Sunshine Act Meetings

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Friday, July 29, 1988

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONSUMER PRODUCT SAFETY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 53 Page 29721, July 25, 1988.

PREVIOUSLY ANNOUNCED DATE OF MEETING: Wednesday, July 27, 1988.

CHANGES: Agenda revised by deleting previous item 1 concerning staff participation in voluntary standards activities.

FOR A RECORDED MESSAGE CONTAINING THE LATEST AGENDA INFORMATION, CALL: 301-492-5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 301-492-6800.

July 26, 1988.

[FR Doc. 88-17191 Filed 7-27-88; 8:58 am]

BILLING CODE 6355-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 4:07 p.m. on Monday, July 25, 1988, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider requests for financial assistance pursuant to section 13(c) of the Federal Deposit Insurance Act.

In calling the meeting, the Board determined, on motion of director C.C. Hoe, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by chairman L. William Seidman, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsection (c)(4), (c)(6), (c)(8), (c)(g)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, NW., Washington, DC.

Dated: July 26, 1988.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 88-17184 Filed 7-26-88; 5:11 pm]

BILLING CODE 671401-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, August 3, 1988.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Issues related to the Board's capital adequacy guidelines.
2. Proposals regarding the Board's 1988 budget.
3. Proposed amendments to Regulation C (Home Mortgage Disclosure) to implement the Home Mortgage Disclosure Act amendments that permanently extend the Act and expand its coverage. (Proposed earlier for public comment; Docket No. R-0635)
4. Any items carried forward from a previously announced meeting.

Note. This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Date: July 27, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-17243 Filed 7-27-88; 2:02 pm]

BILLING CODE 6210-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS.

TIME AND DATE: Approximately 12:00 noon, Wednesday, August 3, 1988, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: July 27, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-17244 Filed 7-27-88; 2:02 pm]

BILLING CODE 6210-01-M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: (53 FR 27594 July 21, 1988).

STATUS: Closed/open meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: Monday, July 18, 1988.

CHANGES IN THE MEETING: Deletions/additions.

The following item will not be considered at a closed meeting scheduled for Tuesday, July 26, 1988, at 2:30 p.m.

Formal order of investigation.

The following item will be considered at a closed meeting scheduled for Tuesday, July 26, 1988, at 2:30 p.m.

Institution of injunctive action.

The following item will be considered at a closed meeting scheduled for Thursday, July 28, 1988, following the 9:30 a.m. open meeting.

Institution of injunctive action.

The following item will not be considered at an open meeting scheduled for Thursday, July 28, 1988, at 9:30 a.m.

Consideration of whether to propose for public comment Rule 17 and amendments to Rule 2 and Form U-3A-2 under the Public Utility Holding Company Act of 1935. Rule 17 would specify the circumstances in which non-utility diversification by an intrastate public-utility holding company would not be deemed detrimental to the public interest or the interest of investors or consumers. Amended Rule 2 would provide that a claim of exemption under Rule 2 by an intrastate public-utility holding company, in order to be effective, would require the holding company to meet one of the safe harbor provisions of Rule 17, and amended Form U-3A-2 would require the company to furnish information supporting its ability to rely on one of the safe harbor provisions of Rule 17. For more information, please contact Sidney L. Cimmet at (202) 272-7430.

Commissioner Cox, as duty officer, determined that Commission business required the above changes.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Martha Peterson at (202) 272-7502.

Jonathan G. Katz,

Secretary.

July 25, 1988.

[FR Doc. 88-17239 Filed 7-27-88; 12:48 pm]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meeting during the week of August 1, 1988.

A closed meeting will be held on Tuesday, August 2, 1988, at 2:30 p.m.

The Commissioner, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Cox, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, August 2, 1988, at 2:30 p.m., will be:

Institution of injunctive actions.

Institution of administrative proceedings of an enforcement action.

Settlement of administrative proceedings of an enforcement action.

Settlement of injunction action.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Patrick Daugherty at (202) 272-3077.

Jonathan G. Katz,

Secretary.

July 26, 1988.

[FR Doc. 88-17238 Filed 7-27-88 12:48 pm]

BILLING CODE 8010-01-M

federal register

Friday
July 29, 1988

Part II

Environmental Protection Agency

40 CFR Part 350

Trade Secrecy Claims for Emergency Planning and Community Right-to-Know Information; and Trade Secret Disclosures to Health Professionals; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 350

[FRL-3388-1]

Trade Secrecy Claims for Emergency Planning and Community Right-to-Know Information; and Trade Secret Disclosures to Health Professionals

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule publishes the procedures for claims of trade secrecy made by facilities reporting under sections 303(d)(2) and (d)(3), 311, 312 and 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (Act), and for EPA's handling of such claims, for submission and handling of petitions requesting reviews of trade secrecy claims, and for disclosure to health professionals of information claimed as trade secret.

DATE: This rule is effective August 29, 1988.

ADDRESS: The record supporting this rulemaking is contained in the Superfund Docket located in Room LG–100 at the U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket is available for inspection by appointment only between the hours of 9:00 a.m. and 4:00 p.m. Monday through Friday, excluding Federal holidays. The docket phone number is (202) 382–3046. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services.

FOR FURTHER INFORMATION CONTACT: Beverly D. Horn, Attorney-Advisor, Office of General Counsel, Contracts and Information Law Branch, LE–132G, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 382–5460, or the Emergency Planning and Community Right-to-Know Information Hotline at 1–800–535–0202 (in Washington, DC and in Alaska at (202) 479–2449).

SUPPLEMENTARY INFORMATION: The contents of today's Preamble are listed in the following outline:

I. Introduction

A. Authority

EPA publishes this rule pursuant to sections 322, 323, and 328 of the Emergency Planning and Community Right-to-Know Act of 1986 (also known as Title III or the Act), of the Superfund Amendments and Reauthorization Act (SARA) of 1986, Pub. L. 99–499. Section 322 provides the procedures for claiming trade secrecy and confidentiality for information submitted under sections 303 (d)(2) and (d)(3), 311, 312 and 313 of the Act. It also provides a process whereby members of the public can file petitions requesting the disclosure of chemical identities claimed as trade secret. Section 323 provides procedures for access to chemical identities, including those claimed as trade secret, by health professionals who need the information for diagnosis, treatment, or research.

B. Background of this Rulemaking

The Superfund Amendments and Reauthorization Act of 1986, Pub. L. 99–499, signed into law on October 17, 1986, amends and reauthorizes portions of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. 9601 *et seq.* Title III contains the Emergency Planning and Community Right-to-Know Act of 1986, which is itself a free-standing statute. It contains provisions requiring facilities to report to State and local authorities, and EPA, the presence, use and release of extremely hazardous substances (described in sections 302 and 304), and hazardous and toxic chemicals (described in sections 311, 312, and 313 respectively). For the reporting required in sections 303, 311, 312 and 313, a submitter may under certain circumstances claim the identity of the chemical reported as trade secret.

1. Section 303

Section 303 involves the formulation of comprehensive emergency response plans for extremely hazardous substances. These are any of the substances on a list published by EPA under section 302. The regulations implementing section 303 (and, because of their relationship, sections 302 and 304) were published on April 22, 1987, at 52 FR 13378, codified at 40 CFR Part 355. On December 17, 1987, the Agency deleted three of the substances from the Extremely Hazardous Substances List, and on February 25, 1988, the Agency deleted an additional 36. These deletions were published in rulemakings at 52 FR 48072 and 53 FR 5574, respectively.

Any facility where an extremely hazardous substance under section 302 is present in excess of the threshold quantity (as determined by EPA) must report to the State emergency response commission, established under section 301 of the Act. The local emergency planning committee (LEPC), also established under section 301 of the Act, will contact any facility that has identified itself in order to formulate a local emergency contingency plan. In this planning process, a facility is required to provide the local emergency planning committee with information the committee requests, except that the facility may withhold trade secret chemical identity from the committee. The facility must also inform the committee of any relevant changes which occur or are expected to occur which may affect the contingency plan. When informing the committee of these changes, the facility may also withhold trade secret chemical identity from the committee. Trade secret claims for chemical identities withheld from facility reports must be substantiated according to the requirements of this regulation.

2. Sections 311 and 312

Section 311 requires the owner or operator of facilities subject to the Occupational Safety and Health Act of 1970 (OSHA) and regulations promulgated under that Act (25 U.S.C. 651 *et seq.* as amended, 52 FR 31852, August 24, 1987) to submit material safety data sheets (MSDS), or a list of the chemicals for which the facility is required to have an MSDS, to the local emergency planning committees, State emergency response commissions, and local fire departments. The facilities were required to submit the MSDS or alternative list by October 17, 1987, or three months after the facility is required to prepare or have an MSDS for a hazardous chemical under OSHA regulations, whichever is later. In addition, a revised MSDS or list must be submitted to the LEPC within three months following the discovery of significant new information concerning an aspect of a hazardous chemical for which an MSDS or list was previously submitted. Facilities in the non-manufacturing sector will be required to submit the MSDS or alternative list when the OSHA Hazard Communication Standard (HCS) is expanded to cover the nonmanufacturing sector. Any trade secret chemical identity may be withheld from the MSDS or list of chemicals, provided the submitter follows the trade secret claims procedures under the section 322 regulation.

Under section 312, owners and operators of facilities that must submit an MSDS under section 311 are also required to submit additional information on the hazardous chemicals present at the facility. Beginning March 1, 1988, and annually thereafter, the owner or operator of such a facility must submit an inventory form containing an estimate of the maximum amount of hazardous chemicals present at the facility during the preceding year, an estimate of the average daily amount of hazardous chemicals at the facility, and the location of these chemicals at the facility. Section 312(a) requires owners or operators of such facilities to submit the inventory form to the appropriate local emergency planning committee, State emergency response commission, and local fire department on or before March 1, 1988, (or March 1 of the first year after the facility first becomes subject to the OSHA MSDS requirements for a hazardous chemical) and annually thereafter on March 1. For the non-manufacturing sector, facilities are first required to submit an MSDS or alternative list when the HCS is expanded to cover the non-manufacturing sector; if the expansion becomes effective in 1988, the first Tier I or Tier II reports are required beginning March 1, 1989.

Section 312 specifies that there be two reporting "tiers" containing information on hazardous chemicals at the facility in different levels of detail. "Tier I," containing general information on the amount and location of hazardous chemicals by category, is submitted annually. "Tier II," containing more detailed information on individual chemicals, is submitted upon request by the State or local agencies. There will be no trade secrecy claims for Tier I reporting since no specific chemical identity is required to be given. However, submitters may withhold trade secret chemical identity from the Tier II form, and facilities should be prepared to submit their trade secret claims as appropriate, even if the Tier I report is initially submitted.

As noted above, the Department of Labor recently published a final HCS rulemaking at 52 FR 31852, on August 24, 1987, expanding coverage of the facilities required to maintain MSDSs. The number of facilities thereby subject to reporting under sections 311 and 312 will have expanded from 350,000 to over 4 million, when the expansion becomes effective.

The final rule for sections 311 and 312 was published on October 15, 1987 at 52 FR 38344, 40 CFR Part 370.

3. Section 313

Under section 313, a toxic chemical release inventory form (published by EPA) must be filed with a designated State agency and EPA. This form must be filed for any toxic chemical (on a list published by EPA) which is manufactured, processed or otherwise used in amounts exceeding the threshold quantity at a covered facility. The form also indicates the total annual releases of the chemical to the environment. A covered facility is any facility with 10 or more employees in Standard Industrial Classification (SIC) Codes 20–39. The rule for section 313 was published on February 16, 1988, at 53 FR 4500, 40 CFR Part 372. As with other sections of Title III, trade secret chemical identity may be withheld from the toxic chemical release inventory form.

4. Section 322

The section 322 regulations contain the procedures which a submitter must follow in order to file a trade secrecy claim. Trade secrecy claims are submitted to EPA only, by including with the appropriate 303, 311, 312 or 313 submittals, as explained below, both a sanitized and unsanitized trade secret substantiation form. The unsanitized version must contain the chemical identity claimed as trade secret, and the sanitized version is identical to the unsanitized version in all respects except that the trade secret chemical identity is deleted, and in its place a generic class or category to describe the chemical is included. This sanitized version is the one that is submitted to the State or local authorities, as appropriate.

Section 322(b) of Title III requires a submitter to substantiate its trade secrecy claim when submitting the filing containing the chemical identity claimed as trade secret. This up-front substantiation will consist of the answers to six questions which are intended to elicit sufficient factual support to indicate whether the claim will meet the criteria set forth in the statute for a claim of trade secrecy.

In order to fully answer the six questions in the substantiation, a submitter may need to include additional trade secret or other confidential information. The statute in section 322(f) allows submitters to designate as confidential any information in the substantiation entitled to protection under 18 U.S.C. 1905 (the Federal Trade Secrets Act). Claims of confidentiality in the substantiation are more expansive in scope than those allowed under the reporting requirements of the Act, and are limited solely to information necessary to substantiate the trade secrecy claim. A detailed explanation on how to make a trade secrecy claim for information in the substantiation is found under section II.G. of this Preamble.

The section 322 regulation also contains the procedures to be used by the public for requesting disclosure of chemical identity claimed as trade secret. (This public petition process does not cover requests for public disclosure of information claimed as trade secret in the substantiation other than chemical identity. These requests for disclosure must be submitted under EPA's Freedom of Information Act regulations at 40 CFR Part 2.) The section 322 regulation also sets forth procedures the Agency must follow in making a determination as to whether any trade secrecy claim is valid. These determinations will be made by the program designated to receive and handle trade secrecy claims for that particular reporting section in Title III. The Office of General Counsel will hear intra-agency appeals from the determinations of trade secrecy.

5. Section 323

The section 323 regulation contains provisions allowing health professionals to gain access to chemical identities, including those claimed as trade secret, in three different situations. The first situation is for non-emergency treatment and diagnosis of an exposed individual. Second, access is permitted for emergency diagnosis and treatment. Finally, health professionals employed by a local government may receive access to a trade secret chemical identity to conduct preventive research studies and to render medical treatment. In all situations but the medical emergency, the health professional must submit a written request and a statement of need, as well as a confidentiality agreement, to the facility holding the trade secret. The statement of need verifies that the health professional will be using the trade secret information only for the needs permitted in the statute, and the confidentiality agreement ensures that the health professional will not make any unauthorized disclosures of the trade secret. In the event of medical emergency, the health professional granted access to chemical identify claimed as trade secret may be required to execute a confidentiality agreement.

C. Summary of Public Participation

EPA issued a proposed rule for trade secrecy claims and for trade secret disclosures to health professionals, which was published in the **Federal Register** on October 15, 1987 (52 FR 38312). The proposed rule contained the form for the substantiation to accompany claims of trade secrecy and requirements for making claims of trade secrecy under the Act. After publication, EPA received over 40 written comments on the proposed rule. In addition, EPA held public meetings in Washington, DC, Chicago, IL, Boston, MA, Dallas, TX, and San Francisco, CA. Attendees at these meetings presented oral comments representative of a wide range of interests including the affected industry, environmental and other public interest groups, State and local governments, and individual citizens. These comments are part of the official record of this rulemaking

II. Trade Secrecy Claim Procedure

A. Definition of Trade Secret

1. Overview of Trade Secrecy Claims

The Emergency Planning and Community Right-to-Know Act of 1986 does not give facilities blanket authority to withhold any information they consider sensitive or confidential. The purpose of the Act is to provide information to the public, and the statute limits the types of information that may be withheld as well as the circumstances in which a claim of trade secrecy can be made.

Regardless of the basis for a trade secret (e.g., a chemical's presence at a facility, its use for a particular process, or its production in a certain quantity), the only information that a facility may withhold from an Act's report (other than location information, as explained below) is the specific chemical identity. When a facility makes a claim of trade secrecy, it must provide all of the information normally required to be reported with the sole exception of the specific identity of the chemical being claimed as trade secret.

Submitters of trade secrecy claims must distinguish two concepts: (1) What may be withheld; and (2) the basis for withholding information. As noted, the only information that may be withheld from a public report is the *identity* of a chemical found at a facility.

The basis, or reasons, for considering a chemical identity as a trade secret can vary. In most instances, the presence of the chemical at a facility is the basis for a chemical being a trade secret. However, in certain instances facilities may believe the connection between the chemical identity and other information that must be included on the Act's reports, such as quantity or process information, may also be a basis for a claim of trade secrecy. For example, a facility may believe that its estimate of the maximum amount of chemical X on site on its toxic chemical reporting form under section 313 is a trade secret, even though public knowledge of its use of chemical X is not. In such a case, the connection or as it is sometimes termed, the linkage, of the chemical identity with the quantity information is the basis for the facility's trade secrecy claim. However, the facility may only withhold the chemical identity (i.e., chemical X in this example); the quantity on site must still be reported. As Congress provided, public reports would not disclose the specific chemical, although a generic name for chemical X must be provided as a substitute, as well as data on its hazardous characteristics and adverse health effects. Hence, what can be withheld is only the chemical identity, but facilities may base their trade secrecy claims on the connection between the chemical identity and a broader set of information required on the Act's reports.

This discussion, so far, has dealt with trade secrecy claims for chemical identity on the reports required under the Act. This is the class of trade secret claims addressed by the rule. However, two other classes of confidential information are also involved under the Act, and rules for treatment of these are different.

First, when facilities explain why a chemical is a trade secret, it is recognized that they may need to cite other confidential information (such as process or financial data) in their substantiations. The statute and the rule allow facilities to make claims of confidentiality, explained below, for information they provide on their substantiations accompanying claims. Second, location information required under section 312 is considered a separate class of confidential information, and is provided only to State and local recipient(s). Section 312 location information should not be sent to EPA. The statute does not require facilities to justify the confidentiality of either of these two types of information under section 322. Under section 324, copies of the publicly available substantiations for trade secrecy claims are accessible during normal business hours through the designated State and local authorities, and through EPA, as appropriate. These substantiations are also accessible under the Freedom of Information Act, as discussed at section V.C. of this Preamble.

2. Rationale

The definition of a trade secret in this regulation is equivalent to that in the Restatement of Torts, section 757, and the regulation developed by the Occupational Safety and Health Administration to implement its Hazard Communication Standard, 52 FR 31876 (August 24, 1987), 29 CFR 1910.1200. The OSHA Hazard Communication Standard requires disclosure of the specific chemical identity of chemicals to which employees are exposed in the workplace, except in those cases in which the identity of the chemical in question can be justified by a facility to be a bona fide trade secret. The U.S. Court of Appeals ruling in *United Steelworkers of America v. Auchter*, 763 F.2d 728 (3d Cir. 1985), required that OSHA amend its Hazard Communication Standard to adopt a definition of trade secret that conformed to common law protections. OSHA selected the generally accepted definition provided in the Restatement of Torts, section 757, Comment b (1939), which reads: " 'trade secret' may consist of any formula, pattern, device, or compilation of information which is used in one's business, and which gives [the employer] an opportunity to obtain an advantage over competitors who do not know or use it."

The Emergency Planning and Community Right-to-Know Act of 1986 only allows trade secrecy claims for a subset of the material which is traditionally covered under trade secrecy law. Section 322(a) specifically states that submitters under Title III may withhold only the "specific chemical identity (including the chemical name and other specific identification)" as a trade secret. The "specific chemical identity" means either the chemical name or other specific identification that reveals the precise chemical designation of the substance, such as the Chemical Abstract Services Registry Number (CASRN).

In the proposed rule, EPA set forth several options for determining the permissible basis for claims of trade secrecy for specific chemical identity. The most narrow interpretation of the statute would be to limit all claims of trade secrecy to claims protecting either the composition of the chemical, or the presence of the chemical at the facility. Congress stated in the Conference Report that, "the knowledge of [the] presence [of a specific chemical] at the purchasing facility could effectively define for its competitors the process and/or products being made there." H.R. Conf. Rep. No. 99-962, 99th Cong., 2d Sess. 304 (1986).

The second option set forth in the proposed rule was to allow, as a basis for a claim of trade secrecy for chemical identity, that the connection, or "linkage" between chemical identity and other information on the Title III form would reveal the trade secret. Throughout the Conference Report Congress displayed general concern for the protection of all legitimate trade secrets. For instance, in discussing the reporting requirements under section 313, it was noted, "[t]he conference substitute provides for reporting categories of use and ranges of chemical present because the exact [identity] of identified chemical[s] at a facility or the exact amount present may disclose secret processes." *Id.* at 298. Similarly, in discussing the reporting requirements under section 312, Congress stated, "[i]n order to protect chemical process trade secret information, reporting ranges may need to be broad." *Id.* at 290. Congress probably anticipated that it would be possible for the Act's reporting forms to be structured broadly enough to avoid compromising legitimate trade secrets. In the proposed rule, the Agency stated that it was making every effort to do this. EPA believed that even with the use of broad ranges and reporting categories, however, the amount of detail requested on the Act's forms would in some cases allow competitors of submitters to compare and thus to link information, thereby revealing valuable trade secrets.

EPA's proposed interpretation of the basis for a claim of trade secrecy for chemical identity was supported by several comments from industry voicing concurrence with Congressional intent to provide trade secret protection to trade secret information about use, processing, and handling which might be linked to corresponding chemical identities reported under sections 311, 312, or 313. Industry commenters referred to the definition of trade secret put forth in the Restatement of Torts to assert that the Agency's linkage concept is firmly rooted in traditional trade secret law, where trade secrecy of chemical identity occurs because of links between that chemical identity and other data. Consequently, some commenters suggested that denial by the Agency of trade secret protection to linked information, and its disclosure to the public, would constitute a taking under the Takings clause of the Fifth Amendment, even though the specific identities of component chemicals might be well known to the public.

EPA also received some comments from public interest groups which disagreed with this interpretation. They argued that trade secrecy claims should be restricted solely to claims for the presence or chemical composition of the chemicals present at a facility, and not allowed for any linkages between chemical identity and other data. These comments claimed that the four criteria listed under section 322(b) apply only to trade secrecy claims for specific chemical identities, and reflect Congressional intent to maximize the availability of information to the public. One group asserted that trade secret regulations intended to protect claims for linkage "will encourage the filing of excessive claims of trade secrecy, as well as claims that cannot be substantiated in accordance with section 322(b)" of the statute.

After carefully considering the comments, the OSHA HCS, the Conference Report, and trade secret case law, EPA has decided to allow trade secrecy claims for chemical identity to be made to protect the linkage between a specific chemical identity and other information about its use, production, storage, or processing. Such claims will be permitted even in cases when the specific chemical identity is already known to the public; however, the submitter will always have to prove that its trade secret meets the four criteria under section 322(b) by submitting the up-front substantiation described in section II.G. of this Preamble. In all trade secrecy claims the specific identities of chemicals present at the facility are the only reporting information that may be withheld, in accordance with the statute; all other information requested on the Act's forms must be reported.

Generally accepted trade secret law found under the Restatement of Torts and the OSHA Hazard Communication Standard supports protection of linkage information. According to these precedents, confidential information does not necessarily depend on public knowledge of one component of a production process; rather, it is often the means by which components are combined and used which renders the information a protectable trade secret.

The Agency believes that this interpretation of the basis for a claim of trade secrecy will not involve great numbers of additional claims beyond those that could also be based on the narrower concept of simple presence at a facility. Submitters of trade secrecy claims for linkage information will still have to meet the same four criteria in section 322(b) which all trade secrecy claims must meet.

EPA also believes that this interpretation does not run counter to the purpose of the Act—that of public disclosure—because the requirement of an up-front substantiation, which will cause submitters to justify their claims, will limit spurious claims. Further, EPA's intention is to routinely evaluate trade secrecy claims and to vigorously prosecute those submitting frivolous claims. The $25,000 penalty per frivolous claim under such circumstances is evidence of Congress intent to deter such claims. All submitters should be aware that supplemental information submitted to EPA after the initial substantiation should clearly confirm the validity of their claim as set out in the initial substantiation, or they may be subject to the penalty for frivolous claims.

3. Emission and Effluent Data

The Natural Resources Defense Counsel, Citizens for a Better Environment, and OMB Watch have argued in their comments that EPA cannot allow claims of trade secrecy for data collected on the section 313 toxic release inventory form because this data is emission or effluent data that is required to be made public by the Clean Air Act and the Clean Water Act.

Section 322(b) of Title III requires that a trade secrecy claimant demonstrate, when making a trade secrecy claim, that the chemical identity claimed as trade secret "is not required to be disclosed, or otherwise made available, to the public under any other Federal or State law." The commenters claimed that under section 114(c) of the Clean Air Act and section 308(b) of the Clean Water Act, emission and effluent data, respectively, are required to be made public and, therefore, when collected under Title III must be made public. Section 114(c) of the Clean Air Act requires that:

Any records, reports, or information obtained under [the Clean Air Act] shall be available to the public, except that upon a showing satisfactory to the Administrator by any person that records, reports, or information, or particular part thereof (*other than emission data*) to which the Administrator has access under this section, would divulge methods or processes entitled to protection as trade secrets * * * the Administrator shall consider such record * * * confidential. (Emphasis added.)

Section 308(b) of the Clean Water Act has a similar provision excepting effluent data from confidential treatment.

Information which has been determined administratively (by EPA) or judicially (by a court on appeal from an EPA determination) to constitute emission or effluent data within the meaning of section 114(c) of the Clean Air Act, or section 308(b) of the Clean Water Act is clearly required to be disclosed to the public and could not be withheld from disclosure under section 322(b). Thus, a company could not claim as trade secret under Title III information which is part of a class of information for which EPA has, by regulation or otherwise, prohibited a claim of business confidentiality, such as information required in National Pollutant Discharge Elimination System (NPDES) permit applications. 40 CFR section 122.7(c). Also, a company could not claim as trade secret under Title III data already collected by EPA under another statute, such as the Clean Air or Clean Water Acts, where the Agency had decided that the data presented no valid claim of trade secrecy, either because it was emission or effluent data or for other reasons, such as, that no valid trade secrecy claim was presented.

The question posed by the comments concerns the exact meaning of the prior disclosure language—does this language concern only the circumstances described above, where EPA has determined, either generically or specifically, whether the information is eligible for trade secret status, or does it also concern circumstances where the information's trade secret status is undetermined. The commenters argued that information which EPA could obtain, but has not requested, under the Clean Air or Clean Water Acts and which could constitute emission or effluent data, cannot be claimed as trade secret on the section 313 form or in other Title III submissions.

The comments also raised the same question regarding information in EPA's possession which could constitute emission or effluent data but as to which no determination has been made. The commenters argued that this information also cannot be claimed as trade secret if later submitted under Title III. In so arguing, the commenters assumed that the definitions of emission and effluent data are self-executing and therefore that no trade secrecy claims should even be accepted by EPA for information which could be emission or effluent data.

There is no discussion of this issue in the Conference Report or elsewhere; however, EPA's position is that the most probable interpretation is that Congress intended to prevent trade secret claimants from claiming as secret information which was already in the possession of a State or Federal agency and was required to be disclosed, either because no claim of confidentiality was permitted under State or Federal law, or because a decision had been made that no valid claim was presented.

The comments did not address the threshold issue of the definition of emission or effluent data, merely asserting that EPA's definitions are "self-executing." EPA does not consider this definition to be self-executing. The definition of emission data provides:

(2)(i) "Emission data" means, with reference to any source of emission of any substance into the air—

(A) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

(B) Information necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including, to the extent necessary for such purposes, a description of the manner or rate of operation of the source); and

(C) A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

40 CFR 2.301(a)(2)(i) (A), (B), and (C).

Whether information constitutes emission or effluent data depends on what information is "necessary" to make the needed determination. EPA has to date made no determinations that categories of information always constitute emissions data. Instead, EPA has proceeded on a case-by-case basis.

The regulations interpreting the Clean Water Act contain a similar definition for effluent data, information "necessary to determine the identity * * * or other characteristics * * * of any pollutant which has been discharged by the source * * *" 40 CFR 2.302(a)(2)(i). The NPDES regulations under the Clean Water Act (CWA) do not, however, allow confidential treatment of information required by, or contained in NPDES permits or permit applications, or of data concerning the discharge of pollutants regulated in the permit, and accordingly, that data is not allowed trade secrecy treatment under section 313. Submitters claiming this information as confidential may be subject to penalties under section 325(d) for submission of frivolous claims.

Submitters should be aware that data submitted on the section 313 form will be used for activities conducted under the Clean Water Act (including implementation of section 304(1) of the Clean Water Act and development of NPDES permit limits) and Clean Air Act. EPA is in the process of developing a class determination under 40 CFR 2.207 which would find that information, including chemical identities, submitted on the section 313 form regarding releases to air or to waters of the United States or to Publicly Owned Treatment Works, is emission or effluent data under the Clean Air or Clean Water Acts and, as such, is not eligible for confidential treatment under section 322 of Title III.

The commenters also argued that the definition of emission and effluent data includes not only data which was actually collected under section 114(c) and 308(b), but data which "could have been" collected under these sections, citing 40 CFR 2.301(b)(2) and 2.302(b)(2). Thus, the commenters argued that any data which *could* be gathered under the Clean Air Act cannot be claimed trade secret when submitted to the Agency under section 313.

The Clean Air Act regulations at 40 CFR 2.301(b)(2) state:

Information will be considered to have been provided or obtained under section 114 of the Clean Air Act if it was provided in response to a request by EPA made for any of the purposes stated in section 114, or if its submission *could have been required* under section 114, regardless of whether section 114 was cited as the authority for any request for the information * * * (Emphasis added.)

The comparable section of the Clean Water Act regulations has a similar provision. See 40 CFR 2.302(b)(2).

On this basis, the commenters argued that because the data collected under section 313 of Title III is emission or effluent data which could have been collected under section 114(c) of the Clean Air Act or section 308(b) of the Clean Water Act, no trade secrecy claims can be made for chemical identities of chemicals for which emission or effluent data is included on a Title III submission.

The commenters have misconstrued the meaning and function of the "could have been" language. It serves to prevent submitters from thwarting EPA's statutory right to obtain data by voluntarily submitting it to the Agency for the use of the Clean Air or Clean Water programs, and then arguing, as voluntarily submitted, that it is not subject to statutory limits on trade secret or confidential business information.

For these reasons, EPA does not agree with the commenters, assertions that the provisions of the Clean Air and Clean Water Acts render most trade secrecy claims invalid under section 313. The final rule adopts the interpretation set forth in the proposed rule with respect to the meaning of the language under section 322(b), regarding whether information claimed as trade secret is required to be disclosed under another State or federal law. Thus, information is required to be disclosed under another Federal or State law if:

(i) It is information that is specifically or is in a class that is determined administratively (by EPA) or judicially (by a court on appeal from an EPA determination) to constitute emission or effluent data within the meaning of section 114(c) of the Clean Air Act or section 308(b) of the Clean Water Act; or

(ii) It is information which is either specifically or in a class for which EPA or any other State or Federal Agency has disallowed confidential treatment, such as information required by EPA in NPDES permit applications; or

(iii) It is information collected by EPA or another State or Federal Agency where the State or Federal Agency has decided that the data presented no valid claim of trade secrecy (for any reason).

B. Methods of Claiming Trade Secrecy

There are five different types of submissions that can be made under Title III on which a facility may make a claim of trade secrecy. These are: (1) The notification (to a local emergency planning committee) of any changes at a facility which would affect emergency plans, under section 303(d)(2); (2) answers to questicns posed by local emergency planning committees under section 303(d)(3); (3) material safety data sheets or chemical lists submitted under section 311; (4) Tier II emergency and hazardous chemical inventory forms submitted under section 312; and (5) the toxic release inventory form submitted under section 313.

1. Basic Requirements

The basic requirements for making a claim are similar, although there are some differences between submissions under the different sections. These differences will not affect the validity of a submitter's claim, provided the submitter adheres to all of the requirements.

When fashioning reporting requirements under Title III, EPA has made every effort to avoid unnecessary duplication. To this end, when reporting under section 303 (d)(2) and (d)(3), and under section 311 using an MSDS, EPA only needs to receive a copy of the submittal sent to the State and local authorities. This submittal is a public document, and should not contain the specific chemical identity claimed as trade secret. EPA is not requesting an unsanitized version of this submittal.

When reporting under section 311 using the list approach, and for all section 312 Tier II forms, and section 313 reports, EPA must receive at the same time both an unsanitized and a sanitized version of the reporting form. A sanitized copy of the reporting form is one in which the chemical identity claimed as trade secret is deleted and in its place is included the generic class or category of the chemical claimed trade secret. This sanitized copy should be identical to the copy submitted to the appropriate State and local organizations in all respects except that it does not contain the chemical identity.

Finally, EPA must receive substantiations for each chemical claimed as trade secret under all reporting sections, as explained in section II.G. below. EPA must receive both sanitized and unsanitized versions of the substantiation. Although these items are the minimum required for a claim of trade secrecy under all sections, EPA suggests that submitters carefully review the requirements under each section before filing a trade secrecy claim.

In this rule, the term "sanitized" is used to refer to the copy of the report or substantiation which does not contain the chemical identity of the chemical that is being withheld as trade secret. The term "unsanitized" refers to a report or substantiation that contains the trade secret chemical identity. EPA received some comments from the public objecting to the use of these terms on the grounds that an "unsanitized" item is sometimes regarded as "unclean." EPA has decided to retain these terms because they are terms of art often used to indicate whether or not these documents contain information that may be released to the general public; their continued use helps to clarify the terms of the rule.

EPA received some questions as to whether a trade secret claim must be made at the same time the Title III submittal is submitted. Section 322 requires a submitter making a claim of trade secrecy to include in the submittal an explanation of why the information is claimed to be a trade secret. This clearly requires that the substantiation must be filed concurrently with the submittal.

To facilitate accurate processing and filing of these confidential documents, submitters of claims to EPA should arrange the parts of each claim in the following order: (1) The unsanitized trade secret substantiation, (2) the sanitized trade secret substantiation, (3) the unsanitized reporting document (not applicable to section 303 reports and section 311 MSDSs, as explained below), and (4) the sanitized reporting document. Each substantiation and reporting document should be individually stapled but the Agency requests that the individual parts for each claim be assembled into a single package using only a binder clip or rubber band. Do not staple the individual parts together.

When facilities submit trade secrecy claims for more than one chemical, EPA requests that the three or four parts associated with each chemical be assembled as a set and each set for different chemicals be kept separate within the package sent to EPA.

2. Users of Trade Name Products

Reports and claims regarding mixtures and trade name chemical products raise a number of special issues. Public comments were received on a number of points that EPA clarifies below.

Public comments indicated some users are concerned as to their responsibilities in cases where they do not know the chemical identity of mixtures and trade name products. Commenters were concerned about whether they had to submit a trade secrecy claim if they did not know the specific chemical identity of the product they use, even though they do not consider that the fact that they use the product is a trade secret. EPA does not require a trade secrecy claim if the user does not consider its use of the product as a trade secret. For example, if a user does not know the specific chemical identity of a chemical and must provide a common name or trade name on the Title III submittal, EPA does not require a claim of trade secrecy for the omitted chemical identity because this identity, being unknown to the user, cannot be provided in such an instance. This issue is also discussed in the section 313 final rule addressing supplier notification. See 53 FR 4500.

If the submitter considers its use of the trade name chemical as a trade secret, it may file a trade secrecy claim according to the usual procedures set forth in this rule. The user will be allowed to file for trade secrecy treating the trade name as the chemical identity and filling out those parts of the Title III submittal sent to EPA that it can supply without knowing the specific chemical identity. The user must still file a complete substantiation. When making trade secrecy claims for trade name products, some commenters indicated that portions of the substantiation questions would not apply to their trade secrecy claim, however. If so, EPA requires that the user making a trade secrecy claim for its use of a trade name chemical must answer each question by explaining why it believes the question to be inapplicable.

EPA does *not* extend permission to file trade secret claims for common or trade names to users that know the specific chemical names of the chemical to be reported and consider that chemical use to be a trade secret. If users know the chemical names of substances they use and wish to file a trade secrecy claim, they must make the claim in terms of the chemical names of the substances. On the other hand, downstream chemical users and chemical licensees who happen to know the chemical identity of the trade name chemical are not required to submit claims of trade secrecy based solely on their knowledge of the specific chemical identity since this requirement would entirely duplicate the trade secrecy claim of the original chemical manufacturer and serve no purpose.

In the rulemaking process, EPA considered more extensive requirements on users making trade secrecy claims for their uses of trade name chemicals. One approach would have required suppliers to inform EPA of the chemical identity and complete the substantiation questions for the users who wished to make a trade secrecy claim. Another option considered was the "best efforts" approach based on the proposed section 313 rule (52 FR 21151, 21155), which would have required the user to make multiple attempts to obtain the chemical identity from the supplier, including offering to enter into a confidentiality agreement with the supplier.

In some cases, it may be especially difficult for facilities to acquire from their suppliers the identity of chemicals claimed trade secret by their supplier. Users of chemicals may encounter instances where the supplier does not have the same interest in providing information to them or in protecting the confidentiality of their trade secrets. Suppliers may, in some instances, sell to competitors from whom a facility wishes to keep chemical identities or applications a trade secret. EPA decided on the more pragmatic approach of allowing users of trade secret chemicals who wished to make a trade secrecy claim for their use of the trade name chemical to file claims based on their current knowledge, rather than having to rely upon obtaining cooperation from suppliers.

3. Licensees

One commenter stated that the rule does not address trade secret protection in the context of licensing arrangements that include private confidentiality agreements between suppliers and users. The commenter asserted that in these instances, a facility that is licensed to produce or otherwise use a trade secret chemical may have information about that chemical, including its chemical identity. At the same time, neither the chemical identity nor the use of the chemical is the trade secret of the licensee, and the licensee may not be able to justify it as such. As a response to this circumstance, the commenter suggested that the rule provide for a blanket trade secret substantiation by the licensor with a letter submission by the licensee referring back to the licensor's substantiation or explanation submission.

EPA requires in the above situation that users who are licensees of trade secret chemicals and who wish to make a trade secrecy claim for their own use of the chemical, file a claim of trade secrecy. If possible, these submitters should obtain the information necessary to complete the substantiation form, where relevant, from the supplier with whom they signed the confidentiality agreement, to the extent such information is needed to answer the questions on the form. If, upon review of the claim EPA requests supplemental information which the licensee does not have, the licensee will be required to contact the licensor who must contact EPA directly with the necessary information.

4. Addresses for Claims and Petitions

All trade secret claims and petitions requesting disclosure of identities claimed as trade secret should be sent to the following address:

U.S. Environmental Protection Agency, Emergency Planning and Community Right-to-Know Program, P.O. Box 70266, Washington, DC 20024-0266

Submitters may hand deliver their submittals to:

Title III Reporting Center, 470/490 L' Enfant Plaza East, SW., 7th Floor, Suite 7103, Washington, DC

C. Claims Under Sections 303(d)(2) and 303(d)(3)

Section 303 concerns the formulation of contingency plans by local emergency planning committees. Section 303(d)(2) states that owners or operators of facilities must promptly inform committees of any relevant changes occurring at the facilities as the changes occur or are expected to occur. Section 303(d)(3) states that owners or operators of facilities must promptly provide information to committees when committees request information from facilities necessary for the development and implementation of emergency plans.

A trade secrecy claim under section 303(d)(2) must include a copy of the notification of changes in the facility that was provided to the local committee. This notification may be in the form of a letter or other written communication. The document must include the name and address of the submitter. A trade secrecy claim under section 303(d)(3) must include a copy of the information requested by the local emergency planning committee and the information provided by the facility in response to the request. A letter or other written communication containing this information is sufficient. The document must include the name and address of the submitter.

In both of these submittals, where there is a need to refer to a specific chemical identity, the generic class or category of each chemical ("class" is synonymous with "category") claimed as trade secret should be used instead of the trade secret chemical identity. The generic class or category for chemicals subject to section 303 reporting is discussed below in this section.

EPA is taking the burden-reducing step of not requiring submitters to prepare an unsanitized version of this document for the reason that EPA will be receiving the claimed chemical identity on the unsanitized version of the substantiation form. For each chemical identity claimed as trade secret in a section 303 report, a complete substantiation must be submitted to EPA. The substantiation will be discussed in greater detail in section II.G. below. Claims should be packaged as described in section II.B.1. of this preamble, and in instructions to the substantiation form.

Generic Class or Category

When a local emergency planning committee develops its contingency plan, identification of the specific chemicals that are present in its jurisdiction is vital to the development of the plan and is the first issue to be resolved in the initial preparation of the plan. As stated above, if a facility does not wish to reveal the specific chemical identity to the committee in the context of sections 303 (d)(2) and (d)(3), the section 303 submittal must include in the place of chemical identity, the generic class or category of the chemical claimed as trade secret. The purpose of the generic class or category is to provide a description of the chemical that is not as specific as the specific chemical identity. The generic class or category should provide the best description possible of the claimed chemical, as explained below.

The purpose of a contingency plan is to provide effective, expedient emergency response to aid response workers and community residents in the event of a chemical release. In order to prepare an effective contingency plan, the hazards involved with the specific chemicals such as explosivity or flammability and the adverse health effects associated with the release must be known. Only by knowing this information, can proper equipment and procedures be used to contain the release. If chemical identity is claimed as trade secret by a facility, such information can in many circumstances still be obtained through the determination of a generic class or category that reflects the information, as well as by other questions posed to the facility by the local emergency planning committee.

The proposed rule set forth for public comment three alternatives regarding the choice of generic class or category for Title III submittals under sections 303 (d)(2) and (d)(3). The alternatives all required negotiation because the Agency believed it would be impossible to devise a finite list of generic classes or categories that would incorporate the wide variety of safety factors that LEPCs and the general public may desire to know. These safety factors included chemical release hazards, adverse health effects information, distance of the affected community from the facility, level of sophistication of the first responder, and type of land use near the facility. Language in the proposed rule suggested that safety factors should be reflected in the generic class or category chosen.

The alternatives suggested in the proposed rule were:

(1) LEPCs and owners or operators would negotiate a suitable class or category, with no example list offered by the Agency;

(2) The sections 311–312 hazard categories would be provided as examples from which LEPCs and owners or operators could choose a class or category, or if they believed it to be necessary, the parties could choose another hazard-based class or category which better reflected the safety information described above;

(3) LEPCs and facilities would negotiate a class based on chemical structure.

The proposed rule on trade secrets did not discuss generic class or category determinations for section 313 submittals; another alternative was adopted by EPA in the final rule for section 313. The section 313 proposed rule stated that owners or operators should choose a generic class or category based on the preassigned class or category code for each chemical which was set out in the section 313 proposed rule. This process was changed in the section 313 final rule to allow reporting facilities to use any generic class or category that is structurally descriptive of the chemical claimed as trade secret. This change was made because of the possibility that trade secrecy could be compromised when the preassigned class or category was cross-referenced with one or more of the four adverse health effect categories provided for the section 313 chemicals in the Toxic Release Inventory database.

The comments received on the alternatives were divided. Some of the commenters wanted EPA to publish a finite list of classes or categories based on hazard categories alone, and allow facilities to choose the appropriate class or categories. Some commenters wanted facilities to choose a class based on chemical function or chemical structure without negotiation with LEPCs, State Emergency Response Commissions (SERCs), or fire departments. A few commenters supported the requirement of negotiation of generic class or category among the parties involved.

EPA has reevaluated the necessity for negotiation in choosing generic class or category and has decided to follow the process chosen for the section 313 final rule. Allowing owners or operators to choose classes on their own based on chemical structure is preferable to the options set forth in the proposed rule for several reasons. First, it will be simpler for industry, LEPCs, SERCs, and fire departments than requiring the time-consuming process of negotiation; second, negotiation of generic classes could also be technically burdensome to LEPCs; and third, this approach will provide greater consistency for choosing generic class or category under the various sections of the law.

Although owners or operators will be choosing generic classes or categories on their own, EPA is advising that classes be chosen following the guidelines of the Act's legislative history. The Conference Report directs that generic class or category be defined only as broadly as necessary to protect the specific chemical identity from disclosure, and it should at the same time reflect the thrust of the law to transmit chemical information to the public. Thus, EPA advises that classes be determined so that information on the specific chemical identity's release hazards and adverse health effects are included in the class or category. As an example of such a class, volatile aldehyde is a generic class that is functionally descriptive of the chemical acid aldehyde and provides information on the chemical's volatility.

D. Claims Under Section 311

As provided in the rule for sections 311–312, when reporting, a submitter of a section 311 report must submit either an MSDS for each hazardous chemical (above a threshold quantity), or a list of the hazardous chemicals with the chemical or common name of each hazardous chemical as provided on the MSDS.

Claims of Trade Secrecy for MSDSs

Submitters must send to EPA a copy of the MSDS, and an unsanitized and sanitized substantiation. An explanation of the substantiation is set forth in section II.G. below. Claims should be packaged as described in section II.B.1 of this preamble, and the instructions to the substantiation form.

EPA is not requiring submitters to provide an unsanitized version of the MSDS. The Agency received comments indicating that most facilities do not have "unsanitized" copies (i.e., copies indicating chemical identities) of MSDSs on file under the HCS where they have claimed chemical identity as trade secret. In such cases, facilities have on file only MSDSs that omit the chemical names of trade secret chemicals and instead contain a common name for the chemical. For a facility to supply an "unsanitized" MSDS—i.e., one containing the chemical identity of a chemical claimed as trade secret—to EPA under the section 322 rule, as proposed, the facility would have had to modify an MSDS that did not previously indicate the chemical identity. One suggestion by commenters was to allow facilities to attach supplements of their own design indicating the chemical identities. EPA decided, however, that because the information on chemical identity will be provided to EPA in the unsanitized version of the substantiation form attached to the MSDS, a supplement or unsanitized MSDS is therefore unnecessary. Hence, EPA is taking the burden reducing step in the final rule of not requiring an unsanitized MSDS (though the requirements for unsanitized copies of sections 311 lists, 312 Tier II forms, and 313 forms remain unchanged from the proposed rule).

Three commenters stated that trade secrecy claims should not be necessary under section 322 in cases where a specific chemical identity has already been withheld as trade secret on an MSDS under OSHA's Hazard Communication Standard. Section 322(a) states that a person required to submit information under Title III may withhold from such submittal the specific chemical identity. When the specific chemical identity is claimed as trade secret under the HCS, the identity does not appear on the MSDS that the facility keeps on file under that standard. The commenters argued that because the identity is not present when these MSDSs are to be submitted under section 311, the submitters are not "withholding" chemical identity and thus a claim of trade secrecy under section 322 should not be required.

EPA disagrees with this argument for several reasons. First, if a manufacturer of a chemical were not required to file a trade secrecy claim under Title III because it had already treated the chemical as a trade secret under the HCS, the detailed, upfront substantiation provisions of section 322 would be circumvented. The HCS allows chemicals to be treated as trade secrets at the discretion of facilities, provided the facility can substantiate the secret if challenged. Congress was more strict in enacting Title III in this regard, requiring that the claim be substantiated at the time it is made.

Further, under the commenters' view, the public would be denied the means to petition for review of the trade secret claim because no claim would ever have been made, and no similar option for review by the general public exists under the HCS. Therefore, EPA requires that a claim of trade secrecy must be filed for section 311 MSDS submittals even when the chemical identity is previously withheld from the MSDS as trade secret under the OSHA HCS.

Reporting of mixtures on the MSDS is discussed below.

Claims of Trade Secrecy for the Section 311 List

The list option under section 311 is structured so that submitters may report either the chemical or common names of a chemical on the list. Submitters wishing to claim chemical identity as trade secret must submit to EPA an unsanitized version of the list which contains the chemical identity or identities which are being claimed. The submitter must also send a sanitized version of the list in which the chemical identity or identities are replaced with generic classes or categories. When more than one chemical is claimed as a trade secret, to avoid confusion the order of chemical names found on the unsanitized list must match the order of generic classes or categories found on the sanitized list. As with all other trade secrecy claims under Title III, submitters must also send to EPA a sanitized and unsanitized version of the substantiation. Claims should be packaged as described in section II.B.1 of this preamble and in the instructions to the substantiation form.

Since submitters have the option of reporting chemicals on the section 311 list by either chemical or common name, some submitters may believe that even with the use of the common name trade secret chemical identity will be revealed. In this instance submitters may want to make a claim of trade secrecy for the chemical identity. However, in other instances, as commenters noted, the use of the common name may sufficiently protect trade secret chemical identity, and the submitter may decide that no trade secrecy claim needs to be filed. LEPCs may later request the MSDSs for the chemicals on the list. If the submitter has made no trade secrecy claim for the chemical on the list, (because the use of the common name sufficiently protected trade secret chemical identity), but the specific chemical identity is withheld from the MSDS distributed to the LEPC, then the submitter must, at that time, file a trade secrecy claim with EPA regarding that MSDS.

Mixtures Reporting on the MSDS, Section 311 List, and Section 312 Tier II Form

For reporting mixtures under sections 311 and 312 (on MSDSs, lists, or Tier II forms) the submitter may provide the required information on each hazardous component in the mixture, or may provide the required information on the mixture as a whole.

If a mixture is reported as a whole by common name on the section 311 MSDS, section 311 list, or section 312 Tier II form, no trade secrecy claim needs to be filed with EPA if the submitter believes that common name sufficiently protects trade secrecy. However, if the common name or other identifier, e.g., CAS number, insufficiently protects trade secret chemical identity the submitter may file a trade secrecy claim. Claims are to be made in the manner specified for the MSDS, section 311 list or section 312 Tier II form, whichever is appropriate.

EPA received some comment on the question of whether trade secrecy claims need to be made for hazardous components of mixtures reported on the OSHA MSDS. Commenters indicated that EPA should consider instances where the specific chemical identities of hazardous components of mixtures would be claimed as trade secret on the OSHA MSDS. These commenters argued that although OSHA usually requires hazardous components to be listed on an MSDS when a mixture is reported as a whole, section 311 is silent regarding whether such hazardous components must be submitted. These commenters argued therefore, that no trade secrecy claim needed to be submitted to EPA for those hazardous components listed on the OSHA MSDS. EPA believes that since Congress authorized the reporting of mixtures as a whole under sections 311 and 312, and since health and safety data are provided for the mixtures on MSDSs, no trade secrecy claims need to be made for hazardous components when a mixture is reported as a whole.

Two commenters suggested that to reduce the paperwork burden on themselves and the Agency, EPA should allow trade secret claimants of mixtures to submit one claim rather than several claims in the situation where the same hazardous chemical is present in many different mixtures. This approach is permitted in section 311(a)(3) of the statute, which states that only one MSDS is required to be submitted for each component where the reporting is on the hazardous component(s) of the mixture, and not on the mixture itself.

Generic Class or Category

The procedures for determining generic class or category are outlined in the Generic Class or Category subsection of section II.C.

E. Claims Under Section 312

Section 312 requires the submission of emergency and hazardous chemical inventory forms. Information filed on the Tier I emergency and hazardous chemical inventory form will not involve claims of trade secrecy since chemical identity is not requested on the form. Trade secrecy claims under section 312 may involve only Tier II inventory forms where the specific chemical identity or other specific identifier is reported.

Submitters are permitted to report Tier II chemicals by either chemical or common names. In some instances, as commenters noted, the use of the common name may sufficiently protect trade secret chemical identity, and the submitter may decide that no trade secrecy claim needs to be filed. However, some submitters may believe that even with the use of the common name trade secret chemical identity will be revealed. In this instance submitters may want to make a claim of trade secrecy for the chemical identity.

To make a trade secrecy claim on the Federal section 312 Tier II inventory form, the submitter must check the trade secret box which appears to the right of the space for chemical identity on the form. EPA must receive an unsanitized copy of the form, which will include the trade secret chemical identity. EPA must also receive a sanitized version of the form which must be a duplicate of the original except that the chemical identity will be deleted and in its place the generic class or category of that chemical will be inserted. The two copies should be attached by rubber band or binder clip (not stapled) to each other, the unsanitized form on top and the sanitized form on the bottom. When more than one chemical is claimed as a trade secret, to avoid confusion the order of chemical names found on the unsanitized Tier II form (the top page) must match the order of generic classes or categories found on the sanitized form. The sanitized Tier II form should be sent to the requesting State emergency response commission, local emergency planning committee, or fire department. In addition, a sanitized and unsanitized substantiation must be included for each chemical claimed as trade secret, as explained in section II.G. of this preamble. Claims should be packaged as described in section II.B.1 of this preamble and in the instructions to the substantiation form.

A few States have expressed an interest in using State-designed Tier II inventory forms rather than the Federal inventory form. Under § 370.4l of the final rule for sections 311 and 312, facilities will meet section 312 requirements if they submit the Federal form, an identical State form, or an identical State form with supplemental questions authorized under State law. If a submitter wishes to make a trade secrecy claim, however, it must use the Federal form as its section 312 Tier II submittal. EPA believes it cannot accept State forms for this purpose because State forms may contain additional information not required under this Federal law, some of which may be confidential, and EPA does not wish to accept extraneous confidential materials requiring confidential handling under State law. State forms that collect confidential information under State right-to-know laws are covered under State confidentiality laws.

Claims of confidentiality regarding the *location* of chemicals in facilities are not covered by Title III trade secret protection. The confidential location information should not be sent to EPA, but only to the requesting entity. This information will be kept confidential by that entity under section 312(d)(2)(F) which refers to section 324. Section 324(a) states that upon request by a facility owner or operator subject to the requirements of section 312, the State emergency response commission and the appropriate local emergency planning committee must withhold from disclosure the location of any specific chemical required by section 312(d)(2) to be contained in a Tier II inventory form. This process of confidential treatment of location information is separate from the process for treatment of trade secret information contained in the rule for section 322.

F. Claims Under Section 313

Trade secrecy claims under section 313 must include a copy of the toxic release inventory form. This form is published at 53 FR 4540. The submitter must check the box on the form indicating a trade secrecy claim and include a generic class or category. This generic class or category must be structurally descriptive of the chemical claimed as trade secret, as described in the Generic Class or Category subsection of section II.C. of this preamble.

EPA must also receive a sanitized copy of the toxic release inventory form which is identical to the original except that the chemical identity will be deleted, leaving the generic class or category. A substantiation for each claimed chemical identity must also be submitted, as described in section II.G. below. Claims should be packaged as described in section II.B.l of this preamble and in the instructions to the substantiation form.

G. Initial Substantiation

Section 350.7 of the proposed rule required that all claims of trade secrecy must be substantiated by the claimant providing specific answers to seven questions set forth in the section. The answers to each of the questions posed, or an explanation as to why that question is not applicable, were to be provided on the substantiation form in § 350.27 and to accompany the submission. The questions posed in the rule (and the identical questions on the form) were based on the four statutory criteria in section 322(b) of Title III and are intended to elicit from a submitter all the information necessary to fulfill the statutory criteria.

The information submitted in response to these questions is the basis for EPA's initial determination as to whether the substantiation is sufficient according to the statutory criteria to support a claim of trade secrecy. Consequently, the role of the initial substantiation in the trade secret protection process as well as the specific language of individual questions asked under § 350.7(a) received considerable comment.

A description of the relationship between the rule and the statutory scheme is as follows. The first decision EPA must make after receiving a petition to disclose trade secret chemical identity or after initiating such a decision on its own concerns the sufficiency of the trade secret claim, that is, whether, assuming all assertions made in support of the claim are true, the assertions are sufficient to support a claim of trade secrecy for the chemical identity. EPA must make this determination of sufficiency based solely on the information which the trade secret claimant submits in the substantiation included with its Title III submission. See section 322(d)(2). It is only when a submitter's claim is deemed sufficient that it is entitled to "supplement the explanation with detailed information to support the assertions." See section 322(d)(3)(A). Then, EPA is to determine whether the "assertions in the explanation are true and the specific chemical identity is a trade secret." See section 322(d)(3)(B).

A major concern of several commenters was that the initial substantiation requirements were too detailed and burdensome, and that they undercut the statutory scheme noted above. Commenters argued that Congress clearly intended to establish a two-step process for substantiation of trade secrets, as expressed in section 322(d)(3)(A). The commenters asserted that the proposed rule blurred the distinction between the two-step trade secret substantiation process by requiring the "detailed information" initially.

The commenters proposed several options to remedy their concerns. The commenters argued that claimants should be allowed to make assertions in the initial substantiation and that details supporting the assertion need only be supplied when a third party files a petition for disclosure. One commenter argued the foregoing point by stating that EPA should merely accept the assertion by a submitter that competitive harm will result if an alleged trade secret is made public—no up-front substantiation should be required for that particular assertion, and only upon challenge would a substantiation be required. The commenter felt that this option would assist a company in meeting filing deadlines because the time-consuming substantiation form would be delayed pending a challenge to the claim.

EPA has carefully considered the commenter's statements. One approach that was considered, though not adopted, was, instead of utilizing the proposed form, listing the four statutory requirements as set forth in the statute and requesting the submitter to verify that it believes it has met these requirements. The Agency chose not to adopt this method because of concerns that responses might not include the specific facts necessary for EPA to evaluate the sufficiency of a trade secret claim, as Congress required in the statute.

The Agency has concluded that while Congress did not intend the information collected up-front to consist solely of conclusory statements parroting the four criteria of trade secrecy set forth in the statute, neither was an overly detailed information collection intended, which could prove unduly burdensome. EPA has sought to strike a balance between these two extremes.

In striking this balance, the Agency has decided to make some changes in the rule as proposed (and discussed below), in order to lessen the amount of detail required in the up-front substantiation, so that the reporting burden is not so great. More specific additional details may still be requested as supplemental information.

The Agency has also revised § 350.7(a) (Substantiating claims of trade secrecy) and the substantiation form to state that a submitter must assert "where applicable" specific facts. This change is intended to reduce uncertainty as to when detail is required and to relieve claimants of the burden of having to certify as true speculative statements or negative conclusions, which commenters pointed out as a problem with some of the questions as proposed. EPA is concerned that adoption of this change might encourage claimants to not provide specific detail in many cases where their assertions require it; the change is not intended to relieve submitters of this responsibility.

The comments also raised issues concerning several of the individual questions or sub-parts to questions, proposed in § 350.7(a), and these are discussed individually below.

Question 1. The question as proposed read: "Describe the specific measures taken to safeguard the confidentiality of the chemical identity claimed as trade secret."

Two comments were received concerning the text of Question 1. These comments stated that the question requested information not required by the Act. However, the Agency disagrees since the statute in specific terms requires this information. Basic to the law of trade secrets is the requirement that the owner of a trade secret has taken steps to protect the secret from disclosure. Therefore, the question is a necessary and required first inquiry in determining whether trade secret protection is warranted for the specific chemical identity.

The Agency also received comments that proposed Question l did not request all the information specifically required by section 322(b) of the statute; that is, whether the submitter intends to continue taking measures to safeguard its trade secret information. The commenter also noted that this information was expected under the sufficiency criteria. (See discussion of sufficiency criteria below under section IV.C.) The Agency agrees with the commenter that such information is required, and has revised Question 1 accordingly.

Question 1 has been revised to read as follows: "Describe the specific measures you have taken to safeguard the confidentiality of the chemical identity claimed as trade secret, and indicate whether these measures will continue in the future."

Question 2. The question as proposed read: "Have you disclosed this chemical identity to any person not an employee of your company or of a local, State or Federal government entity, who has not signed a confidentiality agreement requiring them to refrain from disclosing the chemical identity to others?"

Section 350.7(a)(2) and Question 2 ask whether the submitter has disclosed the chemical identity to any person not a company or government employee who has not signed a confidentiality agreement. The one significant comment on the question noted that the proposed regulation specifies a signed confidentiality agreement, whereas, the statutory language upon which this Question is based requires persons claiming a trade secret to show that persons dealing with the alleged trade secret are "bound by a confidentiality agreement." The form of the agreement is not specified. The commenters cited State law, common law, and custom as establishing that unwritten trade secrecy agreements are enforceable.

EPA agrees with the commenters that Congress did not specify that the confidentiality agreement must be a written document. Indeed, the purpose of the question is to ascertain whether there exists a confidential relationship between a submitter and other parties that would prevent disclosure. The threshold test for a confidentiality agreement is whether it is legally enforceable. Although having a written agreement, as proposed, simplifies substantiation of the fact that the information was treated as a trade secret and steps were taken to secure its secrecy, EPA agrees that the requirement for a written agreement is not specified by Congress and the intent of the requirement can be met without a writing.

One minor comment was received which did not require any change in the rule. Several commenters cited to situations in which a trade secret is inadvertently disclosed; however, the company does not sustain an injury because the error is corrected before the trade secret falls into the hands of a competitor. They requested that Question 2 of the Proposed Form be expanded to allow for explanation of inadvertent or mistaken disclosures that were promptly corrected or retrieved before competitors became aware of the disclosure.

The Agency does not believe that any change in the form or question was necessary in response to this comment. The submitter must answer affirmatively to Question 2, but then should attach an explanation. EPA will consider the explanation in the context of all the other steps the submitter has taken to protect the trade secret.

EPA has deleted the reference to a "writing" in the final § 350.7(a)(2) and Question 2. The final Question 2 reads: "Have you disclosed the information claimed as trade secret to any other person (other than a member of a local emergency planning committee, officer or employee of the United States or a State or local government, or your employee) who is not bound by a confidentiality agreement to refrain from disclosing this trade secret to others?" This formulation of the question avoids the double negative in the proposed question about which some commenters complained.

Question 3. The question as proposed read: "List all local, State, and Federal government entities to which you have disclosed the specific chemical identity. For each, indicate whether you asserted a confidentiality claim for the chemical identity and whether the government entity denied that claim."

One commenter thought that the question did not address situations where information deemed "confidential" is often submitted to the government and the claim left unchallenged, without a determination of the claim's validity. The commenter stated that even if the claim is not expressly denied, it is possible that the confidentiality claim would be denied if eventually reviewed.

In this question, EPA is attempting to ascertain the submitter's efforts to protect its trade secret. The most important elements of this question are whether chemical identity was previously claimed as trade secret and whether the claim was ever denied. If the claim of trade secrecy was denied and the chemical identity therefore made public, the submitter would not be able to meet the statutory test for confidentiality. Therefore the Agency will not revise Question 3 to include the question of whether the submission was reviewed under the other authority.

Several commenters questioned whether an explanation should be permitted in instances where there is a qualified or partial grant of confidentiality by a government entity, or of where a prior determination does not affect the current claim. One commenter stated that Question 3 does not consider the potential situation of a qualified or partial grant of confidentiality by a government entity, since the question does not request an explanation in the event that a particular government entity has denied a trade secrecy claim. The commenter asserted that there may be circumstances in which a partial or total denial of the claim should not adversely affect the claim being made under Title III. A second commenter observed that the fact that the specific chemical identity of a chemical has been disclosed in some context in the past should not result in forfeiture of trade secret status if the disclosure was not tied to the specific Title III information that is at issue.

Another aspect to this issue is raised by a third commenter who alleged that Question 3 does not take into consideration the trade secret status of chemicals whose identity may have been disclosed to a government agency under circumstances where the confidential connection to the submitting firm remains undisclosed. Specifically, the commenter cites to the nonconfidential Toxic Substances Control Act (TSCA) inventory where specific chemical substances are reported without claims of confidentiality because the inventory is compiled in such a manner as not to link a chemical with a firm.

The Agency must collect information on whether the submitter has disclosed the information claimed as trade secret to a State, local or Federal agency, including previous disclosures to EPA under Title III or other statutes, and the steps the submitter took to protect this data. In doing so, the Agency is also attempting to discover whether there has been a public disclosure of the information. Submitters who believe it necessary to explain special circumstances may do so. The Agency also wishes to point out that it is sometimes possible to link specific chemical substances with the reporting firm under the non-confidential TSCA inventory. The submitter must have claimed the information reported as confidential to assure that there is no link under the inventory.

One commenter stated that if "disclosure" was defined too broadly it would negate the intent of the Community Right-to-Know aspect of Title III. A company might be reluctant to share information with an LEPC to avoid being held to have disclosed the trade secret. However, the commenter's discussion seemed to indicate that the information being provided to the LEPC would be health and safety data, not the specific chemical identity which constitutes the trade secret. Therefore, the situation described by the commenter would not constitute a disclosure of the trade secret, and the Agency has decided that no revision to the final rule is necessary to respond to this comment.

Question 4. Proposed § 350.7(a)(4) and Question 4 require trade secret claimants to substantiate the harm to their competitive position that would result from disclosure of the information claimed as trade secret. The proposed Question 4 provided:

(1) In order to show the validity of a trade secrecy claim, you must identify your specific use of the substance claimed as trade secret and explain why it is a secret of interest to competitors. Therefore:

(a) Describe the specific use of the chemical substance, identifying the product or process in which it is used. (If you use the substance other than as a component of a product or in a manufacturing process, identify the activity where the substance is used.)

(b) Has your company or facility identity been linked to the specific chemical identity of the substance in publications or other information available to the public (of which you are aware)? ☐ Yes ☐ No. Is this linkage known to your competitors? ☐ Yes ☐ No. If the answer to either question is yes, explain why this knowledge does not eliminate the justification for trade secrecy.

(c) If this use of the substance is unknown outside your company, explain how your competitors could deduce this use from disclosure of the chemical identity together with other information on the form.

(d) Explain why your use of the substance would be valuable information to your competitors.

Several commenters asserted that it is unreasonable for the Agency to require claimants to characterize their competitors' knowledge of the information claimed to be trade secret, as in Questions 4 (b) and (c). They argued that it is impossible to state what someone else knows, and that the inability to provide an accurate assessment of what competitors know should not endanger a trade secret claim. This requirement was also claimed to be inconsistent with the common law of trade secrecy, which does not require a trade secret claimant to show the knowledge, motivation, or capabilities of its competitors in order to avoid forfeiture of a trade secret. Moreover, commenters argued, a substantiation should not be determined insufficient on the basis that a competitor is aware of the claimant's use of a substance. As long as the information confers an advantage on the firms that do know it and it is treated as a secret by each of them, the information should qualify for trade secret status. Finally, one commenter went so far as to suggest that any reference to competitors' knowledge should be deleted altogether.

The problem of requiring claimants to assert facts concerning the knowledge of competitors is related to a more general complaint of commenters that the criteria of proposed § 350.7 tended to be phrased as "negative conclusions," and thus were difficult to prove. Commenters asserted that these provisions would place claimants in the untenable position of being required to certify the accuracy of statements that cannot be anything more than speculation.

Commenters are correct in stating that trade secrecy claimants should not be required to certify to the truth of speculative statements. It is also true that more than one person can claim trade secrecy protection regarding the same information. Nevertheless, one of the factors that the Agency must consider in determining whether information is a trade secret is the *extent* to which the information is known outside of the claimant's business. Therefore, claimants should be required to address their competitors' knowledge if they know whether such knowledge exists.

Accordingly, the Agency has revised § 350.7(a)(4) and Question 4 to require claimants to characterize their competitors' knowledge of the information claimed as trade secret, to the extent that they know whether such knowledge exists.

One commenter also stated that the term "substance" is used for the first time in substantiation Question 4, is not defined, and therefore is ambiguous. The commenter suggested that EPA define the term or, preferably, replace it with a term that is already among the terms used in the rule. In order to conform Question 4 with terminology used throughout the rule, EPA has replaced the term "substance" with the phrase "chemical claimed as trade secret" in the final rule.

Several individual questions within Question 4 also received comment, and are discussed in order.

Question 4(a). This question asks the submitter to describe the specific use of the chemical substance, identifying the product or process in which it is used. One commenter suggested that EPA delete the term "specific" as it relates to the use or process of the chemical being described because no more than a general description is necessary here. The commenter also asked the Agency to clarify that a facility need only provide process or use information that is relevant to the claim being made, i.e., that the claim of trade secrecy may not relate solely to the use of the chemical, but may relate to other factors.

EPA disagrees with the commenter on the specificity of use information that is required. Such information is always relevant to a trade secrecy claim. Although information regarding use may not always be sufficient, standing alone, for the Agency to determine the validity of a trade secrecy claim, it is necessary information in the Agency's evaluation of the claim which should, together with other required information, enable the Agency to make the determinations required by Title III. Accordingly, EPA has retained the requirement for information regarding the specific use in the final rule, but has revised § 350.7(a)(4)(i) and Question 4(a) to substitute the term "chemical" for "substance" (as explained above).

Question 4(b). This question asks whether the company or facility identity has been linked to the specific chemical identity of the substance in publications or other information available to the public and whether this linkage is known to competitors. The one comment received suggested that the subquestion, "Is this linkage known to your competitors?", should be deleted, because the claimant cannot know the answer, making it speculative. Further, the commenter stated that even if the linkages were known by a competitor, this would not necessarily render the trade secret invalid.

As discussed above, EPA agrees that the knowledge of competitors may not be known. EPA has amended the final rule to reflect this change. In addition, EPA added a reference to patents in this question, which are a subset of publications. The discussion under Question 7 describes in detail the reasons why the requirements of the substantiation dealing with patents can be adequately addressed in the modified Question 4(b). Therefore, in the final rule, § 350.7(a)(4)(ii) and Question 4(b) have been revised to read as follows: "Has your company or facility identity been linked to the specific chemical identity claimed as trade secret in a patent, or in publications or other information sources available to the public or your competitors (of which you are aware)? If so, explain why this knowledge does not eliminate the justification for trade secrecy."

Question 4(c). The question asks the submitter to explain how competitors could deduce a trade secret use from disclosure of the chemical identity together with other information on the reporting form. One commenter stated that this question should be deleted as speculative. The commenter argued that if chemical identity as related to use could be deduced from other information on a Title III submission, there would hardly be reason for the claimant to incur the time and expense of submitting a trade secrecy claim. Another commenter argued that this question and Question 4(d) (discussed below) appear to be more appropriate for substantiating claims of *use* confidentiality than *chemical identity* confidentiality. The commenter argued that a competitor may be able to determine information on a generic basis sufficient to recognize the specific information it needs in order to learn the trade secret. The commenter stated that a company should be able to protect itself from future competitors as well as present ones.

The Agency is not persuaded by comments that Question 4(c) should be dropped from the substantiation that must be provided by each claimant. Regarding the supposed distinction between use confidentiality and chemical identity confidentiality, the two concepts are not mutually exclusive. Rather, information on the use of a chemical is necessary to determine the validity of a trade secrecy claim as to the identity of that chemical.

The final rule, however, contains a revision of § 350.7(a)(4)(iii) and Question 4(c) that substitutes "chemical claimed as trade secret" for the term "substance."

Question 4(d). The question requires the submitter to explain how his use of the substance would be valuable information to competitors. One commenter asked the Agency to clarify that submitters are not required to include a dollar estimate in their statement of "value," particularly since such an estimate would be speculative and, therefore, would not be certifiable as a "specific fact." Another commenter suggested that this question be revised to read, "Explain why the information for which chemical identity is being claimed trade secret would be valuable information to other business entities." This commenter stated that it is not only "competitors" but other business entities that could use trade secret information to the detriment of the claimant.

First, EPA does not intend for submitters to provide a dollar estimate as the sole measure of value in Question 4(d). Such a requirement would indeed put submitters in the position of certifying what could be highly speculative information. Reasonable dollar estimates may be worthwhile in the final determination, and may be requested as supplemental information. Second, the law of trade secrecy refers to "competitors," not "other business entities," as the universe of entities against whom trade secrecy protection applies.

The only change that has been made to § 350.7(a)(4) and Question 4(d) in the final rule has been the substitution of the term "chemical" for the term "substance."

The final version of question 4 reads: "In order to show the validity of a trade secrecy claim, you must identify your specific use of the chemical claimed as trade secret and explain why it is a secret of interest to competitors. Therefore:

(i) Describe the specific use of the chemical claimed as trade secret, identifying the product or process in which it is used. (If you use the chemical other than as a component of a product or in a manufacturing process, identify the activity where the chemical is used.)

(ii) Has your company or facility identity been linked to the specific chemical identity claimed as trade secret in a patent, or in publications or other information sources available to the public (of which you are aware)? If so, explain why this knowledge does not eliminate the justification for trade secrecy.

(iii) If this use of the chemical claimed as trade secret is unknown outside your company, explain how your competitors could deduce this use from disclosure of the chemical identity together with other information on the Title III submittal form.

(iv) Explain why your use of the chemical claimed as trade secret would be valuable information to your competitors."

Question 5. The proposed Question 5 read: "Indicate the nature of the harm to your competitive position that would likely result from disclosure of the specific chemical identity, including an estimate of the potential loss of sales or profitability."

Two commenters stated that an estimate of the potential loss of sales or profitability should not be required. One of these commenters asked EPA to indicate in the Preamble to the final rule that detailed information need not be submitted in response to this question at the time of an initial submission. The commenter stated that this question would be time-consuming due to the amount and diverse sources of marketing and other data required to provide an accurate estimate.

A more detailed estimate of the potential loss of sales or profitability may be more appropriate as part of a supplemental substantiation (at which time EPA assesses the factual accuracy of the submitter's assertion). The purposes of an initial substantiation may be fulfilled by requiring a description of the nature of harm to competitive position that may result from trade secret disclosure, and an explanation of why such harm would be substantial. EPA agrees with these commenters, and has dropped the requirement to develop a loss of sales estimate as part of the initial substantiation.

One commenter requested that EPA recognize that trade secrets developed by "serendipity" are protectable under section 322 of Title III. The commenter noted that although the submitter may not have gone to any great expense to develop the trade secret, the secret nevertheless may be of great value to the submitter. This is consistent with the intent of the statute and the sufficiency criteria described in the final rule. The costs discussed in the rule relate to the cost to a competitor of replicating the information, not to the owner of the information in developing it originally. Although information will not be protectable as trade secret if it is readily available public knowledge, nothing will prevent the protection as trade secret information which the claimant has discovered with minimal effort by a stroke of good fortune.

Accordingly, EPA has revised § 350.7(a)(5) and Question 5 to read as follows: "Indicate the nature of the harm to your competitive position that would likely result from disclosure of the specific chemical identity, and indicate why such harm would be substantial."

Question 6. The proposed question 6 read: "To what extent is the substance available to the public or your competitors in products, articles, or environmental releases?

Describe the factors which influence the cost of determining the identity of the substance by chemical analysis of the product, article, or waste which contains the substance (e.g., whether the substance is in pure form or is mixed with other substances), and provide a rough estimate of that cost."

The issue of discovery of a chemical by reverse engineering arises in Question 6 of the substantiation form, § 350.7(a)(6), although the term "reverse engineering" is not mentioned in the question. This section of the substantiation is derived from the fourth statutory criterion (that chemical identity is not readily discoverable through reverse engineering) and the question requires answers that reflect on whether the trade secret claimed can be reverse engineered.

Most comments regarding reverse engineering focused on the difference between the proposed rule's use of the term "reasonably learn" as opposed to the statutory term "readily discoverable" as the appropriate standard of sufficiency for evaluating a chemical's susceptibility to discovery by reverse engineering. Commenters generally objected to the proposed rule's use of the term "reasonably learn", primarily on the basis that it would provide less protection for trade secrets than would the statutory standard "readily discoverable." The statutory term was also favored because it is a generally accepted and understood term employed in analytic chemistry, while "reasonably learn" is not.

Most commenters who addressed this issue explained that given sufficient time and ample resources, the discovery of almost any chemical by reverse engineering would be considered "reasonable." The commonly understood definition of the statutory standard, on the other hand, takes into account whether the time and resources necessary to successfully reverse engineer a product are readily available. Conversely, one commenter supported a definition that would deny trade secret protection if an identity is at all discoverable by reverse engineering.

Essentially, the reasonably learn versus readily discoverable issue is a matter of terminology. The Agency's choice of the term "reasonably learn" in the proposed rule was derived from the statute's directive in section 322(c) that the regulations regarding reverse engineering be "equivalent to comparable provisions" in OSHA's Hazard Communication Standard, and any revisions to the HCS required by *United States Steelworkers v. Auchter*, 763 F.2d 728 (3d Cir. 1985).

The definition of trade secrecy in the HCS was determined by the *Auchter* court to be legally deficient with respect to determining the legitimacy of trade secret claims because it failed to account for a chemical's susceptibility to reverse engineering. The revised HCS accordingly adopted the Restatement's definition of trade secret as an appendix, which requires consideration of the ability of others to discover the secret by legitimate means, including reverse engineering.

It is apparent from these revised OSHA regulations, as well as from the Restatement's definition and applicable case law, that the generally understood meaning of "readily discoverable" by reverse engineering requires that the chemical identity at issue be discoverable using readily available equipment, generally known analytic techniques, and that the required costs, time, and resources are reasonable considering the benefits derived. This is the standard the Agency intended by its initial choice of the "reasonably learn" language. The Agency also intended, with the use of this language, to avoid denying trade secrecy claims on a purely theoretical ability to reverse engineer, since this would disregard the costs involved.

The Agency has replaced the term "reasonably learn" with "readily discoverable." This standard is consistent with the revised OSHA HCS and the holding of *Auchter*, as directed by section 322(c). In order to avoid any confusion about the applicable standard, and to make it as consistent as possible with the HCS, the Agency has also adopted the Restatement definition of trade secret as an appendix.

These changes should be recognized as changes in terms solely for the purpose of promoting clarity; it does not indicate a substantive change in the standard.

Commenters also perceived other practical and legal problems arising from the proposed trade secret definition with respect to reverse engineering. Section 350.7(a)(6) and Question 6 of the proposed rule requested trade secrecy claimants to "provide a rough estimate of [the] cost" of determining the identity of the trade secret substance through reverse engineering. The development of such cost estimates was considered useful by the Agency because cost is a factor to consider in determining whether a trade secret is readily ascertainable by reverse engineering. Commenters nevertheless pointed out difficulties, such as that developing a preestimate of the costs to reverse engineer would be speculative owing to the uncertainties of analytic chemistry, and that the costs will vary widely from company to company for analysis of similar chemical compounds because of differences in available resources and equipment and in the level of training and sophistication of those conducting the analyses.

Definitional problems were also raised, such as whether the cost estimate should include costs other than those to conduct the chemical analysis (i.e., the costs to develop and replicate the product once the chemical constituents have been identified), and whether the estimates should include the cost of the necessary equipment. Commenters also noted that the uncertainty of reverse engineering costs contributes to the trade secret's protection, since unknown costs may influence a competitor's decision not to undertake such an analysis.

The concerns regarding the possible compromise of trade secret protection by providing an estimate of the costs to reverse engineer seem to be the result of some confusion about the rule's requirements. If cost information is itself confidential information that information may be claimed as such on the trade secret substantiation.

Nevertheless, trade secret law requires some indication of the cost to discover the trade secret in order to determine the validity of the claim. If the cost of identifying the trade secret by reverse engineering exceeds the value of the trade secret itself, the trade secret is not considered to be readily discoverable. However, as one commenter correctly pointed out, cost is an inexact proxy for the pertinent factual determination of whether the trade secret is disclosable by reverse engineering. The variation in resources available to different companies also makes dollar comparisons difficult, thereby lessening the value of dollar-specific estimates.

While it is impossible to determine the ease or difficulty of reverse engineering without considering the costs and equipment involved, it is apparent that the requirement to develop specific dollar estimates will not appreciably further the inquiry at the initial stage of substantiating a trade secret under Title III. More useful to the analysis are the descriptions of the factors influencing the cost of identifying the substance sufficient to disclose the trade secret through chemical analysis. Accordingly, the Agency in the final rule has deleted the requirement to provide a "rough cost estimate" of the costs of reverse engineering in the substantiation form, but has retained the requirement to provide a description of the factors that influence the costs of analysis.

Claimants may still be requested to develop cost estimates as supplemental information following the initial review of the substantiation. The descriptions of cost factors in the substantiation must be as specific and detailed as practicable and should include information regarding the level of expertise needed, the type of equipment required, the time involved, and so forth. It is in the submitter's best interest to provide a well-detailed description of those factors that are indicative of cost, so that the Agency can make a realistic appraisal of this express statutory criterion. The failure to provide a sufficiently detailed description will likely jeopardize a trade secrecy claim.

Section 350.7(a)(6) and Question 6 of the trade secret substantiation form request information regarding the trade secret chemical's availability in both final products and in environmental releases. Commenters objected to the requirement to assess availability in environmental releases, citing myriad practical problems attendant to analyzing waste streams, such as the extent to which a waste flow may be treated prior to discharge, varying flow rates, dilutions, unintended reactions, the presence of impurities, and similar factors. These factors are asserted to make it economically impractical to conduct such a chemical analysis, and to adversely affect the ability of presently-available technologies to detect the chemical at all.

The Agency recognizes that, as a practical matter, the likelihood of successfully identifying a chemical present in facility wastes is less than the likelihood for analysis of a finished product available on the open market. Nevertheless, the assessment of whether the chemical identity is discoverable in a waste stream or release is not significantly different from the same assessment for the discoverability of a chemical present in a product available to the public or competitors. The salient question is, given the compound or mixture under scrutiny, can it be readily reverse engineered to identify the chemical that is claimed as trade secret. In order to address those cases in which a release is of sufficient purity such that the chemical is susceptible to discovery through reverse engineering, or where technological advances make such analysis feasible, this factor has been retained in the final rule.

Commenters also suggested that presumptions be established against a product's susceptibility to reverse engineering in certain cases. However, because assessing whether a "secret" can be discovered by reverse engineering or other investigatory method is fact-specific and often a unique inquiry, the Agency does not believe that a decisionmaking process punctuated by presumptions in lieu of specific fact-finding is useful or appropriate.

One commenter questioned whether a history of disinterest on the part of competitors in the trade secret chemical should be taken into consideration in determining whether a chemical is discoverable by reverse engineering. EPA agrees that a history of disinterest in a claimant's product is relevant to a trade secret claim, as it is some indication that the secret is not generally known to competitors. The history of disinterest may also be some indication that the chemical is not susceptible to reverse engineering, but it cannot be considered dispositive.

The final question 6 reads: "(i) To what extent is the chemical claimed as trade secret available to the public or your competitors in products, articles, or environmental releases? (ii) Describe the factors which influence the cost of determining the identity of the chemical whose identity is being claimed trade secret by chemical analysis of the product, article, or waste which contains the chemical (e.g., whether the chemical is in pure form or is mixed with other substances)."

Question 7. The proposed question 7 read: "Is your use of this substance subject to any U.S. patent?

If so, identify the patent and explain why (A) it does not connect you with the substance and (B) why it does not protect you from competitive harm.

Patent Number: ______.

The commenters raised several issues concerning the patent question. First, they pointed out that a patent is a "publication" and, as such, is covered by Question 4 in the substantiation. Next, the commenters described several situations in which a patent would not reveal the trade secret, for example, the specific identity of the valuable substance is buried in a large listing of substances, or the use of the identified substance is the trade secret (i.e., the linkage is the trade secret). Also, the commenters feared that a "yes" answer to Question 7 would disqualify the claim for trade secret protection, even though trade secret protection and patent protection are not identical.

Merging Question 7 into Question 4(ii) satisfies many of the commenter's concerns. Question 4(ii) now expressly considers patents, as well as any other publications, in the relevant context of whether the publication of the chemical identity eliminates the submitter's claim for trade secret protection.

The second issue under Question 7 that must be addressed is why patent protection does not adequately protect the claimant from competitive harm. Eliminating Question 7 does not leave this issue unaddressed because of its merging into Question 4(ii) and because the Agency intends to gather additional detail on this issue in supplemental questions to the submitter.

EPA has determined that the substance of Question 7 can be adequately addressed in Question 4(ii), on publications, and Question 5 on competitive harm. Therefore, Question 4(ii) has been amended to specifically reference patents. In the final rule, § 350.7(a)(4)(ii) and Question 4(ii) read: "Has your company or facility identity been linked to the specific chemical claimed as trade secret in a patent, or in publications or other information sources available to the public or your competitors (of which you are aware)? If so, explain why this knowledge does not eliminate the justification for trade secrecy."

Finally, commenters raised a question about the requirement in the proposed rule, in § 350.5(g), that trade secrecy claims with missing substantiations or lacking a response to each question would be rejected without notice to the submitter, and the chemical identity would be made available to the public. Various commenters criticized this provision as unduly harsh, and noted that various circumstances could occur, such as clerical errors or explanations being separated from the substantiation forms which could result in EPA receiving an incomplete substantiation. EPA agrees and accordingly, this provision has been deleted. However, if a company's submissions indicate a disregard for the rule's requirements, EPA will consider this in evaluating whether a claim is frivolous.

H. Substantiation Form

A discussion of the comments on and changes to each of the questions on the substantiation form is found in section II.G. above. The form itself is designed to provide sufficient space for submitters to succinctly answer each question. The Agency is looking only for specific facts, briefly stated within the space permitted to indicate that the submitter has met the prima facie threshold of trade secrecy. If submitters believe it necessary to make an attachment, they may, although such instances should be rare. Additional, more extensive facts can be gathered in the supplemental round of questions.

The Agency also received several public comments on the certification statement included at the bottom of the form. The preamble of the proposed rule required that a corporate officer sign the certification form. Several commenters suggested this was unduly burdensome in a large corporation because the officer would be required to handle a large number of submissions and would not have personal knowledge about the information contained in each submission. A few commenters also suggested that the word "immediately" should be deleted from the phrase "based on my inquiry of those individuals immediately responsible for obtaining the information" because large corporations would have an intermediary between the person gathering the information and the signer of the certification. Also, the certifications for sections 312 and 313 do not contain this language.

EPA has added a definition of "senior management official" to § 350.1 of the rule. The certification form must now be signed by an owner, operator or a senior management official. The Agency believes this requirement balances the commenter's concerns of burden on the corporate officer who may not have personal knowledge of the information with the need to assure high level responsibility for the information on the substantiation form, in accordance with Congressional intent. The Agency accepts the commenters' reasoning concerning the word "immediately" in the certification and has deleted the word in this final rule.

EPA received comment requesting the deletion of the last two sentences of the certification statement. The two-tiered substantiation process described in section II.G. allows the submitter to supply and the Agency to request more factual information concerning the trade secret substantiation. EPA is not requesting that the up-front substantiation contain as much detail as was originally proposed, thus there must be additional details for some of the questions available upon request. This requirement will not be deleted.

The last sentence of the certification concerns the penalty for a frivolous claim. One commenter requested that the Agency not interpret the certification requirements to provide a basis for asserting individual liability against corporate officers. EPA will not delete this provision; however, the language has been modified. In most cases, the company, not the individual signer, would be liable for the civilly or administratively imposed penalty. In addition, knowingly providing false or misleading statements to the United States government is a criminal offense under 18 U.S.C. 1001, and language to this effect has been added.

One commenter requested clarification as to whether the owner, operator or senior management official who signs the trade secret certification must be the same individual who signed the section 312 or section 313 certification. The Agency does not require the same individual to sign all the forms; the Agency wishes to encourage the most knowledgeable individuals with sufficient authority to sign each certification. This balance of knowledge and authority for all sections of Title III may not be possible for one individual in a large corporation with various divisions.

Finally, the Agency received one comment stating that the phrase requiring the official to verify that the substantiation was "true, accurate and complete to the best knowledge and belief" of that official was unduly burdensome and defeated the purpose of the trade secret provisions. The Agency believes that the language in the proposed rule is appropriate to convey the serious nature of the certification statement and the trade secret substantiation and has retained it in the final rule.

I. Claims of Confidentiality in the Substantiation

Sometimes the submitter may need to refer to the chemical identity claimed as trade secret in the substantiation for that chemical. Also, in order to supply a complete explanation of its claim of trade secrecy, the submitter may include other trade secrets or confidential business information in the explanation.

Section 322(f) allows submitters to claim as confidential on the substantiation form any information which falls within 18 U.S.C. 1905, the federal Trade Secrets Act, which requires the federal government to protect trade secrets and confidential business information unless another federal statute authorizes disclosure. Thus, the information which may be claimed confidential in the substantiation includes the specific chemical identity, as well as any other trade secret or confidential business information.

One commenter requested that the term "business confidentiality," which is defined in the Definitions section, be deleted wherever it appears. The commenter requests that the term "confidential business information" be used in its place. The Agency agrees that "confidential business information" has a common usage in the law of trade secrets. However, "business confidentiality," as defined in the final rule, is the same term used in the Agency's confidential business information regulations at 40 CFR Part 2.

To make these claims, the submitter must clearly label what information it considers to be trade secret or confidential. This substantiation is to be submitted to EPA, along with a sanitized substantiation, in which the trade secret and confidential business information is deleted. If any of the information claimed as trade secret on the substantiation is the chemical identity of a claimed chemical, then the submitter should include the appropriate generic class or category of that chemical on the sanitized version of the substantiation.

No substantiation needs to be submitted for information that the submitter includes in the substantiation and claims as trade secret or confidential. The submitter need only sign the certification included at the end of the substantiation form, as discussed above in section H. The claims of trade secrecy and confidentiality for information submitted in the substantiation are not subject to the petition process described below because this process applies only to claims of trade secrecy for the chemical identity made under Title III. Instead, requests for disclosure of other trade secret or confidential material must be submitted pursuant to the Freedom of Information Act regulations under 40 CFR Part 2.

The Agency received a comment requesting that the unsanitized substantiations be automatically classified as confidential under Executive Order 12600 which sets forth designation and notification procedures for confidential business information under FOIA. The provisions of this rule are in compliance with the Executive Order; unsanitized substantiations claimed as confidential are treated as such until determined otherwise.

J. Updating Substantiations Submitted Prior to Final Rule

Several commenters suggested that, in order to achieve "fundamental fairness," EPA should allow companies that submitted their Title III submittals prior to the effective date of this final rule on trade secrets to update their substantiations without penalty.

EPA agrees with this comment. Submitters could not know exactly what information would be required on the substantiation form until the final rule on section 322 is published. Thus, submissions filed prior to the effective date of this final rule will be allowed to be updated. Submitters may wish to utilize the final rule for filing submittals immediately upon publication, prior to the effective date, and are free to do so.

Commenters also requested that previous substantiations be returned to them when they submit an updated version. This is not possible, however. The Federal Records Retention Act requires that government keep such submittals as part of the Agency's record in order to support the Agency's activities and decisions.

K. Cross-Referencing of Substantiations

EPA has been encouraged by industry commenters to develop a reporting option that would allow trade secret claimants to cross-reference trade secret substantiations already submitted to EPA in subsequent Title III filings involving the same chemical and trade secret. Because the same chemical involving the same trade secret may be reported under different sections of Title III, and because these reports require periodic updating, claimants argued that the trade secret substantiations for each claim would be the same.

At least three different scenarios involving cross-referencing were identified by the commenters: (1) Subsequent reports involving the same chemical reported under different sections could all reference and rely on the same trade secret substantiation (multi-section referencing); (2) subsequent reports involving the same chemical and the same section—e.g., annual section 313 toxic chemical release reporting—could reference and rely on the earlier submitted substantiation (multi-year referencing); and (3) multi-facility companies could cross-reference a single substantiation when reporting for each of their facilities at which the same chemical is present, both for reporting under different sections (multi-facility referencing) and in subsequent years (multi-facility, multi-year referencing).

The issues raised by these comments require the Agency to strike a balance between a submitter's ease and convenience in making and substantiating trade secret claims, and the relative burdens, costs, and risks posed by altering the trade secret substantiation requirements to accommodate this proposed method of reporting.

On the one side of the balance, EPA's analysis indicates that a submitter's reporting burden is not reduced by cross-referencing.

First, a submitter must review their prior-prepared substantiations to identify one that is appropriate and relevant for re-use (that is, an identical substantiation). Cross-referencing requires that the submitter provide EPA with information sufficient to accurately identify the prior-submitted substantiation. Without cross-referencing, a submitter wishing to re-use an appropriate and relevant substantiation would be expected to photocopy the form, alter the reporting section check-off box, and re-sign the certification statement. The time and costs associated with each of these tasks are approximately equal, the costs for the cross referencing method being slightly higher for the submitter.

This somewhat counter-intuitive result is traceable to the labor-intensive procedures for cross referencing. While cross-referencing reduces the amount of paper involved, it is a slightly more complex process that increases the labor costs for submitters. The result is that there is no net savings for submitters achievable by cross referencing on a per document basis.

Second, EPA does not expect the number of trade secret substantiations that will be identical to be high, further reducing the potential for cross referencing to be an effective burden-reducing reporting method. The overall number of trade secret claims should not be high—approximately 0.1 percent of all Title III filings are expected to include trade secret claims—and because of the inexact nature of trade secrets and the differences in information required to be disclosed under each of the five reporting sections for which trade secret claims are allowed, the universe of substantiations that will be identical and appropriate for re-use should be small. There is thus a low potential for cross referencing to measurably reduce a submitter's reporting burden.

Weighing against cross referencing are a variety of costs and other factors not consonant with the disclosure focus of the Title III program.

Trade secrets by definition run counter to the right-to-know intent of Title III, and just as the decision to make a trade secret claim should not be taken lightly, neither should substantiations be prepared as a routine document. The Agency encourages claimants to closely examine the reported information required in each case, and carefully assess whether and how that information affects what the submitter believes to be a trade secret. This explanation must be included in the substantiation. Even where previously created substantiations are relevant and appropriate for referencing, the claimant should have taken the time to carefully review the substantiation to determine its applicability to another claim. EPA procedures are designed to encourage this process.

Cross referencing has the potential to discourage such reviews and makes more likely the preparation and use of "boilerplate" substantiations for routine use. A review of substantiations submitted thus far under sections 311–312 indicates that many submitters are treating trade secret substantiations in this way. This is not consistent with the clear congressional intent that facilities subject to Title III provide EPA and the public with specific and detailed information when making a trade secret claim. Moreover, because of their general nature, boilerplate substantiations are more likely to be found insufficient to support a trade secret (thereby imperiling the claim), than is one specifically prepared to support a particular claim.

Finally, the costs to the Agency to implement a cross referencing system are not justified by the small potential for reducing a submitter's reporting burden. Cross referencing adds up to nearly 50 percent to the Agency's costs on a per document basis, exclusive of other system design and development costs and requirements. And because cross referencing increases the risk of an inadvertent disclosure of submitter's trade secret information (due, for example, to faulty identification information), additional quality-control procedures and security measures are required, at increased cost.

On balance, weighing the lack of any savings in the time and costs required for submitters to prepare a substantiation against the increased costs to the EPA and to the Title III program, cross referencing is not justifiable as a viable and effective reporting alternative. However, EPA is sensitive to and understands the burdens imposed by the extensive reporting requirements of Title III.

One significant factor contributing to the number of duplicate reports required is the number of different recipients specified by the Act. Within this statutory framework, EPA has investigated and will continue to investigate ways to reduce the overall reporting burden without compromising the primary objective of Title III. Toward this end, EPA has been able to identify and plans to implement other improvements to streamline the reporting process.

One burden-reducing improvement is the deletion of the requirement for the creation of an "unsanitized" MSDS when making a trade secret claim under section 311. Since most Title III reports and trade secret claims involve section 311, this should represent a significant savings. For similar reasons, EPA also deleted the requirement for unsanitized section 303 reports. In addition, EPA considered—and rejected—a requirement for claimants to substantiate as trade secrets the hazardous components of mixtures reported as a whole under section 311, which would have significantly added to the reporting burdens of complying with the trade secret rule.

EPA has taken steps to reduce the Title III reporting burden in other ways, such as permitting facilities to report their non-trade secret information by magnetic media.

EPA will continue to investigate ways to make compliance easier and more cost-effective both for EPA and for those subject to this law, while meeting the mandate received from Congress. Weighing the potential benefits of referencing against the costs and burdens, it does not appear that cross referencing is a viable method. However, EPA will look at the number of opportunities for cross referencing through the summer of 1989 and if actual experience provides contrary data, this issue will be revisited. Also, EPA will permit cross referencing of previous submissions sent to States on a State by State basis, as the States allow.

L. Submissions to State and Local Authorities

If a trade secrecy claim is made with respect to a particular submission, the sanitized Title III submittal and the accompanying sanitized substantiation must be sent to the appropriate State or local authorities, as required under section 322(a)(2)(ii) of the statute. Specifically, under section 303, the submittal and accompanying sanitized substantiation should be sent to LEPCs, and under sections 311–312 the MSDS or a sanitized section 311 list or Tier II submittal, as appropriate, and accompanying substantiation should be sent to the SERCs, the LEPCs and to local fire departments. Finally, a sanitized 313 submittal and substantiation must be sent to the designated State entity. If a Title III reporting form or a substantiation containing trade secret information is sent to a State or local authority by the submitter, under the law of trade secrets it will constitute public disclosure of the information, and the claim will be considered invalid.

Several commenters requested that EPA delete the requirement that a sanitized copy of the substantiation be sent to the State authorities and the local emergency planning committees. Section 322(a)(2)(A)(ii) requires that a trade secret claimant include in its section 303 (d)(2) and (d)(3), sections 311–312 and section 313 submittals an "explanation of the reasons why such information is claimed trade secret." Finally, these sections provide that all facilities subject to the Act submit this Title III submittal to the appropriate state and local authorities. Therefore, EPA cannot delete this requirement.

III. Petitions Requesting Review of Trade Secrecy Claims

Section 322 provides for a public petition process to request the disclosure of chemical identity claimed as trade secret. This petition process is only for requesting a review of the validity of a claim that a chemical identity is a trade secret. If requesters want disclosure of other items that have been claimed confidential (that is, items claimed as confidential in the substantiation, rather than the Title III reporting document), such requests for disclosure must be made pursuant to EPA's Freedom of Information Act regulations under 40 CFR Part 2.

The petition requesting disclosure must include the petitioner's name, address, and telephone number. The petitioner may be an individual, corporation, or other entity. It must also include the sanitized copy of the submission (e.g., the MSDS, toxic chemical release inventory reporting form) in which the chemical is claimed as trade secret, and the petitioner must clearly indicate on the form which chemical identity is requested for disclosure. Copies of the section 303 (d)(2) and (d)(3) filings are available at a location designated by the local emergency planning committee. Copies of the section 311 and 312 filings are available at locations designated by the State emergency response commission and the local emergency planning committee. Copies of the section 313 filings are available from EPA and from the designated State agency.

EPA is requiring that a copy of the submission claiming trade secrecy accompany petitions for disclosure of chemical identity claimed as trade secret. The Agency believes that the requirement of a copy serves to prevent any confusion about what disclosure the petitioner is requesting. In the proposed rule, public comment was specifically requested on this issue. All four of the commenters who addressed this issue agreed that a petition for the disclosure of a chemical identity claimed as a trade secret should include a copy of the submission claiming the trade secret.

One commenter requested that the trade secret submitter be informed of the identity of a petitioner who has petitioned for the release of a trade secret specific chemical identity. This is not required by the statute and the Agency has decided not to add it to the final rule. However, the petitioner's name is publicly available under the Freedom of Information Act. Also, the petitioner is free to contact the facility directly.

EPA received several comments concerning standards for the petition process. A few commenters requested that EPA restrict the petition process in order to discourage petitioners who are seeking information for commercial, competitive or harassment purposes. Other commenters highlighted the importance of placing no limits on petitions to disclose the specific chemical identity since no restrictions were set forth in the statute. EPA agrees that it would be inappropriate to require petitioners to have a particular reason for requesting disclosure of chemical identity claimed as trade secret. The statute specifically states that "any person may petition the Administrator" and thus the Agency will not impose restrictions.

At least one commenter requested that EPA limit the number of times a trade secret could be challenged through the petition process, to avoid the filing of multiple petitions for disclosure of the same trade secret. However, the limitations of the statute, as described above, apply to the multiple petition situation as well, and EPA can provide no change in the final rule.

As soon as a petition is filed, EPA will begin the process of reviewing the trade secrecy claim. The time for reviewing the claim may vary, but the statute requires EPA to reach a decision within 9 months.

The petition should be mailed to the address set forth in § 350.16 of the rule, and set forth in this preamble at section II.B.4.

IV. EPA Review of Trade Secrecy Claims

As described in the proposed rule, section 322 defines the process by which EPA determines whether a claimed chemical identity is entitled to trade secrecy. First, EPA must decide whether the answers to the substantiation questions are, if true, sufficient to support the conclusion that the chemical identity is a trade secret. This is the determination of sufficiency referred to in the statute and is made prior to any determination of the validity of the trade secrecy claim. The statute requires EPA to follow different procedures depending on whether EPA decides the answers to the substantiation questions are sufficient or insufficient.

A. Overview of the Process

After receiving a petition requesting disclosure of chemical identity, EPA has 30 days to make a determination of sufficiency. If the claim meets EPA's criteria of sufficiency (explained in IV.C), EPA will notify the submitter that he has 30 days from the date of receipt of the notice to submit supplemental material in writing, supporting the truth of the assertions made in the substantiation. If this additional information is not forthcoming, EPA will make its determination based only upon information previously submitted in the substantiation.

If the claim does not meet the criteria of sufficiency, EPA will notify the submitter, who may either file an appeal within 30 days to EPA's Office of General Counsel or, for good cause shown, amend the substantiation in support of its claim.

Once a claim has been determined to be sufficient, EPA must decide whether the claim is entitled to trade secrecy. If EPA determines that the facts support the claim of trade secrecy, the petitioner will be notified. If EPA determines that the facts do not support the claim of trade secrecy for chemical identity, the submitter will be notified.

The statute provides for intra-agency appeal by the submitter to appeal adverse decisions and for U.S. District Court review after intra-agency appeal. This process is explained below in more detail.

B. Initial Review

Proposed § 350.9(d) required that when EPA receives a petition requesting disclosure of a trade secret, or if EPA decides to initiate a determination of the validity of a trade secrecy claim, EPA shall first determine whether the chemical identity claimed as trade secret is the subject of a prior EPA determination of trade secrecy for that chemical identity at that same facility. If the earlier determination held that the facility's trade secret claim for the chemical identity was invalid, EPA was previously authorized to release the information. Before releasing the information, the proposed rule stated that the Agency would notify the petitioner that the facility's claim for trade secrecy status for the chemical identity is the subject of a prior determination concerning the same facility and that such claim was invalid.

Four commenters discussed the role that prior determinations should play in determining the validity of a trade secret claim. Some commenters said that prior determinations denying claims of trade secrecy should not be determinative of future claims concerning the same chemical, and suggested that this could violate constitutional due process. One commenter suggested that, in the alternative, the section should be revised to give equal weight to prior determinations that *upheld* the trade secret. Two commenters stated that once a specific chemical identity has been determined to be a trade secret, that finding of validity should be determinative against subsequent challenges to the same chemical.

While the Agency is not changing the scope of the provisions dealing with prior determinations in the final rule, EPA believes that some clarification of § 350.9(d) would better explain the nature of the prior determination and would respond to the commenter's concerns. The purpose of § 350.9(d) is to establish a simple procedure for releasing a chemical identity which has already been disclosed in a prior determination for the same chemical identity at the same facility. If the trade secret has been previously disclosed, Title III does not permit EPA to continue to withhold the chemical identity as a trade secret. Obviously, if the chemical identity has been revealed, the chemical identity is no longer a trade secret. Of course, the Agency's prior determination that the trade secret is invalid must have survived any appeals before the disclosure provision will be applied. The value of this provision was to expedite release of chemical identity which has already been revealed, but to satisfy due process EPA will not disclose the identity until the submitter has exhausted his challenges to the initial

Agency determination upon appeal to OGC and in U.S. District Court. The final rule has been amended to clarify this point.

The Agency is bound by the prior disclosure only if the chemical identity claimed as trade secret that is the subject of the second petition is identical to the trade secret disclosed when the prior determination held the claim to be invalid. There may be instances where the use of the chemical identity claimed as trade secret that is subject to the prior petition (and Agency determination) is different from the trade secret use that is the subject of the second petition. The information on different Title III submittals could represent different uses, one that did not qualify for trade secret protection under Title III and one that does. In short, EPA agrees with commenters to the extent that § 350.9(d) in the final rule will not automatically disclose a chemical identity until the Agency has determined that the identical trade secret has been held invalid in a prior determination.

The Agency will not be bound by a prior decision upholding trade secret protection in this rule. Trade secrets can be lost over time and the burden is on the claimant to prove that the chemical identity meets the statutory criteria upon receipt of a petition for disclosure. However, the Agency's prior determination of validity will be considered in later determinations.

Two commenters asked that a trade secret claimant be given adequate notice before a chemical identity is released. One of these commenters stated that if a prior determination was made that a facility's chemical identity was not a trade secret, EPA should delay 30 days before releasing the information in order for the claimant to seek judicial review. EPA has provided notice of intent to release chemical identity in various sections of the proposed rule where the Agency has determined that the chemical identity claimed as trade secret is not entitled to protection. The case of disclosure of chemical identity where a prior determination has been made is not significantly different from those other cases where the rule provides for notice and the opportunity to appeal to U.S. District Court before release of the claimed trade secret. As a result, § 350.9(d) of the final rule will be referenced to an amended § 350.18(c) which contains detailed requirements for notice of intent to release chemical identity determined not to be trade secret.

C. Determination of Sufficiency

A person withholding specific chemical identity from a submission under Title III must make specific factual assertions that are sufficient to support a conclusion that the chemical identity is a trade secret. These assertions are made by completely answering all of the questions listed in § 350.7 of the rule (and found also on the Trade Secrets Substantiation form), where EPA has listed the questions that must be answered to fully address the four requirements set forth in section 322(b) of the statute.

To assist submitters in answering the questions, EPA indicates in § 350.13 of the rule the criteria that it regards as the legal basis for evaluating whether answers provided by submitters are sufficient to support the trade secrecy of a chemical. Submitters may wish to examine these criteria in preparing their answers to the questions contained on the form.

EPA received several comments discussing the proposed sufficiency criteria. Some comments suggested that the Agency reduce the detail of the sufficiency criteria, so that the sufficiency criteria are not overinclusive of the statutory criteria and, in turn, the questions on the proposed form. The suggestions leaned toward making the sufficiency criteria identical to the proposed questions. Other comments suggested altering the proposed questions so that they identically reflect the sufficiency criteria. This way a claimant can directly address the criteria that EPA is seeking in order to establish a prima facie case of trade secrecy. Finally, other comments suggested that EPA review the proposed substantiation form to match the trade secrecy factors in section 322(b). This would substitute for the proposed sufficiency criteria altogether.

EPA determined that the sufficiency criteria, as proposed, are a valuable aid in evaluating the sufficiency of trade secret claims. While the substantiation form elicits specific facts, the criteria stated at § 350.13 are the legal standard used to determine whether the submitter has established a prima facie case for trade secrecy. The facts from the form are considered against the sufficiency criteria to make that determination.

The commenters' suggestions would alter the purpose of the criteria and undermine the ability of the Agency to determine whether or not submitters have made a prima facie case for trade secrecy under the initial review process. EPA did make changes in the sufficiency criteria to reflect changes made in the substantiation questions.

Submitters are encouraged to use the sufficiency criteria as a guide in formulating their answers to the substantiation questions. Both the questions and the criteria reflect the trade secrecy provisions of section 322(b) of Title III.

Under the first criterion, the facts must show that reasonable safeguards have been taken against unauthorized disclosure of the specific identity, that the specific chemical identity has not been disclosed to any person not bound by a confidentiality agreement including local, State or Federal government entities, and that any safeguards will be continued in the future.

Under the second criterion, the submitter must show that the chemical identity claimed as trade secret is not required to be released: (1) Under a determination by a State or Federal agency that the chemical identity in question is not a trade secret, or (2) under a State or Federal law which does not allow the chemical identity to be claimed as trade secret. This criterion was also discussed in section II.A. of this preamble under emission and effluent data.

Under the third criterion, as proposed, to show that disclosure of the information is likely to cause substantial competitive harm, the facts must show that either competitors do not know that the substance can be used in the fashion used by the submitter and that duplication of the specific use cannot be determined by competitors' own research activities or that competitors are unaware that the submitter is using the substance in this manner.

Some of the comments on substantiation Question 4 also raised similar concerns with this criterion. The final sufficiency requirement has been amended where appropriate to reflect the Agency's determination that a submitter cannot be required to certify another's state of knowledge, yet must adequately support his claim of trade secrecy. The revised § 350.13(a)(3) reads as follows, in the final rule:

(i) Either:

(A) competitors do not know *or the submitter is not aware that competitors know* that the *chemical whose identity is being claimed trade secret* can be used in the fashion that the submitter uses it, and competitors cannot easily duplicate the specific use of this chemical through their own research and development activities; or

(B) competitors are not aware *or the submitter does not know whether competitors are aware* that the submitter is using *this chemical* in this fashion.

(ii) The fact that the submitter manufactures, imports or otherwise uses *this chemical* in a particular fashion is not contained in any publication or other information source (*of which the submitter is aware*) available to competitors or the public.

(Emphasis added to show changes in final rule.)

Several commenters, following the lead of the Chemical Manufacturers Association and the American Petroleum Institute, requested that EPA revise the final rule to recognize that just because one (or even several) competitors in a field of many know that a substance is being used in a particular fashion, this does not prevent the use from constituting a trade secret. EPA agrees with the commenters. The law of trade secrets does not require that the owner of the information be the only one aware of the information for it to be of value. The language of the rule refers to the knowledge of "competitors," and this is open-ended enough to encompass a claim asserted in a factual situation where some competitors are aware of a secret of which others are unaware. Therefore, EPA recognizes the validity of the commenters' arguments but has not changed the language of the final rule to reflect this. Trade secrecy claimants may file substantiations based on a factual situation such as the one described above.

Finally, the fourth criterion requires that a trade secret claimant show that the chemical identity claimed trade secret cannot be readily discovered by reverse engineering of the submitter's products or environmental releases. This requires the claimant to show that the chemical is not available to the public or competitors in the claimant's products or environmental releases. The claimant must show that the chemical identity is only discoverable using equipment that is not readily or generally available, that discovery requires the use of uncommon or exotic analytic techniques, and that the time, costs, and resources required for discovery exceed the benefits provided by the trade secret chemical. The more difficult, costly, and time-consuming the analysis required to discover the identity, the more likely the chemical identity will qualify for trade secret protection.

If the substantiation does contain sufficient answers, EPA will notify the submitter by certified mail. Under the statute, a finding of sufficiency automatically entitles the submitter to submit supplemental information to support the truth of the answers contained in the substantiation. This could include any information or documents which would demonstrate the veracity of the submitter's substantiation, or provide even greater detail in support of the submitter's claim. Based on comments on the proposed rule, EPA narrowed the level of detail required in the initial substantiation and thus increased the importance of the material provided in this second stage. This was done in order to decrease the initial burden without sacrificing the amount of information that would be used to determine the veracity of a claim of trade secrecy.

Upon receiving EPA's request for supplemental information, the submitter will have 30 calendar days to submit the information. If EPA does not receive the supplemental information within this time, it will make a trade secret determination based upon the information already submitted. One commenter inquired as to when the 30 days provided to submit additional information to EPA tolls. Specifically, must the information be received by EPA within 30 days or will the Agency adopt a "mailbox rule", as suggested by the commenter? The Agency has decided to adopt the "mailbox rule," and will consider the submission to be timely filed if postmarked within 30 days by certified mail with the U.S. Postal Service.

D. Determination of Insufficiency

If EPA concludes that a substantiation does not contain answers sufficient to support the four requirements of section 322(b), then EPA will find that the trade secret claim is insufficient. The submitter will be notified by certified mail of EPA's finding of insufficiency. The submitter may either appeal EPA's finding to EPA's Office of General Counsel or may amend its original substantiation if it demonstrates good cause to do so.

Good cause was limited in the proposed rule to the following:

(1) The submitter was not aware of the facts underlying the additional information at the time the original substantiation was submitted, and could not reasonably have known the facts at that time; or

(2) Neither EPA regulations nor other EPA guidance called for such information at the time the substantiation was submitted.

The Small Business Administration commented, prior to the publication of the proposed rule, that the good cause standard should include the circumstance where the submitter mistakenly does not provide information but otherwise acts in good faith to comply with the rule, and that such a provision was mentioned in the Conference Report.

Various commenters agreed with the Small Business Administration and criticized this provision as unduly harsh. These commenters noted that various circumstances could occur, such as clerical errors or explanations being separated from the substantiation forms, that would result in EPA receiving an incomplete substantiation.

EPA has evaluated these comments and largely agrees with the commenters. The Agency has included inadvertent omissions as one of the good cause exceptions in the final rule. It is still incumbent on submitters to ensure that claims are complete and properly packaged. Submitters should not be tempted to rely on this good cause exception to routinely cure defective submissions.

One commenter interpreted the "neither-nor" language in the second exception as indicating that the Agency would be giving guidance, which is published without notice and comment, the same weight as regulations. The commenter also noted that the Conference Report used the conjunctive "and." The Agency intended to adopt the same meaning as that included in the Conference Report. Accordingly this language has been changed in the final rule.

EPA has revised the good cause exceptions to read as follows:

"(A) The submitter was not aware of the facts underlying the additional information at the time the substantiation was submitted, and could not reasonably have known the facts at that time; or

(B) EPA regulations and other EPA guidance did not call for such information at the time the substantiation was submitted; or

(C) The submitter had made a good faith effort to submit a complete substantiation, but failed to do so due to an inadvertent omission or clerical error."

The submitter must notify EPA by letter of its contentions as to good cause and should include in that letter the additional supporting material. EPA will notify the submitter by certified mail if the good cause standard has not been met and the additional supporting material will not be accepted. The submitter may then seek review in U.S. District Court. If after acceptance of additional supporting material for good cause, EPA decides the claim is still insufficient, the submitter will be notified by certified mail and may seek review in U.S. District Court.

If EPA reverses itself on appeal or after accepting additional assertions for good cause, and decides that the trade secret claim is sufficient, then the claim will be processed as though it had been initially found to be sufficient. If upon appeal, EPA makes a final determination that the original answers in the substantiation were insufficient, the submitter may request review in U.S. District Court within 30 days of notice of the final determination.

E. Determination of Trade Secrecy

All claims determined to be sufficient either initially, after appeal, or after acceptance of additional material for good cause, will be examined in order to determine whether a valid claim of trade secrecy is presented. In making a determination of trade secrecy, EPA will examine the factual information provided in the substantiation form in light of the four factors under section 322(b).

If EPA decides that the chemical identity is a trade secret, the petitioner shall be notified by certified mail and may seek review in U.S. District Court. If EPA decides that the chemical identity is not a trade secret, the submitter shall be notified by certified mail and may appeal this determination to EPA's Office of General Counsel within 30 days. If EPA does not reverse its decision on appeal, the submitter may seek review in U.S. District Court within 30 days of notice of the final determination.

F. Appeals

Section 350.17 of the proposed rule established procedures for appeal from an EPA determination that a claim presented insufficient support for a finding of trade secrecy under § 350.11(a)(2)(i), or an EPA finding that a specific chemical identity is not a trade secret under § 350.11(b)(2)(i). The proposal provided procedures for filing an appeal to EPA's Office of General Counsel (OGC), a description of the appeal process in OGC, and procedures for further appeal to Federal court if OGC upholds the Agency's rejection of the claim for trade secret protection. The proposed rule did not specify the standard that OGC will apply in considering a submitter's appeal, nor did it provide for a hearing. These two features as well as other details of the appeal process received comment.

Two commenters requested that EPA amend § 350.17 to provide the right to a hearing on appeal to OGC. One of these commenters specified that the hearing should be provided upon request of the trade secret claimant.

One commenter asked that the regulation be revised to establish a standard under which review by OGC on appeal will be conducted. The same commenter further stated that, because a reviewing court will consider the Agency opinion on a de novo basis, OGC should use a de novo standard in reviewing the program office's decisions on appeal.

Four commenters stated that § 350.17 should be revised to require OGC to state the basis for its decision on appeal. Another of these commenters recommended the use of procedures paralleling those referred to in § 350.11(b), which are applicable to EPA's initial decision on a trade secrecy claim and require EPA to provide a claimant with the reasons for EPA's decision.

One commenter requested that the rule be revised to permit a submitter of a trade secret claim to appeal to OGC if his claim is judged to be insufficient, even after he has submitted additional material upon a showing of good cause.

EPA's provisions on appeals in § 350.17 closely follow the scheme for appeals under Title III. Title III did not provide the submitter with an opportunity for a hearing as part of the administrative appeal process and EPA will not include such a provision.

Title III also did not specify a standard of review for the administrative appeal process. In its review, the Office of General Counsel will be examining the entire record of the determination and statement of reasons. This review will encompass the complete file. Submitters who are denied trade secret protection have full access to U.S. District Court.

The Agency agrees with commenters that sound administrative procedures dictate that the submitter be provided with a statement of the reasons for OGC's decision to uphold or reverse the program office's decision on appeal. The final rule has been amended to include a requirement for a statement of reasons to accompany the OGC decisions upon appeal.

Finally, EPA has not changed the final rule to allow an appeal to OGC when a submitter whose trade secrecy claim has been found to be insufficient has chosen to submit additional material in support of its claim (for good cause shown). This provision tracks statutory language that permits the trade secret claimant to either amend the claim in order to meet the sufficiency requirements *or* to appeal the finding of insufficiency to OGC. If the claimant opts to amend the claim, the statute requires that the right to appeal the Agency's initial finding is forfeited. However, the submitter who loses the right to an OGC appeal still has the right to appeal the Agency's adverse determination to U.S. District Court.

Judicial Appeal

Section 350.18(c) of the proposed rule established procedures to be used by EPA when submitters are slow to appeal Agency decisions to U.S. District Court or fail to prosecute the appeal in a timely fashion. One provision of the proposed section received considerable comment. That provision authorized the Agency to disclose the identity of the trade secret, "once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or whenever it appears to the Office of General Counsel, after reasonable notice to the business, that the business is not taking appropriate measures to obtain a speedy resolution of the action."

In urging deletion of the provision, the commenters made several arguments. First, the commenters noted that, once the submitter's appeal is under the court's jurisdiction, there are existing mechanisms to insure a speedy resolution of the case at issue. The Federal Rules of Civil Procedure allow the government to request a status conference to press action (Rule 11) or to move for dismissal of the appeal for failure to prosecute if there is an undue delay (Rule 41). Next, a few commenters maintained that the government's action to speed up the appeal would destroy the trade secret unilaterally during the pendency of action challenging the government's right to make that destruction. The commenters believe this action was unfair and undercut the court's jurisdiction. Moreover, since a trade secret is an intangible property right guaranteed by Constitutional protections, government destruction of that property during the course of the appeal could constitute a violation of submitter's due process rights.

EPA has decided not to delete the provision in question in the final rule. The provision is identical to language in EPA's Confidential Business Information regulations at 40 CFR 2.205(f)(2), and thus makes Title III regulations consistent with similar EPA procedures. The language of proposed § 350.18(c) and final § 350.18(d) states that EPA *may* disclose the trade secret, that is, use of the provision is not mandatory. Also, this disclosure may take place only after reasonable notice to the business. Accordingly, EPA has finalized this section as proposed, except for changing the reference to the party appealing the denial from "business" (used in 40 CFR Part 2) to "submitters" (used in Title III).

G. Common Errors Found on Substantiations

The Agency examined a sample of substantiations received since the proposed rule was issued and discovered a number of errors that occurred frequently enough that the

Agency wishes to alert submitters to the need to carefully prepare their substantiations to avoid these, and other, errors. Common errors found by the Agency fall into the following categories:

(i) Problems associated with not using the EPA substantiation form;

(ii) Certification of the substantiation;

(iii) Contents of responses to questions in the form; and

(iv) Packaging of the claim.

In order for EPA to work together with claimants to adequately protect their trade secrets, EPA strongly advises claimants to submit claims according to the following guidelines. Failure to do so could result in the claim being found insufficient and/or frivolous. Submitters found making frivolous claims are subject to a penalty not to exceed $25,000 per claim. As stated in the preamble, EPA plans to evaluate claims and vigorously prosecute those found to be frivolous.

1. Problems Associated With Not Using the EPA Substantiation Form

The first area of errors concerned non-use of the substantiation form as provided in the rule. Several claimants devised their own substantiation form, or did not use any form at all. In almost every case where a submitter-devised form was used, the forms were inaccurately reproduced. This invariably led to inappropriate and inapplicable responses (many submitters had altered the wording of substantiation questions), and, especially where no form was used, entire areas of information required to be reported were omitted. Almost every submitter-devised substantiation form did not sufficiently identify the reporting facility. Also, many submitter-devised substantiations neglected to report the specific chemical identity, and all but one form that was reviewed for errors omitted the certification statement in its entirety.

EPA is required to collect the information requested by the form. Incomplete substantiations will in all likelihood be found insufficient to support the claim, and the claim will be denied. Moreover, the statute provides that a submitter who fails to provide information in the initial substantiation will be subject to a $10,000 penalty. Substantiations that do not sufficiently identify the chemical or reporting facility increase the likelihood of a finding that the facility is not in compliance.

Several claimants who used the Agency form failed to fill out the form in its entirety, or neglected to submit all the pages of the form. Although missing pages would ordinarily be expected to indicate a mere clerical error, at least one submitter omitted the same page in each filing for the facility, suggesting a systematic disregard for the rule's requirements. Again, the probable consequence of an incomplete substantiation is a $10,000 penalty, and the increased possibility that the claim will be denied.

2. Certification of the Substantiation

The next area of error concerns the substantiation form's certification. Common errors included the certification's inaccurate reproduction or omission in its entirety from submitter-devised forms, unsigned certifications, and photocopied signatures.

The certification statement may not be varied by submitters. It contains specific assurances regarding the quality of the information and statements regarding the submitter's obligations under Title III. Noncompliance with this specific certification requirement may jeopardize the trade secret claim.

An original signature is required for each trade secret substantiation submitted to EPA, both sanitized and unsanitized. An original signature indicates that the submitter is in fact certifying that the particular substantiation provided to EPA is complete, true, and accurate, and that it is intended to support the particular trade secret claim being made. In light of the heavy penalties for noncompliance, this requirement protects both the Agency and the submitter.

3. Contents of Responses to Substantiation Questions

The first common error in this area is the setting forth of conclusory statements rather than descriptive factual assertions. The proposed rule specifically stated that more than a conclusory statement of compliance must be made in the substantiation because EPA is required under section 322(d) to make a determination of sufficiency based upon the information provided by the submitter in the substantiation. To determine sufficiency EPA must decide, assuming that the assertions in the substantiation are true, whether the assertions are sufficient to support a claim of trade secrecy. Descriptive factual statements are necessary for this purpose. Conclusory statements of compliance do not provide enough information for EPA to make this determination. Substantiations containing only conclusory statements are therefore insufficient to support the claim.

In addition, mere conclusory statements are insufficient since EPA is required to evaluate whether the factual assertions are true based on supplemental information that a claimant may be required to submit following the initial review.

The second common problem in this area concerns what information may be claimed trade secret under Title III. EPA has received claims both for entire products (and not the chemical(s) that is (are) the trade secret), and for chemicals that are not reportable under Title III. Only the specific chemical identity required to be disclosed in sections 303, 311, 312, and 313 submissions may be claimed as trade secret. No other information may be withheld as a trade secret from publicly available Title III reports.

The final problem in this area is that location information claimed as confidential under section 312(d)(2)(F) should not be sent to EPA; this information should only be sent to the SERC, LEPC, and the fire department. EPA has received several claims accompanied by blueprints of facilities. It is neither necessary nor appropriate to send such information to the Agency.

4. Packaging of the Claim

The fourth problem area involved packaging of claims. The items required for a complete filing have been varied from the proposed rule, so submitters are advised to pay close attention to what is needed. In order for a claim to be complete under section 322, the submitter must include in the submittal the following items: for section 303 reports and reporting by MSDS under section 311, a complete package will include 3 items: The public 303 report or 311 MSDS, and sanitized and unsanitized substantiation. Reports under section 311 using the list approach, 312 Tier II reports, and 313 toxi release inventory reports will include 4 items: Sanitized and unsanitized 311, 312, or 313 reports, plus a sanitized and unsanitized substantiation for *each* chemical claimed trade secret.

Because multiple chemicals may be reported (and claimed trade secret) using the 311 list method and under 312 Tier II, it is of paramount importance that claimants (1) include in the unsanitized submittals the specific chemical identity being claimed trade secret, and (2) not separate the 311 or 312 filing from the accompanying substantiations.

In some cases, submitters provided separately each of the four parts of a trade secret submittal. The Agency must receive a complete package; otherwise, it is difficult to determine whether a claim is complete and what chemical(s) is (are) being claimed trade secret. If it is not clear that a chemical identity is being claimed trade secret, EPA will not know that it should not make the information available to the public. For the submitter's own protection, securing together all three or four parts of a claim will make it clear that a claim is complete when submitted.

These guidelines and requirements are designed for the submitter's and the Agency's protection. If they are not followed, it will be much more likely that the Agency will conclude, based solely on the information provided by a submitter, that a claim is frivolous or incomplete. It also makes more likely that the Agency will disclose information that the submitter intended to claim trade secret because it was not clear that a claim was being made. At the same time, following these guidelines permits EPA to make appropriate determinations of trade secrecy, and to legally make public those portions of each submittal required to be disclosed. In this way EPA can work to preserve the confidentiality of legitimate trade secrets, and fulfill the Congressional mandate to make non-trade secret information public.

H. Enforcement

Section 325(d) authorizes the Administrator to assess a civil penalty of $25,000 per claim against a trade secret claimant if the Administrator determines that a trade secret claim is frivolous. Two commenters asked for an explanation of the term "frivolous claims." One of these commenters asked for policy guidance and recommended that a good faith test be employed. A third commenter expressed support for the Agency position on frivolous claims, and requested that the Agency determine the validity of each trade secrecy claim without waiting for petitions for disclosure of the information.

A frivolous claim is one without a factual or legal basis or one where the facts and circumstances relied upon to substantiate a trade secrecy claim are without merit. Section 325(c) authorizes the assessment of a civil penalty of $10,000 per violation for any person who fails to furnish a substantiation. These penalties can be assessed by either administrative order or through the appropriate U.S. District Court.

The proposed rule contained a provision indicating that submitters of trade secret claims who failed to submit supplemental information requested by EPA may be liable for a fine of up to $10,000 per violation under section 325(c). When EPA reviewed the statute, it was found that this provision had been inadvertently included in the proposed rule, but was not contained in the Act. The final rule, therefore, contains no such provision.

V. Relationship of Section 322 to Other Statutes

A. Relationship to State Confidentiality Statutes

As stated in the proposed rule, section 321 of Title III provides that nothing in Title III "shall preempt any State or local law." This means that the confidentiality requirements of Title III are not to displace State confidentiality requirements under State Right-To-Know Acts. A State can still prescribe the type of information it will classify as confidential when it gathers information for its own use under a State law, such as a Right-To-Know Act. However, state confidentiality statutes do not govern information gathered under Federal law, here Title III. State confidentiality statutes only apply to information collected pursuant to State law for State use. When information is gathered under Title III, the Federal confidentiality requirements of section 322 apply regardless of whether the information is sent to a State or Federal agency because the information is being gathered pursuant to a Federal statute.

One commenter requested that the "other" information in the Title III trade secret substantiation that is protected under the Freedom of Information Act be covered instead under more protective State law. The commenter argues that this is justified because the information is being sent to State and local entities. As stated above, the destination of the data is irrelevant because it is being gathered pursuant to a Federal statute and thus the only protection allowed is Federally based.

State confidentiality statutes may affect Title III information if State trade secrecy law or regulations prohibit claims of trade secrecy under State law for information that a submitter must also report under Title III. Under the substantiation provisions of Title III, a facility will not be able to justify withholding the information under Title III. One commenter stated that a State law may require submission of data and provide greater public access to the data than would be allowed under Title III protection of trade secrets. In such cases, the data may not be eligible for trade secret treatment under section 322.

B. Overlap with Other EPA-Administered Statutes

Information collected pursuant to EPA regulations under statutes other than Title III may be similar to that collected under Title III. For purposes of confidentiality, information should be claimed as confidential and will be treated by EPA as is required by the statute under which it is collected. However, the mandatory release of information under one statute may affect its trade secret status under another statute.

C. Relationship to Freedom of Information Act

The procedures set out in section 322 apply only to claims of trade secrecy for chemical identity made under Title III. Pursuant to section 322(f), however, submitters may claim as trade secret any other confidential business or trade secret information which is included in the substantiation, or supplemental information submitted in the petition process. Requests for disclosure of this material must be submitted under the Freedom of Information Act regulations at 40 CFR Part 2. EPA will make determinations regarding the disclosure of this material under those regulations.

VI. Release of Trade Secret Information

A. Releases to States

Under section 322(h) of the Act, the States, either the governors or the State emergency response commissions, must provide to any requesting person the adverse health effects associated with extremely hazardous substances (section 303) and hazardous chemicals (sections 311 and 312) claimed as trade secret. The States will not have direct access to the identities of chemicals claimed as trade secret in preparing adverse health effects descriptions. However, the States have information on health effects in the MSDSs submitted under section 311 for this purpose. The MSDS is required to include such information for any substance claimed as trade secret. Thus, governors or State commissions should not be hindered in meeting their responsibilities to provide descriptions of adverse health effects and the trade secret status of the chemicals will not be endangered.

Under section 322(g) of the Act, the Administrator shall provide to the State governor, upon request, any information EPA has obtained under subsection (a)(2), which includes specific chemical identities and substantiations for trade secrecy claims, and under subsection (d)(3), which includes the findings that assertions made in the above substantiation materials are sufficient. Thus, if a State governor wished to request the chemical identities of any or all chemicals claimed as trade secret in any State, EPA will provide this information to the State governor, upon request. However, governors are prevented by section 325(d)(2) from "knowingly and willfully" disclosing trade secret information to the public, as are all other individuals.

EPA considered the advantages and disadvantages of allowing State governors to provide access to trade secret information to SERCs and LEPCs. Public comments also proposed several alternative ways of restricting disclosure of trade secret information released to States.

While providing selected members of SERCs and LEPCs access to chemical identities may provide some benefits to State and local preparedness and planning, it was determined that these potential advantages were outweighed by the possible consequences of unintended disclosure of bona fide trade secrets. Because SERCs often include representatives from industry and the public and LEPCs must include these representatives from industry and the public, it could be very difficult to protect trade secrets from wider disclosure than is intended. EPA determined that the decision of whether State governors may provide trade secret information to any members of SERCs and LEPCs shall be left up to the discretion of the governors themselves. However, EPA has included a provision in the rule which prohibits State governors from releasing trade secret information to non-State employees. One commenter requested that trade secret information be given to a State only after the State has demonstrated its ability to safeguard trade secret information. The Agency requires in the rule that States take the same precautions to safeguard this information as EPA itself does. The Agency believes that this approach is appropriate to adequately protect trade secret information.

The Agency considered the option of allowing State governors to appoint designees to be provided with the authority to request trade secret chemical identities from EPA. This could expedite requests by the State departments of public health for information needed to conduct medical research on the health effects of airborne toxics. However, such an expansion of the list of authorized State representatives beyond governors alone might also increase the likelihood of unintended disclosure of bona fide trade secrets. The Agency concluded that it does not have the authority to determine who State governors may authorize to obtain trade secret information from EPA. Consequently, the EPA determined that only State governors are authorized to request and receive trade secret information directly from EPA, as stated in the statute.

B. Releases to Authorized Representatives of EPA

In addition to contractors and subcontractors, EPA has recently begun to use grantee personnel to perform Agency functions. Public comments raised two points. First, it was suggested that the employees of grantees be required to sign confidentiality agreements (as is required of the employees of contractors and subcontractors). Second, grantees were described as presenting a greater risk of disclosure of trade secrets (because they are typically retired engineers or other technical people having close associations with former employers) and should be placed under greater restrictions than contractors or subcontractors in general. Greater restrictions were suggested to include either requirements for signing written conflict-of-interest statements or requirements that grantees must demonstrate a greater need for trade secret information.

The Agency believes it is appropriate to designate grantees as "authorized representatives," to be treated in the same manner as Federal contractors and subcontractors, as that term is used in this regulation. This includes requiring full confidentiality protection, the same procedures that contractors must follow, and similarly employees of grantees will be required to sign confidentiality agreements.

One commenter objected to proposed § 350.23, which makes contractors authorized representatives of EPA for the purposes of the release of trade secret information. This provision is mandated by the Act, however, and the Agency cannot alter or delete it. Another commenter requested that the Agency add a provision to the final rule to make contractors who receive trade secret information on behalf of EPA aware of potential conflicts of interest. The Agency has decided not to do so because contractors are already required to provide the Agency with such assurances as part of the contractual process.

One commenter stated that EPA should comply with Export Administration Act (EAA) restrictions on the export of technical data through foreign nationals. The commenter suggested that through the petition process, and in particular through releases to health professionals, technical data could be exported. The commenter also questioned whether there exist suitable precautions to prevent the export of technical data through EPA's contractors, subcontractors, and grantees to the EPA. Especially of concern would be the disclosure of confidential business information to a citizen of a Category S or Z country, which are listed in the Export Administration regulations.

EPA has determined that the intent of these regulations is consistent with those implementing the Export Administration Act. The definition of "technical data" found in the EAA regulations reads in part as follows: "Technical data means information of any kind that can be used, or adapted for use, in the design, production, manufacture, utilization, or reconstruction of articles or materials." In section II.A. of the preamble to these regulations, the definition of trade secret protection of specific chemical identity was said to allow for trade secrecy claims to be made to protect the linkage between a specific chemical identity and its "use, production, storage, or processing." While these definitions are similar, it is noteworthy that these regulations are designed to protect the described information from release except under very narrow, clearly defined, and controlled circumstances.

It is not EPA's intention for a foreign national to obtain trade secret information and export the information. The intent of the statute is "community right to know." EPA has every intention of doing everything in its power to assure that the information collected is used to inform and protect local residents from chemical hazards present in their communities. Disclosures which lead to the export of that information out of the United States run counter to that intent.

The statute does not require, and EPA has declined to establish a requirement in these regulations, that petitioners for information claimed as trade secret declare the reasons for their request. It would go beyond the content of the statute for EPA to require them to state that they are citizens of the United States. When the request of a petitioner for release of information claimed to be trade secret is granted, the Agency has determined that the information is not, in fact, a trade secret.

As to the export of technical data through contractors, subcontractors, and grantees to the EPA, these authorized representatives of EPA are required to sign confidentiality agreements and to provide full confidentiality protection.

VII. Disclosure to Health Professionals

Section 323 of Title III consists of three provisions regarding access to chemical identity information by health professionals. These provisions require the facility owner or operator to disclose the chemical identity, including trade secret chemical identity, to a health professional for diagnosis or treatment in both non-emergency and emergency situations, and for purposes of conducting preventive research studies and providing medical treatment by a health professional who is a local government employee. The health professional must sign a statement regarding his need for the chemical identity, and a confidentiality agreement, prior to disclosure, except in emergency situations, when these two documents may be delivered later.

One commenter requested that EPA delete entirely the requirement to provide specific chemical identity to health professionals. The commenter indicated that, in its experience, health professionals were more concerned with obtaining detailed health and safety data than the specific chemical identity. However, the commenter overlooks the fact that the provision of the specific chemical identity, under specified circumstances, is a direct requirement of section 323 of Title III. EPA cannot alter the basic requirements of the statute.

Health professionals may obtain trade secret information for the three purposes set out in the statute. However, they are required to sign a confidentiality agreement and a statement of need stating that they need the information for the purposes set out in the statute.

A. Non-emergency Diagnosis or Treatment

The first provision, part (a) of section 323, requires that in non-emergency situations, an owner or operator of a facility which is subject to the requirements of sections 311, 312, or 313, shall provide the specific chemical identity, if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical to a health professional who requests the identity in writing and describes in a written statement of need described below a reasonable basis for suspecting that the specific chemical identity is needed for diagnosis or treatment of an individual or individuals who have been exposed to the chemical concerned. The health professional must also state that knowledge of the specific chemical identity will assist in diagnosis or treatment of the exposed individual(s). The health professional must certify that the information contained in the statement of need is true and accurate. The health professional must also provide a signed confidentiality agreement described in VII.E to the facility prior to gaining access to trade secret chemical identity. Any health professional performing diagnosis or treatment, not solely doctors or nurses, is permitted access to trade secret chemical identity in a non-emergency situation.

B. Emergency Situations

The second provision of section 323 deals with medical emergencies and requires an owner or operator of a facility subject to the requirements of sections 311, 312, or 313 to immediately provide a copy of an MSDS, an inventory form, or a toxic chemical release form, including the specific chemical identity, if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical, to any treating physician or nurse who requests the chemical identity under emergency conditions as specified in the statute. The treating physicians or nurses must determine that: (1) a medical emergency exists; (2) the specific identity of the chemical concerned is necessary for or will assist in emergency or first-aid diagnosis or treatment; and (3) the individual or individuals being diagnosed or treated have been exposed to the chemical concerned.

In response to public comments, EPA considered whether health professionals other than treating physicians and nurses (such as commercial spill contractors, paramedics, and other emergency medical services workers) should be provided access to trade secret chemical identities under this provision. The Agency decided that only treating physicians and nurses are entitled to such access, in accordance with the specific wording of the statute and following the intent of the OSHA provisions. In a medical emergency, only the doctor or nurse will conduct the medical examination and diagnose the necessary treatment. Most necessary information could be obtained from MSDSs and other Title III forms. Consequently, it is not necessary for personnel other than doctors and nurses to have access to trade secret information.

The requesting physician or nurse in such an emergency does not need to submit a written confidentiality agreement or statement of need prior to receiving the trade secret chemical identity. The owner or operator disclosing such information may, however, require a written confidentiality agreement and statement of need as soon as circumstances permit.

Some industry commenters on the proposed rule expressed concern that although they would be willing to provide information in the case of a true emergency, that the procedures therein would not provide adequate protection against fraudulent attempts to obtain confidential information. EPA considered requiring procedures such as phone calls or the development of a system of identification numbers. These procedures, however, would be burdensome, beyond the scope of the statute and of limited efficiency for the various scenarios possible in emergency situations. For these reasons, EPA decided not to recommend a specific verification procedure. If the facility wishes to verify that the situation is an emergency, the facility must do so without compromising the need to immediately provide the information requested by treating physicians and nurses. Chemical identities absolutely may not be disclosed or used for any purpose other than the proper treatment and diagnosis of a chemically related injury or illness.

C. Preventive and Treatment Measures

The third provision of section 323 deals with preventive and treatment measures by local health professionals. This subsection is intended to allow local health professionals access to information on chemicals in order to facilitate epidemiological and toxicological research and to render medical treatment for the effects of chemical exposures. This subsection requires an owner or operator of a facility to promptly provide the specific chemical identity, if known, of a hazardous chemical, an extremely hazardous substance, or a toxic chemical to any health professional who is a local government employee or under contract with a local government who submits a request in writing and provides a written statement of need and a confidentiality agreement. The statement of need must describe one or more of the needs set forth in the regulations.

Under this section of the statute, EPA interprets the term "health professional" to be any health professional with the professional expertise to perform the types of research and treatment set forth in the statute, and who is employed by the local government. Under this section, such health professionals as physicians, toxicologists and epidemiologists may gain access to trade secret chemical identity.

A few industry commenters argued that a provision should be made for allowing disclosure of relevant health effects information other than the chemical identity in this preventive and treatment measures section. They asserted that other information will be sufficient to conduct the listed types of studies and surveillance. EPA considers it inappropriate to place regulatory limitations on the six statutory situations in which health professionals may seek disclosure of chemical identities because they are explicitly mentioned in the statute.

D. Statement of Need

In the proposed rule, EPA requested comment concerning whether the statement of need should contain a detailed description of why the disclosure of the following information would not be sufficient to enable the health professional to provide medical services: (a) The properties and effects of the chemical, (b) measures for controlling the public's exposure to the chemical, (c) methods of monitoring and analyzing the public's exposure to the chemical, and (d) methods of diagnosing and treating harmful exposure to the chemical. These are the provisions in the Occupational Safety and Health Act Hazard Communication Standard. One commenter objected strongly to the inclusion of these provisions, citing the paramount interest in allowing health professionals to "undertake their own independent course of treatment, and hopefully to prevent future disease." Industry commenters, on the other hand, asserted that, in the vast majority of cases, information necessary for diagnosis and treatment can be provided without disclosing specific chemical identity. They argued for a presumption against disclosure, which would justify a higher standard for the health professional to meet in demonstrating that trade secret information should be disclosed.

The Agency has decided not to explicitly include the OSHA provisions in the final rule. The statutory requirement that a health professional describe "a reasonable basis" why the specific chemical identity is needed will implicitly explain why other information would not be sufficient. The Agency believes the OSHA provisions would be unnecessary.

E. Confidentiality Agreement

The confidentiality agreement required of the health professional must state that the health professional will not use the trade secret chemical identity for any purpose other than the health needs asserted in the statement of need, or as may otherwise be authorized by the terms of the agreement itself. This agreement may be negotiated between the health professional and the facility.

The provisions in the confidentiality agreement will enable the health professional to clearly understand the extent of disclosures permissible. At a minimum, the written confidentiality agreement shall include a description of the procedures to be used to maintain the confidentiality of the disclosed information and a statement by the health professional that he will not use the information for any purpose other than the health needs asserted in the statement of need. Also, the health professional must agree not to release the information under any circumstances, except as authorized by the terms of the agreement. However, this authorized disclosure may be structured so that the health professional may release the trade secret chemical identity to other health professionals if the professionals routinely rely on each other's expertise for needed advice. The agreement may also specify that the first health professional may disclose the trade secret chemical identity to other health professionals if such disclosure is necessary in order for the first professional to learn necessary information to render a professional opinion. Except in those instances specified in the confidentiality agreement, the health professional may not be permitted to release the information to other health professionals. The health professional may be permitted to write articles for medical journals or to go on speaking tours discussing the chemical involved if such activity does not result in the disclosure of the identity of the chemical and the facility's relationship to that chemical.

The proposed rule included a reasonable pre-estimate of damages as an appropriate legal remedy in the event of a breach of the confidentiality agreement. Commenters expressed concern that inclusion of pre-estimates of damages in confidentiality agreements may have a chilling effect on health professionals, discouraging them from entering into such agreements. Many health professionals may be unable or unwilling to assume the liability associated with such a provision in exchange for obtaining information necessary for them to provide proper treatment or diagnosis. Several commenters characterized this liability as "unreasonable" and "not contemplated by the legislation." EPA agrees with the commenters and the provision for a pre-estimate of damages has been deleted from the final rule. The Agency believes that the underlying purpose of the confidentiality agreement is to protect a facility's trade secret chemical identity from unlimited and unbridled disclosure, not to make it overly burdensome or difficult for the health professional to obtain the specific identity of a chemical.

This confidentiality agreement is subject to State law and State contractual remedies. Also, nothing in this regulation precludes the facility or health professional from pursuing non-contractual remedies to the extent permitted by law.

F. Related Issues

Following the receipt of a written request, the facility owner or operator to whom such request is made shall promptly provide the requested information to the health professional. EPA considered specifically defining "promptly" and "immediately" to mean a particular number of days. Two commenters discussed the Agency's failure to define the term "immediately" in the context of the requirement to release chemical identification information to health professionals. One of these commenters asked that the Agency define the term, while the other commenter expressed support for the Agency's decision to not specify a particular time period to provide the information. For the reasons stated above, the Agency will refrain from defining "immediately" more specifically. The Agency did not receive any comments on this issue and has decided not to define the terms because of the concern that defined times will limit the speed of response. The statute requires "immediate" provision of data in the case of medical emergencies and EPA interprets this to mean that the owner or operator will provide the data over the telephone, without requiring a written statement of need or a confidentiality agreement in advance.

As stated in the proposed rule, the Agency is aware of the possible situation where the owner or operator of a facility is unable to provide the chemical identity because the manufacturer of the chemical has kept the identity confidential. In these situations, EPA suggests that the owner or operator of the facility put the requester in touch with the supplier of the chemical, but the facility is not responsible for supplying information which it cannot obtain for itself.

EPA received a comment that if a patient becomes aware, or wishes to learn, the chemical identity of a substance he was exposed to, he should be required to sign a confidentiality agreement. Since the provisions of section 323 deal only with the release of information to health professionals, the Agency cannot require disclosures to patients as part of this rulemaking.

The regulation authorizes health professionals to refer to trade secret chemical identity in discussions with EPA personnel, who themselves are authorized to have access to Title III trade secret information. This is based on a provision of the OSHA Hazard Communication Standard. Several commenters suggested that the Title III regulations should restrict the release of confidential information from health professionals to EPA to a greater extent than was provided in the proposed rule. Specifically, several commenters stated that Title III trade secret regulations should mirror the procedures in the OSHA Hazard Communication Standard, which requires that the government provide notice to the facility owner or operator whenever a health professional transmits trade secret information to the government agency. Based on the comments, EPA considered three options for restricting releases of trade secret information from health professionals to the Agency. First, EPA considered the addition of a requirement similar to OSHA's that notice be given to the facility owner or operator whenever a health professional provides trade secret information to EPA. The second option considered was the limitation of communications between EPA and the health professional to the generic class or category, in non-emergency situations. The third option considered was to establish procedures similar to Confidential Business Information (CBI) Procedures utilized under TSCA. In this option, the health professional would be required to verify that an EPA employee is on a CBI authorized access list before disclosing trade secret chemical identities.

EPA evaluated the options and decided that each one would impede timely transmission of important health effects data necessary for proper diagnosis and treatment. The procedures would be administratively cumbersome and they are not explicitly required by the statute. The Agency is already fully aware of the necessity to protect trade secret information and believes additional procedures are unnecessary.

EPA construes section 323 to mean that a facility is not permitted to deny disclosure of a specific chemical identity to a health professional under any circumstances provided there is a written statement of need and a written confidentiality agreement. Section 325(c) empowers EPA to assess civil penalties of up to $10,000 for failure to disclose the trade secret chemical identity to health professionals in emergency situations, as required by section 323(b). Health professionals may also sue under section 325(e) in U.S. District Court to obtain the information.

VIII. Summary of Supporting Analyses

A. Regulatory Impact Analysis

1. Purpose

Executive Order (E.O.) No. 12291 requires each federal agency to determine if a regulation is a "major" rule as defined by the Order and to prepare a Regulatory Impact Analysis (RIA) in connection with each major rule. EPA has determined that the requirements and procedures established in this rulemaking for treatment of chemical data considered to be trade secret by facilities reporting under other sections of Title III do not constitute a major rule under E.O. No. 12291. The Agency has prepared an economic analysis to assess the economic impacts of the final regulation on affected industry and government entities. The following summary of results are presented in detail in *Regulatory Impact Analysis in Support of Final Rulemaking under Sections 322–323 of the Superfund Amendment and Reauthorization Act of 1986.*

2. Methodology

EPA conducted an assessment of the costs and benefits associated with this final rule and the primary provisions of sections 322 and 323, including the preparation of trade secrecy claims by facilities; the processing and storing of claims by EPA; the public petition and review process; the provision of adverse health effects data for chemicals whose identities are withheld as trade secrets; and special access procedures under which facilities must promptly provide chemical data to members of the health profession.

This analysis considered the costs that five groups will incur as a result of the rule and the section 322–323 provisions. These five groups are: facilities, EPA, public petitioners, States, and health professionals.

The economic analysis conducted for the final rule took into account public comments on the proposed rule and modifications made to other Title III reporting provisions. Among the changes incorporated into the economic analysis supporting the final rule are the trade secret claims made by non-manufacturing facilities submitting reports under sections 311 and 312 of SARA; increased costs for the public petition and review process; and consideration of the potential for cost savings per claim that may result when facilities file trade secret claims for the same chemical under different Title III reporting sections.

The economic analysis for the final rule confirms that facilities will make trade secret claims in about 0.1 percent of the reports submitted under Title III. This confirmation is based on the low number of trade secret claims having actually been made by facilities in 1987 during the first round of reporting under section 311 of SARA.

3. Results

The economic analysis conducted for the final rule estimated the costs that would be incurred by each of the five groups affected by the rule and the statutory provisions. The aggregate present value costs during the first 10 years of Title III reporting, using a discount rate of 4 percent, are estimated to be approximately $67.6 million, or an average of $6.8 million annually. The following discussion summarizes the costs that each of the major groups is estimated to incur.

Facilities. Industrial facilities incur the largest amount of costs in preparing and filing trade secret claims. They also will incur costs when they respond to public petitions challenging their trade secret claims and when they provide trade secret information to health professionals.

Facilities will incur the greatest costs in 1990, when the section 311 MSDS reporting threshold for non-manufacturing facilities is assumed to decline from 10,000 pounds to 500 pounds. The 1990 facility costs are estimated in the analysis to be approximately $26.4 million.

The analysis also estimates the costs of an individual facility filing a trade secret claim for the first time and the costs to file subsequent trade secret claims. An average facility will incur costs of approximately $1,100 when it files its first trade secret claim, and between $270 and $563 when it files a subsequent claim, depending on the type of claim made. If the public challenges a trade secret claim that a facility makes, the analysis estimates that a facility will incur an average of about $1,300 dollars to provide supplemental information to support the original substantiation. The analysis also estimates that these costs could range as high as $3,400 if a facility's claim is rejected by EPA and the facility appeals the decision to EPA's Office of General Counsel. Finally, the analysis estimates that facilities will incur costs under the provisions of section 323 that range from $110 to $250 in responding to each request made by a health professional for information about trade secret chemicals.

The time burden that this rule places upon facilities having trade secrets is estimated to consist of: 10.4 hours for a facility to become familiar with the provisions of the rule and screen its chemicals to determine which are trade secrets, 22.8 hours to prepare a claim (including 21.3 hours to complete the substantiation form) for the first chemical submitted as a trade secret, and 17.7 hours to prepare additional claims for other chemicals (including 16.2 hours per chemical to complete the substantiation form). In cases where a facility submits claims for the same chemical involving reports made under different sections of Title III, the additional related claims require less effort because the facility will be able to utilize some or all of the information prepared for the first claim (generally associated with the chemical's MSDS filing). The time needed for each such related claim is estimated to range from 1.7 to 14.6 hours.

EPA. The economic analysis estimates the aggregate ten-year present value cost that EPA will incur under the three sections of the rule to be approximately $2.6 million, or an average of $260,000 annually. These costs result from EPA processing and storing trade secret claims, responding to public petitions challenging trade secret claims, and providing adverse health effects information on section 313 chemicals to states and the public.

The processing and storing of trade secret claims and responding to public petitions result in EPA incurring the largest costs. The analysis estimates that EPA will incur costs of approximately nine dollars to process and store each trade secret claim, in addition to annual costs of approximately $60,000 to maintain a record storage and tracking system. The Agency also will incur average costs of approximately $1,900 when the public files a petition to challenge a trade secret claim. The analysis estimates that these costs could range from $1,450 to $5,040, depending on the circumstances of the claim and the decision made about the validity of the petition.

Petitioners. Public petitioners are estimated to incur total present value costs of about $48,000 over the ten year period analyzed in the report. Each public petition filed is estimated to cost the public petitioner approximately $75, and the public is assumed to file an average of 72 petitions annually during the first ten years of Title III reporting. The analysis estimates that the public will file the largest number of petitions in 1990, corresponding to the year in which facilities file the largest number of claims. The total estimated costs incurred by the public in 1990 are approximately $20,000.

States. The economic analysis conducted for the final rule estimates that the present value of costs incurred by the states will be about $443,000 during the first ten years of Title III reporting, or approximately $44,000 annually ($880 annually per state). These costs will be incurred in the course of requesting information from EPA on trade secret chemicals and disseminating adverse health effects information to the public. The analysis estimates that each state will incur costs of $33 to request from EPA adverse health effects information on section 313 chemicals; the state will incur costs of about $56 to respond to each request from the public for adverse health information on section 302–304 and 311–312 chemicals that facilities claim trade secret.

States also will incur costs to compile adverse health effects information on chemicals reported under Title III in preparation for public requests, and to sanitize the profiles in order not to divulge trade secret information. This is estimated to cost states approximately $85,300 in 1988, when they will develop most of the chemical profiles, and approximately $4,200 in each subsequent year to develop profiles for new chemicals that facilities claim trade secret.

Health Professionals. The analysis estimates that the aggregate present value costs to health professionals will be approximately $372,000 during the first ten years of Title III reporting, or approximately $37,200 annually. The analysis also estimates that health professionals will incur a range of costs between $110 and $140 in making a request of a facility for a trade secret, depending on the particular circumstances of the request as described under section 323 of the rule.

Sensitivity Analyses. After calculating aggregate costs for each of the five groups, eight sensitivity analyses were conducted to test the effect of important assumptions on the total costs of the rule. These analyses included the number of trade secret claims that facilities will file, the costs of filing a trade secret claim, the likely effect of linkage on the number of trade secret claims, the number of Tier II claims under section 312, the number of petitions that the public files challenging facility trade secret claims, the number of requests for adverse health effects information, and the number of requests health professionals make for the identity of trade secret chemicals.

The sensitivity analyses demonstrated that the costs of the final rule are most sensitive to the number of trade secret claims that facilities will file and the costs of filing each claim.

Benefits. Benefits may arise as a result of this rule both for facilities and for the public. Relationships among the activities undertaken by various affected groups are complex and only a qualitative discussion of benefits is included in the economic analysis. For facilities, direct benefits may include protection of trade secrets involving chemicals used in production processes, that, by definition, involve information that permit a facility to have a competitive advantage over another facility. For the public, the rule provides a petition and review process that allows challenge of the validity of a trade secret claim through an administrative review process, and allows health effects information to be disclosed without jeopardizing the competitive position of the facility.

B. Regulatory Flexibility Analysis

1. Purpose

Under the Regulatory Flexibility Act of 1980, a Regulatory Flexibility Analysis must be performed for all rule that are likely to have a "significant impact on a substantial number of small entities" (small businesses, small organizations, and small governmental jurisdictions). The analysis contained in this economic analysis addresses the impact of this rule on small entities. Based on this analysis, EPA has concluded that although a large number of small businesses reporting under Title III could be affected by this rule, the costs of the rule generally will be low on a per facility basis and that significant impacts will not result.

2. Methodology and Results

In order to assess the likely economic impacts that this final rule will have on small businesses, EPA compared likely average costs for small facilities to file a trade secret claim with median sales for those facilities, and evaluated whether the rule likely would affect a substantial number of small entities.

The results of the economic analysis show generally that the cost of filing a trade secret claim will not be a burden on facilities because the likely costs of filing a trade secret claim under a worst-case scenario tested in the analysis are less than one percent of median sales.

EPA defined small businesses in this analysis to be those with fewer than 20 employees. The number of small businesses under this definition is estimated to be approximately 2,794,400 facilities (the universe of facilities in categories covered by section 303, the broadest of the sections associated with trade secrecy claims). The economic analysis conducted for the final rule estimates that approximately 61,600 facilities will file trade secret claims during the first ten years of Title III reporting. If all facilities filing trade secret claims met the definition of "small business," this would encompass only 2.2 percent of small businesses, well below the usual level of 20 percent established by EPA to represent a "substantial" number of small facilities.

3. Certification

On the basis of the analyses contained in the economic analysis with respect to the impact of this rule on small entities, I hereby certify that this rule will not have a significant impact on a substantial number of small entities. This rule, therefore, does not require a Regulatory Flexibility Analysis.

C. Paperwork Reduction Act

Public reporting burden for this collection of information is estimated to vary from 27.7 to 33.2 hours per response, with an average of 28.8 hours per response, including 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 estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

OMB has reviewed the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and has assigned OMB Control Number 2050-0078.

List of Subjects in 40 CFR Part 350

Chemicals, Hazardous substances, Extremely hazardous substances, Toxic chemicals, Community right-to-know, Superfund Amendments and Reauthorization Act, Trade secrets, Trade secrecy claims, Intergovernmental relations.

Dated: July 21, 1988.

Lee M. Thomas,
Administrator.

For the reasons set out in the Preamble, Title 40 of the Code of Federal Regulations is amended by adding a new Part 350 to read as follows:

PART 350—TRADE SECRECY CLAIMS FOR EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW INFORMATION: AND TRADE SECRET DISCLOSURES TO HEALTH PROFESSIONALS

Subpart A—Trade Secrecy Claims

Authority: 42 U.S.C. 11042, 11043 and 11048 Pub. L. 99-499, 100 Stat. 1747.

Subpart A—Trade Secrecy Claims

§ 350.1 Definitions.

"Administrator" and "General Counsel" mean the EPA officers or employees occupying the positions so titled.

"Business confidentiality" or "confidential business information" includes the concept of trade secrecy and other related legal concepts which give (or may give) a business the right to preserve the confidentiality of business information and to limit its use or disclosure by others in order that the business may obtain or retain business advantages it derives from its right in the information. The definition is meant to encompass any concept which authorizes a Federal agency to withhold business information under 5 U.S.C. 552(b)(4), as well as any concept which requires EPA to withhold information from the public for the benefit of a business under 18 U.S.C. 1905.

"Claimant" means a person submitting a claim of trade secrecy to EPA in connection with a chemical otherwise required to be disclosed in a report or other filing made under Title III.

"Petitioner" is any person who submits a petition under this regulation requesting disclosure of a chemical identity claimed as trade secret.

"Sanitized" means a version of a document from which information claimed as trade secret or confidential has been omitted or withheld.

"Senior management official" means an official with management responsibility for the person or persons completing the report, or the manager of environmental programs for the facility or establishments, or for the corporation owning or operating the facility or establishments responsible for certifying similar reports under other environmental regulatory requirements.

"Specific chemical identity" means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance. Where the trade name is reported in lieu of the specific chemical identity, the trade name will be treated as the specific chemical identity for purposes of this part.

"Submitter" means a person filing a required report or making a claim of trade secrecy to EPA under sections 303 (d)(2) and (d)(3), 311, 312, and 313 of Title III.

"Substantiation" means the written answers submitted to EPA by a submitter to the specific questions set forth in this regulation in support of a claim that chemical identity is a trade secret.

"Title III" means Title III of the Superfund Amendments and Reauthorization Act of 1986, also titled the Emergency Planning and Community Right-to-Know Act of 1986.

"Trade secrecy claim" is a submittal under sections 303 (d)(2) or (d)(3), 311, 312 or 313 of Title III in which a chemical identity is claimed as trade secret, and is accompanied by a substantiation in support of the claim of trade secrecy for chemical identity.

"Trade secret" means any confidential formula, pattern, process, device, information or compilation of information that is used in a submitter's business, and that gives the submitter an opportunity to obtain an advantage over competitors who do not know or use it. EPA intends to be guided by the Restatement of Torts, section 757, comment b.

"Unsanitized" means a version of a document from which information claimed as trade secret or confidential has not been withheld or omitted.

"Working day" is any day on which Federal government offices are open for normal business. Saturdays, Sundays, and official Federal holidays are not working days; all other days are.

§ 350.3 Applicability of subpart; priority where provisions conflict; interaction with 40 CFR Part 2.

(a) *Applicability of subpart.* Sections 350.1 through 350.27 establish rules governing assertion of trade secrecy claims for chemical identity information collected under the authority of sections 303 (d)(2) and (d)(3), 311, 312 and 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986, and for trade secrecy or business confidentiality claims for information submitted in a substantiation under sections 303 (d)(2) and (d)(3), 311, 312, and 313 of Title III. This subpart also establishes rules governing petitions from the public requesting the disclosure of chemical identity claimed as trade secret, and determinations by EPA of whether this information is entitled to trade secret treatment. Claims for confidentiality of the location of a hazardous chemical under section 312(d)(2)(F) of Title III are not subject to the requirements of this subpart.

(b) *Priority where provisions conflict.* Where information subject to the requirements of this subpart is also collected under another statutory authority, the confidentiality provisions of that authority shall be used to claim that information as trade secret or confidential when submitting it to EPA under that statutory authority.

(c) *Interaction with 40 CFR Part 2, EPA's Freedom of Information Act procedures.* (1) No trade secrecy or business confidentiality claims other than those allowed in this subpart are permitted for information collected under sections 303 (d)(2) and (d)(3), 311, 312 and 313 of Title III.

(2) Except as provided in § 350.25 of this subpart, request for access to chemical identities withheld as trade secret under this regulation is solely through this regulation and procedures hereunder, not through EPA's Freedom of Information Act procedures set forth at 40 CFR Par' 2.

(3) Request for access to information other than chemical identity submitted to EPA under this regulation is through EPA's Freedom of Information Act regulations at 40 CFR Part 2.

§ 350.5 Assertion of claims of trade secrecy.

(a) A claim of trade secrecy may be made only for the specific chemical identity of an extremely hazardous substance under sections 303 (d)(2) and (d)(3), a hazardous chemical under sections 311 and 312, and a toxic chemical under section 313.

(b) Method of asserting claims of trade secrecy for information submitted under sections 303 (d)(2) and (d)(3).

(1) In submitting information to the local emergency planning committee under sections 303 (d)(2) or (d)(3), the submitter may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 303.

(2) To make a claim, the submitter shall submit to EPA the following:

(i) A copy of the information which is being submitted under sections 303 (d)(2) or (d)(3) to the local emergency planning committee, with the chemical identity or identities claimed trade secret deleted, and the generic class or category of the chemical identity or identities inserted in its place. The method of choosing generic class or category is set forth in paragraph (f) of this section.

(ii) A sanitized and unsanitized substantiation in accordance with § 350.7 for each chemical identity claimed as trade secret.

(3) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(4) Section 303 claims shall be sent to the address specified in § 350.16 of this regulation.

(c) Method of asserting claims of trade secrecy for information submitted under section 311.

(1) Submitters may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 311 on the material safety data sheet or chemical list under section 311.

(2) To assert a claim for a chemical identity on a material safety data sheet under section 311, the submitter shall submit to EPA the following:

(i) One copy of the material safety data sheet which is being submitted to the State emergency response commission, the local emergency planning committee and the local fire department, which shall make it available to the public. In place of the specific chemical identity claimed as trade secret, the generic class or category of the chemical claimed as trade secret shall be inserted. The method of choosing generic class or category is set forth in paragraph (f) of this section.

(ii) A sanitized and unsanitized substantiation in accordance with § 350.7 for every chemical identity claimed as trade secret.

(3) To assert a claim for a chemical identity on a list under section 311, the submitter shall submit to EPA the following:

(i) An unsanitized copy of the chemical list under section 311. The submitter shall clearly indicate the specific chemical identity claimed as trade secret, and shall label it *"Trade Secret."* The generic class or category of the chemical claimed as trade secret shall be inserted directly below the claimed chemical identity. The method of choosing generic class or category is set forth in paragraph (f) of this section.

(ii) A sanitized copy of the chemical list under section 311. This copy shall be identical to the document in paragraph (c)(3)(i) of this section except that the submitter shall delete the chemical identity claimed as trade secret, leaving in place the generic class or category of the chemical claimed as trade secret. This copy shall be sent by the submitter to the State emergency response commission, the local emergency planning committee and the local fire department, which shall make it available to the public.

(iii) A sanitized and unsanitized substantiation in accordance with § 350.7 for every chemical identity claimed as trade secret.

(4) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(5) Section 311 claims shall be sent to the address specified in § 350.16 of this regulation.

(d) Method of asserting claims of trade secrecy for information submitted under section 312.

(1) Submitters may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 312.

(2) To assert a claim the submitter shall submit to EPA the following:

(i) An unsanitized copy of the Tier II emergency and hazardous chemical inventory form under section 312. (The Tier I emergency and hazardous chemical inventory form does not require the reporting of specific chemical identity and therefore no trade secrecy claims may be made with respect to that form.) The submitter shall clearly indicate the specific chemical identity claimed as trade secret by checking the box marked "trade secret" next to the claimed chemical identity.

(ii) A sanitized copy of the Tier II emergency and hazardous chemical inventory form. This copy shall be identical to the document in paragraph (d)(2)(i) of this section except that the submitter shall delete the chemical identity or identities claimed as trade secret and include instead the generic class or category of the chemical claimed as trade secret. The method of choosing generic class or category is set forth in paragraph (f) of this section. The sanitized copy shall be sent by the submitter to the State emergency response commission, local emergency planning committee or the local fire department, whichever entity requested the information.

(iii) A sanitized and unsanitized substantiation in accordance with § 350.7 for every chemical identity claimed as trade secret.

(3) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(4) Section 312 claims shall be sent to the address specified in § 350.16 of this regulation.

(e) Method of asserting claims of trade secrecy for information submitted under section 313.

(1) Submitters may claim as trade secret the specific chemical identity of any chemical subject to reporting under section 313.

(2) To make a claim, the submitter shall submit to EPA the following:

(i) An unsanitized copy of the toxic release inventory form under section 313 with the information claimed as trade secret clearly identified. To do this, the submitter shall check the box on the form indicating that the chemical identity is being claimed as trade secret. The submitter shall enter the generic class or category that is structurally descriptive of the chemical, as specified in paragraph (f) of this section.

(ii) A sanitized copy of the toxic release inventory form. This copy shall be identical to the document in paragraph (e)(2)(i) of this section except that the submitter shall delete the chemical identity claimed as trade secret. This copy shall also be submitted to the State official or officials designated to receive this information.

(iii) A sanitized and unsanitized substantiation in accordance with § 350.7 for every chemical identity claimed as trade secret.

(3) If the submitter wishes to claim information in the substantiation as trade secret or business confidential, it shall do so in accordance with § 350.7(d).

(4) Section 313 claims shall be sent to the address specified in § 350.16 of this regulation.

(f) Method of choosing generic class or category for sections 303, 311, 312 and 313. A facility owner or operator claiming chemical identity as trade secret should choose a generic class or category for the chemical that is structurally descriptive of the chemical.

(g) If a specific chemical identity is submitted under Title III to EPA, or to a State emergency response commission, designated State agency, local emergency planning committee or local fire department, without asserting a trade secrecy claim, the chemical identity shall be considered to have been voluntarily disclosed, and non-trade secret.

(h) A submitter making a trade secrecy claim under this section shall submit to entities other than EPA (e.g., a designated State agency, local emergency planning committee and local fire department) only the sanitized or public copy of the submission and substantiation.

§ 350.7 Substantiating claims of trade secrecy.

(a) Claims of trade secrecy must be substantiated by providing a specific answer including, where applicable, specific facts, to each of the following questions with the submission to which the trade secrecy claim pertains. Submitters must answer these questions on the form entitled "Substantiation to Accompany Claims of Trade Secrecy" in § 350.27 of this subpart.

(1) Describe the specific measures you have taken to safeguard the confidentiality of the chemical identity claimed as trade secret, and indicate whether these measures will continue in the future.

(2) Have you disclosed the information claimed as trade secret to any other person (other than a member of a local emergency planning committee, officer or employee of the United States or a State or local government, or your employee) who is not bound by a confidentiality agreement to refrain from disclosing this trade secret information to others?

(3) List all local, State, and Federal government entities to which you have disclosed the specific chemical identity. For each, indicate whether you asserted a confidentiality claim for the chemical identity and whether the government entity denied that claim.

(4) In order to show the validity of a trade secrecy claim, you must identify your specific use of the chemical claimed as trade secret and explain why it is a secret of interest to competitors. Therefore:

(i) Describe the specific use of the chemical claimed as trade secret, identifying the product or process in which it is used. (If you use the chemical other than as a component of a product or in a manufacturing process, identify the activity where the chemical is used.)

(ii) Has your company or facility identity been linked to the specific chemical identity claimed as trade secret in a patent, or in publications or other information sources available to the public or your competitors (of which you are aware)? If so, explain why this knowledge does not eliminate the justification for trade secrecy.

(iii) If this use of the chemical claimed as trade secret is unknown outside your company, explain how your competitors could deduce this use from disclosure of the chemical identity together with other information on the Title III submittal form.

(iv) Explain why your use of the chemical claimed as trade secret would be valuable information to your competitors.

(5) Indicate the nature of the harm to your competitive position that would likely result from disclosure of the specific chemical identity, and indicate why such harm would be substantial.

(6)(i) To what extent is the chemical claimed as trade secret available to the public or your competitors in products, articles, or environmental releases?

(ii) Describe the factors which influence the cost of determining the identity of the chemical claimed as trade secret by chemical analysis of the product, article, or waste which contains the chemical (e.g., whether the chemical is in pure form or is mixed with other substances).

(b) The answers to the substantiation questions listed in paragraph (a) of this section are to be submitted on the form in § 350.27 of this subpart, and included with a submitter's trade secret claim.

(c) An owner, operator or senior official with management responsibility shall sign the certification at the end of the form contained in § 350.27. The certification in both the sanitized and unsanitized versions of the substantiation must bear an original signature.

(d) *Claims of confidentiality in the substantiation.* (1) The submitter may claim as confidential any trade secret or confidential business information contained in the substantiation. Such claims for material in the substantiation are not limited to claims of trade secrecy for specific chemical identity, but may also include claims of confidentiality for any confidential business information. To claim this material as confidential, the submitter shall clearly designate those portions of the substantiation to be claimed as confidential by marking those portions "Confidential," or "Trade Secret." Information not so marked will be treated as public and may be disclosed without notice to the submitter.

(2) An owner, operator, or senior official with management responsibility shall sign the certification stating that those portions of the substantiation claimed as confidential would, if disclosed, reveal the chemical identity being claimed as a trade secret, or would reveal other confidential business or trade secret information. This certification is combined on the substantiation form in § 350.27 with the certification described in paragraph (c) of this section.

(3) The submitter shall submit to EPA two copies of the substantiation, one of which shall be the unsanitized version, and the other shall be the sanitized version.

(i) The unsanitized copy shall contain all of the information claimed as trade secret or business confidential, marked as indicated in paragraph (d)(1) of this section.

(ii) The second copy shall be identical to the unsanitized substantiation except that it will be a sanitized version, in which all of the information claimed as trade secret or confidential shall be deleted. If any of the information claimed as trade secret in the substantiation is the chemical identity which is the subject of the substantiation, the submitter shall include the appropriate generic class or category of the chemical claimed as trade secret. This sanitized copy shall be submitted to the State emergency response commission, a designated State agency, the local emergency planning committee and the local fire department, as appropriate, and made publicly available.

(e) *Supplemental information.* (1) EPA may request supplemental information from the submitter in support of its trade secret claim, pursuant to § 350.11(a)(1). EPA may specify the kind of information to be submitted, or the submitter may submit any additional detailed information which further supports the truth of the information previously supplied to EPA in its initial substantiation, under this section.

(2) The submitter may claim as confidential any trade secret or confidential business information contained in the supplemental information. To claim this material as confidential, the submitter shall clearly designate those portions of the supplemental information to be claimed as confidential by marking those portions "Confidential," or "Trade Secret." Information not so marked will be treated as public and may be disclosed without notice to the submitter.

(3) If portions of the supplementary information are claimed confidential, an owner, operator, or senior official with management responsibility of the submitter shall certify that those portions of the supplemental information claimed as confidential would, if disclosed, reveal the chemical identity being claimed as confidential or would reveal other confidential business or trade secret information.

(4) If supplemental information is requested by EPA and the submitter claims portions of it as trade secret or confidential, then the submitter shall submit to EPA two copies of the supplemental information, an unsanitized and a sanitized version.

(i) The unsanitized version shall contain all of the information claimed as trade secret or business confidential, marked as indicated above in paragraph (e)(2) of this section.

(ii) The second copy shall be identical to the unsanitized substantiation except that it will be a sanitized version, in which all of the information claimed as trade secret or confidential shall be deleted. If any of the information claimed as trade secret in the supplemental information is the chemical identity which is the subject of the substantiation, the submitter shall include the appropriate generic class or category of the chemical claimed as trade secret.

§ 350.9 Initial action by EPA.

(a) When a claim of trade secrecy, made in accordance with § 350.5 of this part, is received by EPA, that information is treated as confidential until a contrary determination is made.

(b) A determination as to the validity of a trade secrecy claim shall be initiated upon receipt by EPA of a petition under § 350.15 or may be initiated at any time by EPA if EPA desires to determine whether chemical identity information claimed as trade secret is entitled to trade secret treatment, even though no request for release of the information has been received.

(c) If EPA initiates a determination as to the validity of a trade secrecy claim, the procedures set forth in §§ 350.11, 350.15, and 350.17 shall be followed in making the determination.

(d) When EPA receives a petition requesting disclosure of trade secret chemical identity or if EPA decides to initiate a determination of the validity of a trade secrecy claim for chemical identity, EPA shall first make a determination that the chemical identity claimed as trade secret is not the subject of a prior trade secret determination by EPA concerning the same submitter and facility, or if it is, that the prior determination upheld the submitter's claim of trade secrecy for that chemical identity at that facility.

(1) If EPA determines that the chemical identity claimed as trade secret is not the subject of a prior trade secret determination by EPA concerning the same submitter and the same facility, or if it is, that the prior determination upheld the submitter's claim of trade secrecy, then EPA shall review the submitter's claim according to § 350.1l.

(2) If such a prior determination held that the submitter's claim for that chemical identity is invalid, and such determination was not challenged by appeal to the General Counsel, or by review in the District Court, or, if challenged, was upheld, EPA shall notify the submitter by certified mail (return receipt requested) that the chemical identity claimed as trade secret is the subject of a prior, final Agency determination concerning the same facility in which it was held that such a claim was invalid. In this notification EPA shall include notice of intent to disclose chemical identity within 10 days pursuant to § 350.18(c) of this subpart. EPA shall also notify the petitioner by regular mail of the action taken pursuant to this section.

§ 350.11 Review of claim.

(a) *Determination of sufficiency.* When EPA receives a petition submitted pursuant to § 350.15, or if EPA initiates a determination of the validity of a trade secrecy claim for chemical identity, and EPA has made a determination, as required in paragraph (d)(1) of § 350.9, then EPA shall determine whether the submitter has presented sufficient support for its claim of trade secrecy in its substantiation. EPA must make such a determination within 30 days of receipt of a petition. A claim of trade secrecy for chemical identity will be considered sufficient if, assuming all of the information presented in the substantiation is true, this supporting information could support a valid claim of trade secrecy. A claim is sufficient if it meets the criteria set forth in § 350.13.

(1) *Sufficient claim.* If the claim meets the criteria of sufficiency set forth in § 350.13, EPA shall notify the submitter in writing, by certified mail (return receipt requested), that it has 30 days from the date of receipt of the notice to submit supplemental information in writing in accordance with § 350.7(e), to support the truth of the facts asserted in the substantiation. EPA will not accept any supplemental information, in response to this notice, submitted after the 30 day period has expired. The notice required by this section shall include the address to which supplemental information must be sent. The notice may specifically request supplemental information in particular areas relating to the submitter's claim. The notice must also inform the submitter of his right to claim any trade secret or confidential business information as confidential, and shall include a reference to § 350.7(e) of this regulation as the source for the proper procedure for claiming trade secrecy for trade secret or confidential business information submitted in the supplemental information requested by EPA.

(2) *Insufficient claim.* If the claim does not meet the criteria of sufficiency set forth in § 350.13, EPA shall notify the submitter in writing of this fact by certified mail (return receipt requested). Upon receipt of this notice, the submitter may either file an appeal of the matter to the General Counsel under paragraph (a)(2)(i) of this section, or, for good cause shown, submit additional material in support of its claim of trade secrecy to EPA under paragraph (a)(2)(ii) of this section. The notice required by this section shall include the reasons for EPA's decision that the submitter's claim is insufficient, and shall inform the submitter of its rights within 30 days of receiving notice to file an appeal with EPA's General Counsel or to amend its original substantiation for good cause shown. The notice shall include the address of the General Counsel, and the address of the office to which an amendment for good cause shown should be sent. The notice shall also include a reference to § 350.11(a)(2)(i)–(iv) of this subpart as the source on the proper procedures for filing an appeal or for amending the original substantiation.

(i) *Appeal.* The submitter may file an appeal of a determination of insufficiency with the General Counsel within 30 days of receipt of the notice of insufficiency, in accordance with the procedures set forth in § 350.17.

(ii) *Good Cause.* In lieu of an appeal to the General Counsel, the submitter may send additional material in support of its trade secrecy claim, for good cause shown, within 30 days of receipt of the notice of insufficiency. To do so, the submitter shall notify EPA by letter of its contentions as to good cause, and shall include in that letter the additional supporting material.

(iii) Good cause is limited to one or more of the following reasons:

(A) The submitter was not aware of the facts underlying the additional information at the time the substantiation was submitted, and could not reasonably have known the facts at that time; or

(B) EPA regulations and other EPA guidance did not call for such information at the time the substantiation was submitted; or

(C) The submitter had made a good faith effort to submit a complete substantiation, but failed to do so due to an inadvertent omission or clerical error.

(iv) If EPA determines that the submitter has met the standard for good cause, then EPA shall decide, pursuant to paragraph (a) of this section, whether the submitter's claim meets the Agency's standards of sufficiency set forth in § 350.13.

(A) If after receipt of additional material for good cause, EPA decides the claim is sufficient, EPA will determine whether the claim presents a valid claim of trade secrecy according to the procedures set forth in paragraph (b) of this section.

(B) If after receipt of additional material for good cause, EPA decides the claim is insufficient, EPA will notify the submitter by certified mail (return receipt requested) and the submitter may seek review in U.S. District Court within 30 days of receipt of the notice. The notice required by this paragraph shall include EPA's reasons for its determination, and shall inform the submitter of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The petitioner shall be notified of EPA's decision by regular mail.

(v) If EPA determines that the submitter has not met the standard for good cause, then EPA shall notify the submitter by certified mail (return receipt requested). The submitter may seek review of EPA's decision in U.S. District Court within 30 days of receipt of the notice. The notice required in this paragraph shall include EPA's reasons for its determination, and shall inform the submitter of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The petitioner shall be notified of EPA's decision by regular mail.

(b) Determination of trade secrecy. Once a claim has been determined to be sufficient under paragraph (a) of this section, EPA must decide whether the claim is entitled to trade secrecy.

(1) If EPA determines that the information submitted in support of the trade secrecy claim is true and that the chemical identity is a trade secret, the petitioner shall be notified by certified mail (return receipt requested) of EPA's determination and may bring an action in U.S. District Court within 30 days of receipt of such notice. The notice required in this paragraph shall include the reasons why EPA has determined that the chemical identity is a trade secret and shall inform the petitioner of its right to seek review in U.S. District Court within 30 days of receipt of the notice. The submitter shall be notified of EPA's decision by regular mail.

(2) If EPA decides that the information submitted in support of the trade secrecy claim is not true and that the chemical identity is not a trade secret:

(i) The submitter shall be notified by certified mail (return receipt requested) of EPA's determination and may appeal to the General Counsel within 30 days of receipt of such notice, in accordance with the procedures set forth in § 350.17. The notice required by this paragraph shall include the reasons why EPA has determined that the chemical identity is not a trade secret and shall inform the submitter of its appeal rights to EPA's General Counsel. The notice shall include the address to which an appeal should be sent and the procedure for filing an appeal, as set forth in § 350.17(a) of this subpart. The petitioner shall be notified of EPA's decision by regular mail.

(ii) The General Counsel shall notify the submitter by certified mail (return receipt requested) of its decision on appeal pursuant to the requirements in § 350.17. The notice required by this paragraph shall include the reasons for EPA's determination. If the General Counsel affirms the decision that the chemical identity is not a trade secret, then the submitter shall have 30 days from the date it receives notice of the General Counsel's decision to bring an action in U.S. District Court. If the General Counsel decides that the chemical identity is a trade secret, then EPA shall follow the procedure set forth in paragraph (b)(1) of this section.

§ 350.13 Sufficiency of assertions.

(a) A substantiation submitted under § 350.7 will be determined to be insufficient to support a claim of trade secrecy unless the answers to the questions in the substantiation submitted under § 350.7 support all of the following conclusions. This substantiation must include, where applicable, specific facts.

(1) The submitter has not disclosed the information to any other person, other than a member of a local emergency planning committee, an officer or employee of the United States or a State or local government, an employee of such person, or a person who is bound by a confidentiality agreement, and such person has taken reasonable measures to protect the confidentiality of such information and intends to continue to take such measures. To support this conclusion, the facts asserted must show all of the following:

(i) The submitter has taken reasonable measures to prevent unauthorized disclosure of the specific chemical identity and will continue to take such measures.

(ii) The submitter has not disclosed the specific chemical identity to any person who is not bound by an agreement to refrain from disclosing the information.

(iii) The submitter has not previously disclosed the specific chemical identity to a local, State, or Federal government entity without asserting a confidentiality claim.

(2) The information is not required to be disclosed, or otherwise made available, to the public under any other Federal or State law.

(3) Disclosure of the information is likely to cause substantial harm to the competitive position of such person. To support this conclusion, the facts asserted must show all of the following:

(i) *Either:* (A) Competitors do not know or the submitter is not aware that competitors know that the chemical whose identity is being claimed trade secret can be used in the fashion that the submitter uses it, and competitors cannot easily duplicate the specific use of this chemical through their own research and development activities; or

(B) Competitors are not aware or the submitter does not know whether competitors are aware that the submitter is using this chemical in this fashion.

(ii) The fact that the submitter manufactures, imports or otherwise uses this chemical in a particular fashion is not contained in any publication or other information source (of which the submitter is aware) available to competitors or the public.

(iii) The non-confidential version of the submission under this title does not contain sufficient information to enable competitors to determine the specific chemical identity withheld therefrom.

(iv) The information referred to in paragraph (a)(3)(i)(A) of this section, is of value to competitors.

(v) Competitors are likely to use this information to the economic detriment of the submitter and are not precluded from doing so by a United States patent.

(vi) The resulting harm to submitter's competitive position would be substantial.

(4) The chemical identity is not readily discoverable through reverse engineering. To support this conclusion, the facts asserted must show that competitors cannot readily discover the specific chemical identity by analysis of the submitter's products or environmental releases.

(b) The sufficiency of the trade secrecy claim shall be decided entirely upon the information submitted under § 350.7, or § 350.11(a)(2)(ii).

§ 350.15 Public petitions requesting disclosure of chemical identity claimed as trade secret.

(a) The public may request the disclosure of chemical identity claimed as trade secret by submitting a written petition to the address specified in § 350.16.

(b) The petition shall include:

(1) The name, address, and telephone number of the petitioner;

(2) The name and address of the company claiming the chemical identity as trade secret; and

(3) A copy of the submission in which the submitter claimed chemical identity as trade secret, with a specific indication as to which chemical identity the petitioner seeks disclosed.

(c) EPA shall acknowledge, by letter to the petitioner, the receipt of the petition.

(d) Incomplete petitions. If the information contained in the petition is not sufficient to allow EPA to identify which chemical identity the petitioner is seeking to have released, EPA shall notify the petitioner that the petition cannot be further processed until additional information is furnished. EPA will make every reasonable effort to assist a petitioner in providing sufficient information for EPA to identify the chemical identity the petitioner is seeking to have released.

(e) EPA shall make a determination on a petition requesting disclosure, in accordance with § 350.11 and § 350.17, within nine months of receipt of such petition.

§ 350.16 Address to send trade secrecy claims and petitions requesting disclosure.

All claims of trade secrecy under sections 303 (d)(2), (d)(3), 311, 312, and 313 and all public petitions requesting disclosure of chemical identities claimed as trade secret should be sent to the following address: U.S. Environmental Protection Agency, Emergency Planning and Community Right-to-Know Program, P.O. Box 70266, Washington, DC 20024-0266.

§ 350.17 Appeals.

(a) *Procedure for filing appeal.* A submitter may appeal an EPA determination under §§ 350.11 (a)(2)(i) or (b)(2)(i), by filing an appeal with the General Counsel. The appeal shall be addressed to: The Office of General Counsel, U.S. Environmental Protection Agency, Contracts and Information Law Branch, Room 3600M, LE-132G, 401 M Street, SW., Washington, DC 20460.

The appeal shall contain the following:

(1) A letter requesting review of the appealed decision; and

(2) A copy of the letter containing EPA's decision upon which appeal is requested.

(b) Appeal of determination of insufficient claim.

(1) Where a submitter appeals a determination by EPA under § 350.11(a)(2)(i) that the trade secrecy claim presents insufficient support for a finding of trade secrecy, the General Counsel shall make one of the following determinations:

(i) The trade secrecy claim at issue meets the standards of sufficiency set forth in § 350.13; or

(ii) The trade secrecy claim at issue does not meet the standards of sufficiency set forth in § 350.13.

(2) If the General Counsel reverses the decision made by the EPA office handling the claim, the claim shall be processed according to § 350.11(a)(1). The General Counsel shall notify the submitter of the determination on appeal in writing, by certified mail (return receipt requested). The appeal determination shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, a statement of the decision on appeal and the reasons for such decision.

(3) If the General Counsel upholds the determination of insufficiency made by the EPA office handling the claim, the submitter may seek review in U.S. District Court within 30 days after receipt of notice of the General Counsel's determination. The General Counsel shall notify the submitter of its determination on appeal in writing, by

certified mail (return receipt requested). The appeal determination shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, a statement of the decision on appeal and the reasons for such decision, and a statement of the submitter's right to seek review in U.S. District Court within 30 days of receipt of such notice. The petitioner shall be notified by regular mail.

(c) *Appeal of determination of no trade secret.* (1) If a submitter appeals from a determination by EPA under § 350.11(b)(2) that the specific chemical identity at issue is not a trade secret, the General Counsel shall make one of the following determinations:

(i) The assertions supporting the claim of trade secrecy are true and the chemical identity is a trade secret; or

(ii) The assertions supporting the claim of trade secrecy are not true and the chemical identity is not a trade secret.

(2) If the General Counsel reverses the decision made by the EPA office handling the claim, the General Counsel shall notify the submitter of its determination on appeal in writing, by certified mail (return receipt requested). The appeal determination shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, a statement of the decision on appeal and the reasons for such decision. The General Counsel shall send the petitioner the notice required in § 350.11(b)(1).

(3) If the General Counsel upholds the decision of the EPA office which made the trade secret determination, the submitter may seek review in U.S. District Court within 30 days of receipt of notice of the General Counsel's decision. The General Counsel shall notify the submitter of the determination on appeal in writing, by certified mail (return receipt requested). The notice shall include the date the appeal was received by the General Counsel, a statement of the decision appealed from, the basis for the appeal determination, that it constitutes final Agency action concerning the chemical identity trade secrecy claim, and that such final Agency action may be subject to review in U.S. District Court within 30 days of receipt of such notice. The General Counsel shall notify the petitioner by regular mail.

§ 350.18 Release of chemical identity determined to be non-trade secret; notice of intent to release chemical identity.

(a) Where a submitter fails to seek review within U.S. District Court within 20 days of receiving notice of a determination of the General Counsel under § 350.17(b)(3) of this subpart that the trade secrecy claim is insufficient, or under § 350.17(c)(3) of this subpart that chemical identity claimed as trade secret is not entitled to trade secret protection, EPA may furnish notice of intent to disclose the chemical identity claimed as trade secret within 10 days by furnishing the submitter with the notice set forth in paragraph (d) of this section by certified mail (return receipt requested).

(b) Where a submitter fails to seek review within U.S. District Court within 20 days of receiving notice of an EPA determination under § 350.11(a)(2)(iv)(B), or § 350.11(a)(2)(v) of this regulation, or fails to pursue appeal to the General Counsel within 20 days after being notified of its right to do so under § 350.11(a)(2)(i) or § 350.11(b)(2)(i), EPA may furnish notice of intent to disclose the chemical identity claimed as trade secret within 10 days by furnishing the submitter with the notice set forth in paragraph (d) of this section by certified mail (return receipt requested).

(c) Where EPA, upon initial review under § 350.9(d), determines that the chemical identity claimed as trade secret in a submittal submitted pursuant to this part is the subject of a prior final Agency determination concerning a claim of trade secrecy for the same chemical identity for the same facility, in which such claim was held invalid, EPA shall furnish notice of intent to disclose chemical identity within 10 days by furnishing the submitter with the notice set forth in paragraph (d) of this section by certified mail (return receipt requested).

(d) EPA shall furnish notice of its intent to release chemical identity claimed as trade secret by sending the following notification to submitters, under the circumstances set forth in paragraphs (a), (b), and (c) of this section. The notice shall state that EPA will make the chemical identity available to the petitioner and the public on the tenth working day after the date of the submitter's receipt of written notice (or on such later date as the Office of General Counsel may establish), unless the Office of General Counsel has first been notified of the submitter's commencement of an action in Federal court to obtain judicial review of the determination at issue, and to obtain preliminary injunctive relief against disclosure, or, where applicable, as described in paragraph (b) of this section, of commencement of an appeal to the General Counsel. The notice shall further state that if Federal court action is timely commenced, EPA may nonetheless make the information available to the petitioner and the public (in the absence of an order by the court to the contrary), once the court has denied a motion for a preliminary injunction in the action or has otherwise upheld the EPA determination, or, that if Federal court action or appeal to the General Counsel is timely commenced, EPA may nonetheless make the information available to the petitioner and the public whenever it appears to the General Counsel, after reasonable notice to the submitter, that the submitter is not taking appropriate measures to obtain a speedy resolution of the action.

§ 350.19 Provision of information to States.

(a) Any State may request access to trade secrecy claims, substantiations, supplemental substantiations, and additional information submitted to EPA. EPA shall release this information, even if claimed confidential, to any State requesting access if:

(1) The request is in writing;

(2) The request is from the Governor of the State; and

(3) The State agrees to safeguard the information with procedures equivalent to those which EPA uses to safeguard the information.

(b) The Governor of a State which receives access to trade secret information under this section may disclose such information only to State employees.

§ 350.21 Adverse health effects.

The Governor or State emergency response commission shall identify the adverse health effects associated with each of the chemicals claimed as trade secret and shall make this information available to the public. The material safety data sheets submitted to the State emergency response commissions may be used for this purpose.

§ 350.23 Disclosure to authorized representatives.

(a) Under section 322(f) of the Act, EPA possesses the authority to disclose to any authorized representative of the United States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to trade secret or confidential treatment under this part. Such authority may be exercised only in accordance with paragraph (b) of this section.

(b)(1) A person under contract or subcontract to EPA or a grantee who performs work for EPA in connection with Title III or regulations which implement Title III may be considered an authorized representative of the

United States for purposes of this § 350.23. Subject to the limitations in this § 350.23(b), information to which this section applies may be disclosed to such a person if the EPA program office managing the contract, subcontract, or grant first determines in writing that such disclosure is necessary in order that the contractor, subcontractor or grantee may carry out the work required by the contract, subcontract or grant.

(2) No information shall be disclosed under this § 350.23(b) unless this contract, subcontract, or grant in question provides:

(i) That the contractor, subcontractor or the grantee and the contractor's, subcontractor's, or grantee's employees shall use the information only for the purpose of carrying out the work required by the contract, subcontract, or grant, and shall refrain from disclosing the information to anyone other than EPA without the prior written approval of each affected submitter or of an EPA legal office, and shall return to EPA all copies of the information (and any abstracts or extracts therefrom) upon request by the EPA program office, whenever the information is no longer required by the contractor, subcontractor or grantee for the performance of the work required under the contract, subcontract or grant, or upon completion of the contract, subcontract or grant;

(ii) That the contractor, subcontractor or grantee shall obtain a written agreement to honor such terms of the contract or subcontract from each of the contractor's, subcontractor's or grantee's employees who will have access to the information, before such employee is allowed such access; and

(iii) That the contractor, subcontractor or grantee acknowledges and agrees that the contract, subcontract or grant provisions concerning the use and disclosure of confidential business information are included for the benefit of, and shall be enforceable by, both EPA and any covered facility having an interest in information concerning it supplied to the contractor, subcontractor or grantee by EPA under the contract or subcontract or grant.

(3) No information shall be disclosed under this § 350.23(b) until each affected submitter has been furnished notice of the contemplated disclosure by the EPA program office and has been afforded a period found reasonable by that office (not less than 5 working days) to submit its comments. Such notice shall include a description of the information to be disclosed, the identity of the contractor, subcontractor or grantee, the contract, subcontract or grant number, if any, and the purposes to be served by the disclosure. This notice may be published in the **Federal Register** or may be sent to individual submitters.

(4) The EPA program office shall prepare a record of disclosures under this § 350.23(b). The EPA program office shall maintain the record of disclosure and the determination of necessity prepared under paragraph (b)(1) of this section for a period of not less than 36 months after the date of the disclosure.

§ 350.25 Disclosure in special circumstances.

Other disclosure of specific chemical identity may be made in accordance with 40 CFR 2.209.

§ 350.27 Substantiation form to accompany claims of trade secrecy, instructions to substantiation form.

(a) The form in paragraph (b) of this section must be completed and submitted as required in § 350.7(a).

(b) Substantiation form to accompany claims of trade secrecy.

BILLING CODE 6560-50-M

United States Environmental Protection Agency
Washington, DC 20460

EPA

Substantiation To Accompany Claims of Trade Secrecy Under the Emergency Planning and Community Right-To-Know Act of 1986

Form Approved
OMB No. 2050-0078
Approval expires 10-31-90

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to vary from 27.7 hours to 33.2 hours per response, with an average of 28.8 hours per response, including 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 estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Part 1. Substantiation Category

1.1 Title III Reporting Section (check only one)

☐ 303 ☐ 311 ☐ 312 ☐ 313

1.2 Reporting Year 19________

1.3 Indicate Whether This Form Is (check only one)

1.3a. ☐ **Sanitized** (answer 1.3.1a below) 1.3.1a. Generic Class or Category	1.3b. ☐ **Unsanitized** (answer 1.3.1b. and 1.3.2b. below) 1.3.1b. CAS Number ☐☐☐☐☐☐ – ☐☐ – ☐ 1.3.2b. Specific Chemical Identity

Part 2. Facility Identification Information

2.1 Name

2.2 Street Address

2.3 City, State, and ZIP Code

2.4 Dun and Bradstreet Number ☐☐ – ☐☐☐ – ☐☐☐☐

Part 3. Responses to Substantiation Questions

3.1 Describe the specific measures you have taken to safeguard the confidentiality of the chemical identity claimed as trade secret, and indicate whether these measures will continue in the future.

3.2 Have you disclosed the information claimed as trade secret to any other person (other than a member of a local emergency planning committee, officer or employee of the United States or a State or local government, or your employee) who is not bound by a confidentiality agreement to refrain from disclosing this trade secret information to others?

☐ Yes ☐ No

3.3 List all local, State, and Federal government entities to which you have disclosed the specific chemical identity. For each, indicate whether you asserted a confidentiality claim for the chemical identity and whether the government entity denied that claim.

Government Entity	Confidentiality Claim Asserted		Confidentiality Claim Denied	
	Yes	No	Yes	No

3.4 In order to show the validity of a trade secrecy claim, you must identify your specific use of the chemical claimed as trade secret and explain why it is a secret of interest to competitors. Therefore:

(i) Describe the specific use of the chemical claimed as trade secret, identifying the product or process in which it is used. (If you use the chemical other than as a component of a product or in a manufacturing process, identify the activity where the chemical is used.)

(ii) Has your company or facility identity been linked to the specific chemical identity claimed as trade secret in a patent, or in publications or other information sources available to the public or your competitors (of which you are aware)?

☐ **Yes** ☐ **No**

If so, explain why this knowledge does not eliminate the justification for trade secrecy.

(iii) If this use of the chemical claimed as trade secret is unknown outside your company, explain how your competitors could deduce this use from disclosure of the chemical identity together with other information on the Title III submittal form.

3.4 (iv) Explain why your use of the chemical claimed as trade secret would be valuable information to your competitors.

3.5 Indicate the nature of the harm to your competitive position that would likely result from disclosure of the specific chemical identity, and indicate why such harm would be substantial.

3.6 (i) To what extent is the chemical claimed as trade secret available to the public or your competitors in products, articles, or environmental releases?

3.6 (ii) Describe the factors which influence the cost of determining the identity of the chemical claimed as trade secret by chemical analysis of the product, article, or waste which contains the chemical (e.g., whether the chemical is in pure form or is mixed with other substances).

Part 4. Certification (Read and sign after completing all sections)

I certify under penalty of law that I have personally examined the information submitted in this and all attached documents. Based on my inquiry of those individuals responsible for obtaining the information, I certify that the submitted information is true, accurate, and complete, and that those portions of the substantiation claimed as confidential would, if disclosed, reveal the chemical identity being claimed as a trade secret, or would reveal other confidential business or trade secret information. I acknowledge that I may be asked by the Environmental Protection Agency to provide further detailed factual substantiation relating to this claim of trade secrecy, and certify to the best of my knowledge and belief that such information is available. I understand that if it is determined by the Administrator of EPA that this trade secret claim is frivolous, EPA may assess a penalty of up to $25,000 per claim.

I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

4.1 Name and official title of owner or operator or senior management official	
4.2 Signature *(All signatures must be original)*	4.3 Date Signed

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BILLING CODE 6560-50-C

Instructions for Completing the EPA Trade Secret Substantiation Form

General Information

EPA requires that the information requested in a trade secret substantiation be completed using this substantiation form in order to ensure that all facility and chemical identifier information, substantiation questions, and certification statements are completed. Submitter-devised forms will not be accepted. Incomplete substantiations will in all likelihood be found insufficient to support the claim, and the claim will be denied. *Moreover, the statute provides that a submitter who fails to provide information required will be subject to a $10,000 fine.* For the submitter's own protection, therefore, the EPA form must be used and completed in its entirety.

The statute for section 322 establishes a two-phase process in which the submitter must do the following:

1. At the time a report is submitted, the submitter must present a complete set of assertions that (if true) would be sufficient to justify the claim of trade secrecy; and

2. If the claim is reviewed by EPA, the submitter will be asked to provide additional factual information sufficient to establish the truthfulness of the assertions made at the time the claim was made.

In making its assertions of trade secrecy, a submitter should provide, where applicable, descriptive factual statements. Conclusory statements of compliance (such as positive or negative restatements of the questions) may not provide EPA with enough information to make a determination and may be found insufficient to support a claim.

What May Be Withheld

Only the specific chemical identity required to be disclosed in sections 303, 311, 312, and 313 submissions may be claimed trade secret on the Title III submittal itself. (Other trade secret or confidential business information included in answer to a question on the substantiation may be claimed trade secret or confidential, as described below.)

Location information claimed as confidential under section 312(d)(2)(F) should *not* be sent to EPA; this should only be sent to the SERC, LEPC, and the fire department, as requested.

Sanitized and Unsanitized Copies

You must submit this form to EPA in sanitized and unsanitized versions, along with the sanitized and unsanitized copies of the submittal that gives rise to this trade secrecy claim (except for the section 303 submittal, and for MSDSs under section 311). The *unsanitized* version of this form contains specific chemical identity and CAS number and may contain other trade secret or confidential business information, which should be clearly labeled as such. Failure to claim other information trade secret or confidential will make that information publicly available. In the *sanitized* version of this form, the specific chemical identity and CAS number must be replaced with the chemical's generic class or category and any other trade secret or confidential business information should be deleted. *You should also send sanitized copies of the submittal and this form to relevant State and local authorities.*

Each question on this form must be answered. *Submitters are encouraged to answer in the space provided.* If you need more space to answer a particular question, please use additional sheets. If you use additional sheets, be sure to include the number (and if applicable, the subpart) of the question being answered and write your facility's Dun and Bradstreet Number on the lower right-hand corner of each sheet.

When the Forms Must be Submitted

The sanitized and unsanitized report forms and trade secret substantiations must be submitted to EPA by the normal reporting deadline for that section (e.g., section 313 submissions for any calendar year must be submitted on or before July 1 of the following year).

Where to Send the Trade Secrecy Claim

All trade secrecy claims should be sent to the following address: U.S. Environmental Protection Agency, Emergency Planning and Community Right-to-Know Program, P.O. Box 70266, Washington, DC 20024–0266.

In addition, you must send sanitized copies of the report form and substantiation to relevant State and local authorities. States will provide addresses where the copies of the reports are to be sent.

Packaging of Claim(s)

A completed section 322 claim package must include four items, packaged in the following order:

1. An unsanitized trade secret substantiation form.

2. A sanitized trade secret substantiation form.

3. An unsanitized 312 or 313 report (it is not necessary to create an unsanitized section 303 submittal or MSDS for submission under section 311).

4. A sanitized (public) section 303, 311, 312, or 313 or report.

It is important to securely fasten together (binder clip or rubber band) each of the reporting forms and substantiations for the particular chemical being claimed trade secret. This process will make it clear that a claim is physically complete when submitted. When submitters submit claims for more than one chemical, EPA requests that the four parts associated with each chemical be assembled as a set and each set for different chemicals be kept separate within the package sent to EPA. Following these guidelines permits the Agency to make the appropriate determinations of trade secrecy, and to make public only those portions of each submittal required to be disclosed.

How to Obtain Forms and Other Information

Additional copies of the Trade Secret Substantiation Form may be obtained by writing to: Emergency Planning and Community Right-to-Know Program, U.S. Environmental Protection Agency, WH–562A, 401 M Street, SW., Washington, DC 20460.

Instructions for Completing Specific Sections of the Form

Part 1. Substantiation Category

1.1 Title III Reporting Section. Check the box corresponding to the section for which this particular claim of trade secrecy is being made. Checking off more than one box for a claim is *not* permitted.

1.2 Reporting Year. Enter the year to which the reported information applies, not the year in which you are submitting the report.

1.3a Sanitized. If this copy of the submission is the "public" or sanitized version, check this box and complete 1.3.1a. which asks for generic class or category. Do *not* complete the information required in the unsanitized box (1.3b.).

1.3.1a Generic Class or Category. You must complete this if you are claiming the specific chemical identity as a trade secret and have marked the box in 1.3a. The generic chemical name must be structurally descriptive of the chemical.

1.3b Unsanitized. Check the box if this version of the form contains the specific chemical identity or any other trade secret or confidential business information.

1.3.1b CAS Number. You must enter the Chemical Abstract Service (CAS) registry number that appears in the appropriate section of the rule for the chemical being reported. Use leading place holding zeros. If you are reporting a chemical category (e.g., copper compounds), enter N/A in the CAS number space.

1.3.2b Specific Chemical Identity. Enter the name of the chemical or chemical category as it is listed in the appropriate section of the reporting rule.

Part 2. Facility Identification Information

2.1-2.3 Facility Name and Location. You must enter the name of your facility (plant site name or appropriate facility designation), street address, city, State and ZIP Code in the space provided. You may not use a post office box number for this location.

2.4 Dun and Bradstreet Number. You must enter the number assigned by Dun and Bradstreet for your facility or each establishment wthin your facility. If the establishment does not have a D & B number, enter N/A in the boxes reserved for those numbers. Use leading place holding zeros.

Part 3. Responses to Substantiation Questions

The six questions posed in this form are based on the four statutory criteria found in section 322(b) of Title III. The information you submit in response to these questions is the basis for EPA's initial determination as to whether the substantiation is sufficient to support a claim of trade secrecy. EPA has indicated in § 350.13 of the final rule the specific criteria that it regards as the legal basis for evaluating whether the answers you have provided are sufficient to warrant protection of the chemical identity. You are urged to review those criteria before preparing answers to the questions on the form.

Part 4. Certification

An *original* signature is required for each trade secret substantiation submitted to EPA, both sanitized and unsanitized. It indicates the submitter is certifying that the particular substantiation provided to EPA is complete, true, and accurate, and that it is intended to support the specific trade secret claim being made. Noncompliance with this certification requirement may jeopardize the trade secret claim.

4.1 Name and Official Title. Print or type the name and title of the person who signs the statement at 4.2.

4.2 Signature. This certification must be signed by the owner or operator, or a senior official with management responsibility for the person (or persons) completing the form. An *original* signature is required for each trade secret substantiation submitted to EPA, both sanitized and unsanitized. Since the certification applies to all information supplied on the forms, it should be signed only after the substantiation has been completed.

4.3 Date. Enter the date when the certification was signed.

Appendix A—Restatement of Torts Section 757, Comment b

b. Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see section 759) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operation of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

Secrecy. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy. Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and to his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Novelty and prior art. A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

Subpart B—Disclosure of Trade Secret Information to Health Professionals

§ 350.40 Disclosure to health professionals.

(a) *Definitions.* "Medical emergency" means any unforeseen condition which a health professional would judge to require urgent and unscheduled medical attention. Such a condition is one which results in sudden and/or serious symptom(s) constituting a threat to a person's physical or psychological well-being and which requires immediate medical attention to prevent possible deterioration, disability, or death.

(b) The specific chemical identity, including the chemical name of a hazardous chemical, extremely hazardous substance, or a toxic chemical, is made available to health professionals, in accordance with the applicable provisions of this section.

(c) *Diagnosis or Treatment by Health Professionals in Non-Emergency Situations.* (1) An owner or operator of a facility which is subject to the requirements of sections 311, 312, and 313, shall, upon request, provide the specific chemical identity, if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical to a health professional if:

(i) The request is in writing;

(ii) The request describes why the health professional has a reasonable basis to suspect that:

(A) The specific chemical identity is needed for purposes of diagnosis or treatment of an individual,

(B) The individual or individuals being diagnosed or treated have been exposed to the chemical concerned, and

(C) Knowledge of the specific chemical identity of such chemical will assist in diagnosis or treatment.

(iii) The request contains a confidentiality agreement which includes:

(A) A description of the procedures to be used to maintain the confidentiality of the disclosed information; and

(B) A statement by the health professional that he will not use the information for any purpose other than the health needs asserted in the statement of need authorized in paragraph (c)(1)(ii) of this section and will not release the information under any circumstances, except as authorized by the terms of the confidentiality agreement or by the owner or operator of the facility providing such information.

(iv) The request includes a certification signed by the health professional stating that the information contained in the statement of need is true.

(2) Following receipt of a written request, the facility owner or operator to whom such request is made shall provide the requested information to the health professional promptly.

(d) *Preventive Measures and Treatment by Local Health Professionals.* (1) An owner or operator of a facility subject to the requirements of sections 311, 312, and 313, shall provide the specific chemical identity, if known, of a hazardous chemical, an extremely hazardous substance, or a toxic chemical to any health professional (such as a physician, toxicologist, epidemiologist, or nurse) if:

(i) The requester is a local government employee or a person under contract with the local government;

(ii) The request is in writing;

(iii) The request describes with reasonable detail one or more of the following health needs for the information:

(A) To assess exposure of persons living in a local community to the hazards of the chemical concerned.

(B) To conduct or assess sampling to determine exposure levels of various population groups.

(C) To conduct periodic medical surveillance of exposed population groups.

(D) To provide medical treatment to exposed individuals or population groups.

(E) To conduct studies to determine the health effects of exposure.

(F) To conduct studies to aid in the identification of chemicals that may reasonably be anticipated to cause an observed health effect.

(iv) The request contains a confidentiality agreement which includes:

(A) A description of the procedures to be used to maintain the confidentiality of the disclosed information; and

(B) A statement by the health professional that he will not use the information for any purpose other than the health needs asserted in the statement of need authorized in paragraph (d)(1)(iii) of this section and will not release the information under any circumstances except as may otherwise be authorized by the terms of such agreement or by the owner or operator of the facility person providing such information.

(v) The request includes a certification signed by the health professional stating that the information contained in the statement of need is true.

(2) Following receipt of a written request, the facility owner or operator to whom such request is made shall promptly provide the requested information to the local health professional.

(e) *Medical Emergency.* (1) An owner or operator of a facility which is subject to the requirements of sections 311, 312, and 313, must provide a copy of a material safety data shreet, an inventory form, or a toxic chemical release form, including the specific chemical identity if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical, to any treating physician or nurse who requests such information if the treating physician or nurse determines that:

(i) A medical emergency exists as to the individual or individuals being diagnosed or treated;

(ii) The specific chemical identity of the chemical concerned is necessary for or will assist in emergency or first-aid diagnosis or treatment; and,

(iii) The individual or individuals being diagnosed or treated have been exposed to the chemical concerned.

(2) Owners or operators of facilities must provide the specific chemical identity to the requesting treating physician or nurse immediately following the request, without requiring a written statement of need or a confidentiality agreement in advance.

(3) The owner or operator may require a written statement of need and a written confidentiality agreement as soon as circumstances permit. The written statement of need shall describe in reasonable detail the factors set forth in paragraph (e)(1) of this section. The written confidentiality agreement shall be in accordance with paragraphs (c)(1)(iii) and (f) of this section.

(f) *Confidentiality Agreement.* The confidentiality agreement authorized in paragraphs (c)(1)(iii), (d)(1)(iv) and (e)(3) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement; and

(iii) May not include requirements for the posting of a penalty bond.

(g) Nothing in this regulation is meant to preclude the parties from pursuing any non-contractual remedies to the extent permitted by law, or from pursuing the enforcement remedy provided in section 325(e) of Title III.

(h) The health professional receiving the trade secret information may disclose it to EPA only under the following circumstances: The health professional must believe that such disclosure is necessary in order to learn from the Agency additional information about the chemical necessary to assist him in carrying out the responsibilities set forth in paragraphs (c), (d), and (e) of this section. Such information comprises facts regarding adverse health and environmental effects.

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