ability and cognitive impairments, especially if they occurred in occupational exposures, were of chronic nature. Therefore, EPA reaffirms its finding that there is sufficient evidence for listing hydrogen sulfide pursuant to section 313(d)(2)(B) for chronic human health effects based upon the available neurotoxicity data.

2. *Crotonaldehyde.* One commenter recommended that crotonaldehyde not be listed because of the lack of sufficient ecotoxicity data. The commenter contended that the compound is neither persistent nor bioaccumulative, and that the proposal to list crotonaldehyde is an example of inappropriately using a few ecotoxicity studies that marginally fall below a "may be sufficient" threshold to determine that the chemical should be listed.

Based on EPA's reanalysis of crotonaldehyde's aquatic toxicity data, EPA has concluded that this chemical is moderately toxic to aquatic organisms (Ref. 3). Its acute LC_{50} values for fish, daphnid, and algae are 0.65, 2.0, and 0.88 mg/L, respectively. The chronic value for fish was found to be 0.16 mg/L, resulting in a concentration of concern (COC) level of 0.016 mg/L. Crotonaldehyde is also not expected to be persistent in the environment based on a stability study showing its half-life to be about 18 hours (Ref. 7). EPA has conducted exposure and release analyses (Refs. 7 and 8) for this chemical and believes that there is not a significant environmental aquatic risk resulting from releases of it from the site-specific manufacturing or from intermediate uses (Refs. 10 and 11). Therefore, the Agency does not believe that crotonaldehyde meets the toxicity criteria of EPCRA section 313(d)(2)(C) and is not listing it in this final rule. However, during the reevaluation of crotonaldehyde's environmental toxicity, the Agency also reexamined its human health effects. Based on a weight-of-evidence analysis, the Agency believes that there are carcinogenicity concerns for crotonaldehyde. Therefore, crotonaldehyde will be proposed for listing pursuant to section 313(d)(2)(B) in the Agency-initiated expansion rule to follow soon.

3. *Ethylenebisdithiocarbamic acid, salts and esters (EBDCs).* One commenter disagreed with the Agency's proposal to add EBDCs to the section 313 list of toxic chemicals without presenting any data regarding the toxicity of EBDCs themselves, but rather because of the presence of ethylenethiourea (ETU), which is

already included on the section 313 list. EPA reaffirms its decision to list EBDCs pursuant to section 313(d)(2)(B) based on the available data for ETU. It is commonly recognized that the biological effects of administered chemicals are frequently due to their impurities or metabolites. EBDCs readily metabolize and degrade to ETU, which has been classified by EPA as a B2 compound; i.e., the compound is a probable human carcinogen based on sufficient evidence from animal studies and lack of data in humans. EPA believes that EBDCs are carcinogenic based on the carcinogenicity of ETU, a contaminant, metabolite and degradation product of EBDCs. Because there is sufficient evidence that EBDCs' contaminant, metabolite and degradation product causes cancer in animal studies and therefore is a probable human carcinogen, EPA believes that this evidence is sufficient to satisfy the EPCRA section 313(d)(2)(B) finding that EBDCs can reasonably be anticipated to cause cancer in humans (Ref. 4). Therefore, the Agency is adding the category "ethylenebisdithiocarbamic acid, salts and esters" to the section 313 list.

4. *Formic acid.* One commenter stated that the data cited to support the listing of formic acid are primarily based on accidental or deliberate poisonings of humans which resulted from the corrosive nature of the acid. According to the commenter, data presented by the Agency demonstrate that the acute toxicity of formic acid is significantly less than that of several chemicals (2-chloroethyl vinyl ether, methyl ethyl ketone peroxide, and 1,4-naphthoquinone) for which the Agency judged the acute lethality values to be "insufficient" for listing. EPA proposed the listing of formic acid under EPCRA section 313(d)(2)(A) based on the acute corrosive nature of the chemical, not just on its acute lethality. Two of the three chemicals cited by the commenter (2-chloroethyl vinyl ether and 1,4-naphthoquinone) were not proposed for listing despite their higher acute lethality values because they are not corrosive (Ref. 4). The third chemical, methyl ethyl ketone peroxide, is corrosive (Ref. 4) and will be referred for further evaluation for potential addition to the section 313 list in a future action.

Specific comments were provided by two commenters regarding exposures to formic acid. According to one commenter, because of formic acid's relatively low vapor pressure, releases of formic acid do not readily vaporize and thus do not result in vapor clouds, nor are formic acid vapors likely to move rapidly offsite in a concentrated form. This commenter, Hoechst Celanese, also presented results of formic acid release modeling from its plant in Pampa, Texas, the largest domestic production plant, and contended that these results show that EPA has no basis to conclude that concentrations of formic acid sufficient to cause human health effects are reasonably likely to exist beyond facility site boundaries as a result of continuous or frequently recurring releases. The other commenter, Monsanto, contended that formic acid waste typically would be neutralized either at the facility or at a treatment plant, or put into an enclosed system such as a deep well. Monsanto presented data showing no releases beyond Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) reportable quantity (RQ) levels (i.e., 5,000 pounds) from any of its plants in the period from January 1990 to September 1992. EPA does not dispute the particular release and exposure data provided by these commenters. However, EPA's own exposure modeling (Refs. 5, 6, and 7), based in part on the information provided by Hoechst Celanese, shows a significant potential for acute human health risk (Ref. 9) from fugitive emissions of formic acid at levels reasonably likely to exist beyond facility site boundaries.

During the reopening of the public comment period following the publication of the notice of availability, one commenter disagreed with the Agency's determination that an NTP study on formic acid (Ref. 12) is sufficient evidence for listing this chemical under EPCRA section 313(d)(2)(B) for chronic human health effects. Specifically, the commenter stated that the effects demonstrated in the chronic study were at concentrations higher than those defined in EPA's draft screening criteria guidelines as sufficient for listing. Therefore, the commenter argued, the study does not lead to the conclusion that there is sufficient evidence to list formic acid for chronic effects. One additional letter was received that was not formally submitted as a comment but that will be treated as a comment by the Agency. This commenter noted that the effects seen in rats and mice were "microscopic changes" that "ranged from minimal to mild in severity." This commenter apparently believes that these effects observed do not constitute sufficient evidence to meet the "much more rigorous listing criteria" of EPCRA section 313.

Chronic effects of formic acid were observed at concentrations which place this substance in the "may be sufficient for listing" category under the EPA's draft hazard assessment guidelines (Ref. 1). Decisions on whether or not to add chemicals in this category are made on a case-by-case basis with reference to the section 313(d) criteria. The NTP study demonstrated that formic acid is capable of producing respiratory lesions in both mice and rats at relatively low doses (128 ppm, 53 mg/kg/day) upon chronic inhalation exposures, resulting in a No Observed Adverse Effect Level (NOAEL) of 32 ppm (13 mg/kg/day). Therefore, the Agency finds that this study provides sufficient evidence to establish that formic acid can reasonably be anticipated to cause in humans chronic health effects as described in EPCRA section 313(d)(2)(B). Thus, EPA's final determination to list formic acid is based on both acute human health effects (313(d)(2)(A)) and chronic human health effects (313(d)(2)(B)). Although EPA has decided to refer other chemicals to the expansion project, because the Agency has not altered its basic proposal to list formic acid, nor is it abandoning its initial basis for listing (313(d)(2)(A)), EPA is adding formic acid at this time.

5. *Methyl mercaptan.* Several commenters contended that the available health data do not support the listing of methyl mercaptan under section 313 as a chronic neurotoxin. One commenter maintained that the findings cited by EPA do not provide sufficient evidence to support a section 313(d)(2)(B) listing but are better evaluated as acute effects under section 313(d)(2)(A). According to the commenter, none of the studies cited by EPA documents a "serious or irreversible neurological disorder" from exposure to methyl mercaptan. Instead, the studies that are cited document acute effects such as death and coma which result from high dose exposures to methyl mercaptan. According to the commenter, such effects are not the type that should be used to support a section 313(d)(2)(B) finding. EPA does not agree that all of the health hazard data that were included in the proposal in support of the section 313(d)(2)(B) finding should have been evaluated instead against section 313(d)(2)(A) for acute effects (Ref. 4). Chronic low exposures to methyl mercaptan have been shown to cause functional neurodisorders in one group of industrial workers. Acute toxicity studies in animals confirm the neurotoxicity symptoms demonstrated in the industrial workers. In addition, methyl mercaptan caused pulmonary effects in rats and hepatic effects in

mice at very low chronic inhalational exposures. Based on EPA's reanalysis of this information, which was cited in the proposed rule for this chemical (Ref. 4), EPA reaffirms its position that these remaining data are sufficient to support a section 313(d)(2)(B) finding based on neurotoxicity and other chronic health concerns. However, the acute toxicity data on methyl mercaptan are not sufficient to support a section 313(d)(2)(A) finding due to the high dose levels to produce effects seen in these studies.

6. *Warfarin and salts.* As discussed in Unit IV.D. of this preamble, four commenters contended that EPCRA does not provide for the addition of a chemical category without individually evaluating and justifying each member of that category. The Agency believes it may satisfy the statutory criteria for adding a chemical category to the list by identifying the toxic effect of concern for at least one member of the category, and then showing why that effect may reasonably be expected to be caused by all other members of that category. The justification for the listing of the category "warfarin and salts" is as follows: warfarin has produced developmental and reproductive effects in humans and animals; the data supporting this were summarized in the proposed rule and will not be reiterated here. Warfarin salts can dissociate readily to the warfarin and salt ions, and therefore are expected to produce similar effects. Therefore, EPA finds it appropriate to list the category "warfarin and salts" pursuant to EPCRA section 313(d)(2)(B).

H. Miscellaneous Comments

One commenter stated that the Agency should add all 80 chemicals and 2 categories that were included in the petition, not just the subsets that were included in the proposal. EPA reiterates that 12 chemicals were not proposed because the hazard assessment did not identify sufficient evidence that these chemicals meet the toxicity criteria for listing. EPA cannot add chemicals that do not meet the toxicity criteria for listing.

One commenter suggested that, for the 12 chemicals for which the data were insufficient for listing, EPA should defer the listing decision rather than deny the petition, so that these chemicals could be added more quickly in the future if additional toxicity information became available. Again, these 12 chemicals were not proposed for listing because the hazard assessment did not identify sufficient evidence that these chemicals meet the toxicity criteria for listing. EPA does not believe that there is any reason to defer a decision on these chemicals. EPA could reconsider listing these chemicals should new toxicity evidence become available in the future and could propose their addition at that time.

One commenter pointed out that the estimates in the proposal for the hourly rate and the number of hours required to fill out a Form R were inconsistent with those in a **Federal Register** notice published on September 10, 1992 (57 FR 41496). These estimates have been revised for the final rule to remedy this inconsistency.

One commenter stated that EPA needs to be sure that the number of chemicals on the section 313 list that are listed solely for environmental effects does not exceed the 25 percent statutory limit. In response, none of the chemicals being added to the list in this action is being listed solely for environmental toxicity. Therefore, this action will not cause the number of chemicals listed solely for environmental effects to exceed the 25 percent limit.

V. Final TSCA Section 5(a)(2) Significant New Use Rule

A. SNUR Statutory Authority

This final SNUR is issued under section 5(a)(2) of TSCA, 15 U.S.C. 2604(a)(2).

B. SNUR Statutory and Regulatory Background

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a "significant new use." The Agency must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Section 5(a)(2) factors generally relate to the extent to which a use changes the volume of a chemical's production or the type, form, magnitude, or duration of exposure to it. Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use.

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR part 720. EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a chemical substance identified in a SNUR are subject to the export notification provisions of TSCA section 12(b) and the import certification requirements of TSCA section 13. The regulations that interpret sections 12(b) and 13 appear at 40 CFR part 707.

C. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. On July 27, 1988 (53 FR 28354), and July 27, 1989 (54 FR 31298), EPA promulgated amendments to the provisions which apply to SNURs in general. In the **Federal Register** of August 17, 1988 (53 FR 31248), EPA promulgated a "User Fee Rule" (40 CFR Part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting significant new use notices to submit certain fees to EPA are discussed in detail in that **Federal Register** document. Interested persons should refer to the CFR and the cited **Federal Register** notices for further information.

D. Summary of this SNUR

This SNUR, proposed in the **Federal Register** of September 8, 1992 (57 FR 41020), requires persons to submit a significant new use notice to EPA at least 90 days before manufacturing, importing, or processing the following chemical substances, in amounts of 10,000 pounds or greater, per year, per facility, for any use:

CAS No.	Name
101-55-3	4-Bromophenyl phenyl ether
353-50-4	Carbon oxyfluoride
50-29-3	DDT
56-53-1	Diethylstilbestrol
62-50-0	Ethyl methanesulfonate
1888-71-7 ...	Hexachloropropene
56-49-5	3-Methylcholanthrene
56-04-2	Methylthiouracil
70-25-7	MNNG (N-Methyl-N'-nitro-N-nitrosoguanidine)
50-07-7	Mitomycin C
1116-54-7 ...	N-Nitrosodiethanolamine
615-53-2	N-Nitroso-N-methylurethane
930-55-2	N-Nitrosopyrrolidine
608-93-5	Pentachlorobenzene
62-44-2	Phenacetin
50-55-5	Reserpine
95-94-3	1,2,4,5-Tetrachlorobenzene
95-35-4	1,3,5-Trinitrobenzene

The chemical substances included in this SNUR are certain substances proposed for addition to the list of toxic chemicals subject to reporting under section 313 of EPCRA, which EPA believes are not currently being produced in amounts of at least 10,000 pounds per year at any facility. In addition, each of the subject substances appears on the TSCA Inventory. (The Inventory is a list of existing chemical substances compiled by EPA under TSCA section 8(b).)

For the purposes of this SNUR, the term "facility" is defined as "all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person)." This definition of "facility," which is being added by today's action to 40 CFR part 721 — Significant New Uses of Chemical Substances, under section 721.3, is substantially the same as that under EPCRA section 329 and 40 CFR Part 372 — Toxic Chemical Release Reporting; Community Right-to-Know.

Trypan blue (CAS No. 72–57–1), paraldehyde (CAS No.123–637), hexachlorophene (CAS No. 70–30–4), and warfarin and salts were listed in the proposed SNUR but are not included in this final SNUR because they appear to be produced in amounts of at least 10,000 pounds per year and otherwise meet the EPCRA section 313 listing criteria. Accordingly, they are among the 21 chemical substances and 2 chemical categories being added today to the EPCRA section 313 list. As a result of their EPCRA listing, including these substances and one chemical category on the SNUR would not at this time further each of EPA's objectives for today's SNUR. (See Unit III.B. of this preamble for further discussion of the manufacturing volume threshold being applied to today's EPCRA section 313 listing action. Unit V.E. of this preamble describes the objectives and rationale for the final SNUR.)

Because trypan blue, paraldehyde, hexachlorophene, and warfarin and salts were included in the SNUR proposal, the export notification requirements of TSCA section 12(b) and 40 CFR part 707 were triggered for these substances. As EPA is not finalizing the SNUR for these substances and chemical category, EPA is withdrawing the proposal for the purposes of TSCA 12(b). As such, TSCA section 12(b) export notifications for trypan blue, paraldehyde, hexachlorophene, and warfarin and salts that would otherwise be required because of the proposed SNUR are no longer required as of the effective date of this rule.

E. Objectives and Rationale for this SNUR.

To determine what would constitute a significant new use of the chemical substances that are the subjects of this SNUR, EPA considered relevant information on the toxicity of the chemical substances, likely exposures associated with possible uses, and the relevant factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new use that is designated in this rule. EPA wants to ensure that:

1. The Agency receives notice of any company's intent to manufacture, import, or process per year, per facility, for any use, the subject chemical substances in amounts of at least 10,000 lbs. per year, per facility, for any use.

2. The Agency will have prospective manufacturing, importing, and processing data available from the significant new use notice, which will facilitate the decision making process regarding the potential future listing under section 313 of EPCRA of the chemical substances that are the subject of this rule.

3. The Agency will have an opportunity to review and evaluate data submitted in a significant new use notice before the notice submitter begins manufacture, importation, or processing for a significant new use.

4. The Agency will be able to regulate prospective manufacturers, importers, or processors of the chemicals listed in this alternative before a significant new use occurs, provided that the degree of potential health and/or environmental risk, or the uncertainty about the risks, is sufficient to warrant such regulation.

EPA has concerns regarding the toxicity of the chemical substances that are included in this SNUR. EPA believes exposures to the substances listed in this rule associated with manufacture, import, processing, use, and associated activities could increase should manufacture, import, or processing volumes equal or exceed 10,000 pounds per year, per facility. The notice required by the SNUR will provide EPA with the opportunity to evaluate activities associated with the significant new use, and an opportunity to protect against unreasonable risks, if any, from exposure to the chemical substances which could result from the proposed significant new use. Additionally, the information submitted with a SNUR notice will be used by EPA to consider initiating a rulemaking under EPCRA section 313 to list the chemical substance that was the subject of the significant new use notice, if appropriate.

F. Comments on the Proposed SNUR

This SNUR was proposed as an alternative to the listing of certain substances under EPCRA section 313. A discussion of the comments received on the SNUR alternative, including EPA's responses to the comments, can be found in Unit IV.C. of this preamble.

VI. Rulemaking Record

The record supporting these final rules is contained in the docket number OPPTS–400069C. All documents, including an index of the docket, are available for viewing and photocopying in the TSCA Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA NCIC is located at EPA Headquarters, Rm. E–G102, 401 M St., SW., Washington, DC 20460.

VII. References

(1) U.S. EPA/OPPT. 1992. Revised Draft Hazard Assessment Guidelines for Listing Chemicals on the Toxic Release Inventory.

(2) U.S. EPA/OPPT/EETD. 1993. "Economic Analysis of the Addition of 23 Chemicals to the EPCRA Section 313 List of Toxic Chemicals."

(3) U.S. EPA. 1993. Memorandum from Richard Clements, Ph.D., to David Brooks, Technical Integrator. "Response to Comments on Petition to Add RCRA Chemicals; Revised September 20, 1993."

(4) U.S. EPA. 1993. Memorandum from Cheng-Chun Lee, Senior Science Advisor, to David A. Brooks, Technical Integrator. "EPCRA Section 313 Petition to Add RCRA Chemicals and Responses to Rebuttal Comments on FR Notice."

(5) U.S. EPA/OPPT/EETD. 1993. Memorandum from Mary Ryan to David Brooks. "Final Exposure/PDR Report."

(6) U.S. EPA/OPPT/EETD. 1993. "Final Chemistry Report for Formic Acid, Methyl Mercaptan, Methyl Chlorocarbonate, p-Chloro-m-cresol, and bis(2-Chloroethoxy)methane," Steven DeVito.

(7) U.S. EPA/OPPT/EETD. 1993. Memorandum from Bob Boethling, Chief, Environmental Fate Section, to David Brooks, Technical Integrator. "Exposure Assessment for Crotonaldehyde--Toxics Release Inventory (TRI) Governor's Petition."

(8) U.S. EPA/OPPT/EETD. 1993. Memorandum from Paul Quillen, Chemical Engineer, to David Brooks, Technical Integrator. "CEB's Release Assessment Document; Governor's Petition to Add RCRA Substances to TRI."

(9) U.S. EPA/OPPT/CSRAD. 1993. Memorandum from David Brooks, Technical Integrator, to Linda Wunderlich, Project Manager. "Acute Human Health Risk Assessments for Three TRI Chemicals."

(10) U.S. EPA/OPPT/CSRAD. 1993. Memorandum from David Brooks, Technical

Integrator, to Linda Wunderlich, Project Manager. "Ecological Risk Assessment for Crotonaldehyde—TRI Governor's Petition."

(11) U.S. EPA/OPPT/CSRAD. 1993. Memorandum from Greg Susanke, Biologist, to David Brooks, Technical Integrator. "Environmental Review of Crotonaldehyde for TRI Listing."

(12) National Toxicology Program (NTP). 1992. NTP Technical Report on Toxicity Studies of Formic Acid (CAS No: 64–18–6) Administered by Inhalation to F344/N Rats and B6C3F1 Mice. NTPTOX 19, NIH Publication 92–3342. Research Triangle Park, NC.

VIII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993) the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Regarding point (1) above, EPA's economic analysis estimates up to 1,689 additional reports entailing annual costs to EPA, industry, and States of about $4.8 million as a result of the addition of the 21 chemicals and 2 chemical categories to the section 313 list of toxic chemicals.

Incremental costs attributable to the promulgated SNURs were considered but, due to the great uncertainty associated with the frequency of occurrence of potentially regulated activities, such costs could only be presented at the unit cost level. These estimates are discussed briefly below.

Unit costs to industry associated with the promulgated SNURs were estimated to range between $2,000 and $10,000 for each significant new use notice or modification request prepared, while costs to EPA for issuing and administering the SNURs were estimated to be $2,000. [Incremental costs to industry in connection with a response not to engage in a significant new use could not be estimated.] As costs would only be incurred in the event that a chemical listed in the rule were manufactured, imported, or processed in excess of the listing threshold, and as such chemicals are currently not manufactured, imported, or processed in excess of 10,000 pounds, it is expected that any overall increase in incremental costs resulting from the promulgated SNURs would be small.

Furthermore, EPA's assessment is that these rules will not adversely and materially affect a sector of the economy. In addition to these economic considerations, the Agency does not believe that these rules meet criteria (2), (3), or (4) as outlined above. Therefore, EPA has determined that these are not "significant" regulatory actions.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review. Although not considered "significant," this rule was sent to OMB for informational purposes.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires each Federal agency to perform a Regulatory Flexibility Analysis for all rules that are likely to have a "significant impact on a substantial number of small entities."

40 CFR part 372 exempts certain small businesses from reporting; specifically, those facilities with fewer than 10 full-time employees. This exclusion exempts about one-half of all manufacturing facilities in Standard Industrial Classification (SIC) codes 20 through 39 from section 313 reporting. Additionally, facilities which manufacture or process less than 25,000 pounds or otherwise use less than 10,000 pounds of these chemicals annually are not required to report for these chemicals under part 372. Therefore, EPA concludes that the rule adding substances to part 372 is not likely to significantly impact a substantial number of small entities.

Additionally, EPA has determined that the final SNURs will not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by the SNURs would likely be small businesses. However, EPA expects to receive few SNUR notices for these chemical substances. Therefore, EPA believes that the number of small businesses affected by the final rules would not be substantial, even if all the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in these final rules under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2070–0093 for the EPCRA rule and 2070–0038 for the TSCA SNURs.

The public reporting burden for this collection of information is estimated to average 53 hours per response for the EPCRA rule. For the SNURs, the public reporting burden is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimates or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2131, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects

40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, Toxic chemicals.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements, Significant new uses.

Dated: November 29, 1993.

Lynn Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR Chapter I is amended as follows:

1. Subchapter J is amended in part 372 as follows:

PART 372—[AMENDED]

a. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

b. In § 372.65 by adding chemicals to paragraph (a) alphabetically and to

paragraph (b) by CAS No. sequence and to paragraph (c) by alphabetically adding the categories to read as follows:

§ 372.65 Chemicals and chemical categories to which the part applies.

* * * * *

(a) * * *

Chemical name	CAS No.	Effective date
* * * * *	*	*
Acetophenone	98-86-2	1/1/94
* * * * *	*	*
Amitrole	61-82-5	1/1/94
* * * * *	*	*
Bis(2-chloroethoxy)methane	111-91-1	1/1/94
* * * * *	*	*
1,4-Dichloro-2-butene	764-41-0	1/1/94
* * * * *	*	*
Dihydrosafrole	94-58-6	1/1/94
* * * * *	*	*
Ethylidene dichloride	75-34-3	1/1/94
* * * * *	*	*
Formic acid	64-18-6	1/1/94
* * * * *	*	*
Hexachlorophene	70-30-4	1/1/94
* * * * *	*	*
Hydrogen sulfide	7783-06-4	1/1/94
* * * * *	*	*
Malononitrile	109-77-3	1/1/94
* * * * *	*	*
Methacrylonitrile	126-98-7	1/1/94
* * * * *	*	*
Methyl chlorocarbonate	79-22-1	1/1/94
* * * * *	*	*
Methyl mercaptan	74-93-1	1/1/94
* * * * *	*	*
2-Methylpyridine	109-06-8	1/1/94
* * * * *	*	*
5-Nitro-o-toluidine	99-55-8	1/1/94
* * * * *	*	*
Paraldehyde	123-63-7	1/1/94
* * * * *	*	*
Pentachloroethane	76-01-7	1/1/94
* * * * *	*	*
Pronamide	23950-58-5	1/1/94
* * * * *	*	*
1,1,1,2-Tetrachloroethane	630-20-6	1/1/94
* * * * *	*	*
Thiram	137-26-8	1/1/94
* * * * *	*	*
Trypan blue	72-57-1	1/1/94
* * * * *	*	*

(b) * * *

CAS No.	Chemical Name	Effective date
*	* * * * * *	*
61-82-5	Amitrole	1/1/94
*	* * * * * *	*
64-18-6	Formic acid	1/1/94
*	* * * * * *	*
70-30-4	Hexachlorophene	1/1/94
*	* * * * * *	*
72-57-1	Trypan blue	1/1/94
*	* * * * * *	*
74-93-1	Methyl mercaptan	1/1/94
*	* * * * * *	*
75-34-3	Ethylidene dichloride	1/1/94
*	* * * * * *	*
76-01-7	Pentachloroethane	1/1/94
*	* * * * * *	*
79-22-1	Methyl chlorocarbonate	1/1/94
*	* * * * * *	*
94-58-6	Dihydrosafrole	1/1/94
*	* * * * * *	*
98-86-2	Acetophenone	1/1/94
*	* * * * * *	*
99-55-8	5-Nitro-o-toluidine	1/1/94
*	* * * * * *	*
109-06-8	2-Methylpyridine	1/1/94
109-77-3	Malononitrile	1/1/94
*	* * * * * *	*
111-91-1	Bis(2-chloroethoxy)methane	1/1/94
*	* * * * * *	*
123-63-7	Paraldehyde	1/1/94
*	* * * * * *	*
126-98-7	Methacrylonitrile	1/1/94
*	* * * * * *	*
137-26-8	Thiram	1/1/94
*	* * * * * *	*
630-20-6	1,1,1,2-Tetrachloroethane	1/1/94
*	* * * * * *	*
764-41-0	1,4-Dichloro-2-butene	1/1/94
*	* * * * * *	*
7783-06-4	Hydrogen sulfide	1/1/94
*	* * * * * *	*
23950-58-5	Pronamide	1/1/94
*	* * * * * *	*

(c) * * *

Category Name	Effective date
* * * * * *	*
Ethylenebisdithiocarbamic acid, salts and esters	1/1/94
* * * * * * *	
Warfarin and salts	1/1/94
* * * * * * *	

2. Subchapter R is amended in part 721 as follows:

Part 721—[AMENDED]

a. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607 and 2625(c).

b. In § 721.3, by adding one definition alphabetically to read as follows:

§ 721.3 Definitions.

* * * * *

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with such person).

* * * * *

c. By adding new § 721.1430 to subpart E to read as follows:

§ 721.1430 Pentachlorobenzene.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance pentachlorobenzene (CAS No. 608–93–5) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

d. By adding new § 721.1435 to subpart E to read as follows:

§ 721.1435 1,2,4,5-Tetrachlorobenzene.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance 1,2,4,5-tetrachlorobenzene (CAS No. 95–94–3) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

e. By adding new § 721.1440 to subpart E to read as follows:

§ 721.1440 1,3,5-Trinitrobenzene.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance 1,3,5-trinitrobenzene (CAS No. 95–35–4) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

f. By adding new § 721.2084 to subpart E to read as follows:

§ 721.2084 Carbon oxyfluoride (Carbonic difluoride).

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance carbon oxyfluoride (CAS No. 353–50–4), also referred to as carbonic difluoride, is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

g. By adding new § 721.2092 to subpart E to read as follows:

§ 721.2092 3-Methylcholanthrene.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance 3-methylcholanthrene (CAS No. 56–49–5) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

h. By adding new § 721.2287 to subpart E to read as follows:

§ 721.2287 DDT (Dichlorodiphenyltrichloroethane).

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance DDT (dichlorodiphenyltrichloroethane) (CAS No. 50–29–3) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

i. By adding new § 721.2355 to subpart E to read as follows:

§ 721.2355 Diethylstilbestrol.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance diethylstilbestrol (CAS No. 56–53–1) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Manufacture, import, or processing of 10,000 pounds or more per year per facility for any use.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance, as specified in § 721.125(a), (b), and (c).

(2) [Reserved]

j. By adding new § 721.3350 to subpart E to read as follows: