ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[OPPTS–82053; FRL–6097–4]

RIN 2070–AC61

TSCA Inventory Update Rule Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The TSCA Inventory Update Rule (IUR) Amendments will help both EPA and the public better identify and mitigate potential exposures and risks associated with TSCA chemicals. Under section 8(a) of the Toxic Substances Control Act (TSCA), EPA currently requires manufacturers (including importers) of certain chemical substances and mixtures on the TSCA Chemical Substances Inventory to report current data regarding production volume, plant site information, and site-limited status. EPA is proposing to require the reporting of additional data that would assist EPA in evaluating potential exposures and risks resulting from industrial chemical operations and commercial and consumer uses of chemical substances. EPA is also proposing to modify reporting and recordkeeping requirements, to remove one reporting exemption and to create others, and to modify its Confidential Business Information (CBI) reporting procedures.

DATES: Comments on this proposed rule must be received no later than October 25, 1999. A public meeting to allow the opportunity for oral comment on this proposed rule will be held on Monday, October 4, 1999, from 9 a.m. to noon at the EPA Auditorium, 401 M St., SW., Washington, DC 20460.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the ''SUPPLEMENTARY INFORMATION'' section of this document.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Susan Krueger, Project Manager, Economics, Exposure and Technology Division (7406), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202) 260-1713, fax: (202) 260-1661; e-mail: krueger.susan@epa.gov.

For general information contact: Christine M. Augustyniak, Associate Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone: (202)554-1404, TDD: (202) 554-0551; e-mail: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Notice Apply to Me?

You may be potentially affected by this notice if you manufacture or import chemical substances and mixtures currently subject to reporting under the Inventory Update Rule (IUR) at 40 CFR part 710 or manufacture or import inorganic chemical substances. In the past, processors of chemical substances have not been required to comply with the requirements at 40 CFR part 710. These proposed amendments do not change the status of processors under the regulations at 40 CFR part 710. Potentially affected categories and entities may include, but are not limited to:

Category	NAICS	Examples of Potentially Regulated Persons
Chemical manufacturers and importers	325, 32411	Chemical manufacturers (including importers) currently subject to IUR reporting Chemical manufacturers (including importers) of inorganic chemical substances

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed above could also be regulated. To determine whether you or your business is affected by this action, carefully examine the applicability provisions in title 40 of the Code of Federal Regulations (CFR), part 710. If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed in the preceding ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information or Copies of this Document or Other Documents?

1. *Electronically*. You may obtain electronic copies of this document and various support documents from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''Federal Register--Environmental Documents.'' You can also go directly to the ''Federal Register'' listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–82053. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, Rm. NE-B607, Waterside Mall, 401 M St., SW., Washington, DC, from noon to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA Nonconfidential Information Center telephone number is (202) 260–7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. Be sure to identify the appropiate docket number (i.e., OPPTS–82053) in your correspondence.

1. *By mail*. Submit your comments to: Document Control Office (DCO) (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: OPPT Document Control Office (DCO) in the East Tower Rm. G-099, Waterside Mall, 401 M St., SW., Washington, DC 20460. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is 202–260–7099.

3. *Electronically*. You may submit your comments electronically by e-mail

to: ''oppt.ncic@epa.gov,'' or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by the docket control number OPPTS–82053. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI Information That I Want to Submit to the Agency?

You may claim information that you submit in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult with the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

E. What Should I Consider As I Prepare My Comments for EPA?

EPA invites you to provide your views on the various options proposed, new approaches EPA has not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide solid technical information and/or data to support your views.
- If you estimate potential burden or costs, explain how you arrived at the estimate.
- Tell us what you support, as well as what you disagree with.
- Provide specific examples to illustrate your concerns.
- Offer alternative ways to improve the rule or collection activity.
- Make sure to submit your comments by the deadline in this proposal.
- At the beginning of your comments (e.g., as part of the ''Subject'' heading), you must properly identify the document you are commenting on by providing the docket control number assigned to the proposal. You may also provide the name, date, and **Federal Register** citation, and the appropriate EPA or OMB ICR number.

II. Authority

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current an inventory of chemical substances in commerce. In 1977, EPA promulgated a rule (42 FR 64572, December 23, 1977) under TSCA section 8(a), 15 U.S.C. 2607(a), to compile an inventory of chemical substances. In 1986, EPA promulgated the IUR (51 FR 21447, June 12, 1986), also under TSCA section 8(a), to facilitate the periodic updating of the inventory and to support activities associated with the implementation of TSCA.

This document proposes amendments to 40 CFR part 710, which currently contains the Inventory Update Reporting Regulations. Failure to comply fully with any provision of a final rule would be a violation of TSCA section 15 and would subject the violator to the penalties of TSCA sections 16 and 17.

TSCA section 8(a)(1) authorizes the EPA Administrator to promulgate rules under which manufacturers (including importers) and processors of chemical substances and mixtures (referred to hereafter as ''chemical substances'') must maintain such records and submit such information as the Administrator may reasonably require. Under TSCA section 8(a), the Agency may collect information, insofar as it is known to, or reasonably ascertainable by the submitter, on the manufacture (including import) and processing of chemical substances. EPA possesses broad discretion in determining the information to be reported under TSCA section 8(a). Some of the types of information which can be required under TSCA section 8(a)(2) include: categories of use for each chemical substance, estimates of the amount manufactured or processed for each category of use, a description of the byproducts resulting from the manufacture, processing, use, or disposal of each chemical substance, an estimate of the number of individuals exposed, and the duration of such exposure. TSCA section 8(a) excludes, with certain exceptions, small manufacturers (including small importers), and processors of chemical substances from reporting requirements established in TSCA section 8(a). However, EPA is authorized by TSCA section 8(a)(3) to require TSCA section 8(a) reporting from small manufacturers (including importers) and processors with respect to any chemical substance that is the subject of a rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6, or that is the subject of an order under TSCA section 5(e), or that is the subject of relief that has been granted pursuant to a civil action under TSCA sections 5 or 7. For purposes of the IUR, the standards for determining whether a business qualifies as a ''small manufacturer or importer'' are defined at 40 CFR 704.3. For additional information, see TSCA sections 2 and 8; H. Rep. 1341, 94th Cong., 2d Sess. 6-7 (July 14, 1976); Sen. Rep. 698, 94th Cong. 2d Sess. 3-5 (March 16, 1976).

III. Summary of the Amendments

In this document, EPA is proposing several changes to the current IUR reporting requirements. First, EPA is proposing to amend 40 CFR 710.32 in order to add exposure-related information to the reporting requirements for chemical substances covered by the IUR. Specifically, the Agency is proposing that manufacturers (including importers) subject to the proposed rule report, in ranges, the number of workers reasonably likely to be exposed to the chemical substance at the site of manufacture or import, and the physical form, average concentration, and maximum concentration of the chemical substance as it leaves the submitter's possession.

Second, EPA is proposing to amend 40 CFR 710.32 in order to require chemical manufacturers (including importers) (''submitters'') of larger-volume chemical substances to report information concerning the processing and use of each reportable chemical substance that is conducted at sites controlled by the submitter and at ''downstream'' sites that receive the reportable chemical substance from the submitter directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.). Specifically, manufacturers (including importers) of these larger-volume chemical substances would be required to report:

1. The type of industrial processing or use operation at each site, including downstream sites.

2. The five-digit North American Industrial Classification System (''NAICS'') codes that best describe the industrial activities conducted by the facilities that use or process the substance.

3. The ''industrial functions'' of the chemical substances.

4. The approximate number of processing and use sites.

5. The estimated number of workers reasonably likely to be exposed to each chemical substance at each site at which the chemical is used or processed.

6. The commercial and consumer uses of reportable chemical substances.

7. The estimated percentages of the submitter's production volume in each industrial function category and commercial and consumer product category.

8. The maximum concentration of the reportable chemical substance in each commercial and consumer product category.

Third, EPA is proposing to revoke the current full exemption from IUR reporting at 40 CFR 710.26(a) for inorganic chemical substances, and instead require partial reporting for these substances. EPA is also proposing to amend 40 CFR 710.26 to create a partial reporting exemption for petroleum process streams.

Fourth, EPA is proposing to amend 40 CFR 710.26 to provide an exemption from IUR reporting for certain forms of natural gas.

Fifth, EPA is proposing to amend 40 CFR 710.32 to require the reporting of additional information to assist in the identification of plant sites reporting under IUR.

Sixth, EPA is proposing to amend 40 CFR 710.28, 710.32, and 710.33 to change the period for which reporting is required from a corporate fiscal year to a calendar year basis.

Seventh, EPA is proposing to amend 40 CFR 710.32 to include two separate confidentiality boxes on the reporting form (Form U) for production volume in exact amounts and in ranges (see Unit VI. of this preamble for a copy of the proposed reporting form). These confidentiality boxes would enable submitters to assert a confidentiality claim for specific production volume information while releasing the more general production volume range as public information.

Eighth, EPA is proposing to amend 40 CFR 710.38 to require upfront substantiation of plant site confidentiality claims made in IUR submissions to EPA.

Ninth, EPA is proposing to add a new section, 40 CFR 710.39, to require submitters to reassert CBI claims made in past IUR reports during each reporting cycle.

Finally, EPA is proposing to amend 40 CFR 710.28 and 710.32 to raise the production volume reporting threshold from the current 10,000 pounds (lbs.) per year threshold to 25,000 lbs. per year, and to add a new larger-volume reporting threshold of 300,000 lbs. per year for the reporting of processing and use information.

Units VI. through VIII. of this preamble provide a discussion regarding changes to the current IUR that would occur upon promulgation of these proposed amendments. The discussion includes the current reporting requirements only to the extent that they would be modified in this proposal. EPA is not reopening the existing requirements for comment where they would not be modified in this proposal. CBI issues are discussed in Unit VIII. of this preamble, although certain of these issues are mentioned briefly in Unit VI. of this preamble.

IV. Background

A. Establishment of the Inventory Update Rule

In the **Federal Register** of June 12, 1986 (51 FR 21447), EPA published the Inventory Update Rule (IUR), which requires chemical manufacturers (including importers) to report to EPA every 4 years the identity of chemical substances manufactured (including imported) annually in quantities over 10,000 lbs. per year at each plant site they own or control. The current IUR excludes several categories of substances, including polymers, inorganic substances, microorganisms, and naturally occurring chemical substances. Plant sites subject to the rule are currently required to report information such as company name, plant site location, plant site Dun and Bradstreet number(s), identity of the reportable chemical substance, and production volume of the reportable chemical substance.

The data reported under IUR are used to update the information collected on the TSCA Inventory, which is a listing of chemical substances in commerce. EPA uses the TSCA Inventory and data reported under the IUR to support many TSCA-related activities and to provide overall support for a number of EPA and other Federal health, safety, and environmental protection activities (See Unit IV.B. of this preamble for further explanation of some of these activities).

B. EPA's TSCA-Related Chemical Screening and Assessment Activities

Congress enacted TSCA to establish a number of new requirements and authorities for identifying and controlling toxic chemical risks to human health and the environment (See TSCA section 2). To implement its responsibilities under TSCA, EPA must identify potential chemical risks, assess the magnitude of the identified risks and, where necessary, manage risks determined to be unreasonable. TSCA provides EPA with the authority to gather data, such as chemical toxicity data, chemical exposure data, and other related data, to determine whether a chemical substance may present an unreasonable risk of injury to human health or the environment, and to institute control actions when risks are determined to be unreasonable. As part of the implementation of this authority, EPA has established the IUR and other regulations to collect information on chemical substances.

Identification of chemical substances, plant sites, and exposures of greatest potential concern and setting priorities for more detailed risk assessment and potential risk management actions are important elements in a successful chemical risk management program. The TSCA Inventory includes more than 75,000 chemical substances. Approximately 8,300 of these chemical substances are non-polymer organic chemical substances manufactured or imported in quantities of 10,000 lbs. per year, as reported under the 1994 IUR data collection. See ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' available in the public record for this proposal and listed at Unit X.A.2.f. of this preamble.

Once a chemical substance has been identified for risk screening under EPA's Existing Chemicals Program, EPA completes an initial review of the chemical. This initial review is designed to select the chemical substances that raise particular concern regarding the risks they present to human health and the environment. At the close of the initial review, three possible outcomes may occur: a testing recommendation, a recommendation for further evaluation, or closure. ''Closure'' may include referrals to other programs or agencies, dissemination of initial review results, or a decision to discontinue further review based on the chemical's low hazard, low risk potential, or because it will be considered for regulatory control as part of a broader cluster of chemical substances. This process is described in more detail in the document entitled, ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' which is available in the public record for this rulemaking and listed at Unit X.A.2.f. of this preamble.

Between 1990 and 1994, 1,924 chemical substances were screened for inclusion in the risk management (RM) program. Of these candidate chemical substances, 561 were selected for more detailed review based on potential risks. Of the 561 chemicals evaluated, 125

(22%) were recommended for testing; 156 (28%) were recommended for further risk management; and 280 (50%) were recommended for closure. The Existing Chemicals Program represents a significant outlay in EPA resources, and is an important component in EPA's ability to manage unreasonable risks presented by chemical substances in commerce.

Effective risk screening and risk management are dependent upon both exposure information and hazard information. The exposure-related information reported under the IUR amendments, in combination with hazard information such as that developed under TSCA section 4 test rules, would allow the Agency to effectively screen and prioritize chemicals. In order to meet the directives put forth by Vice President Gore in his April 21, 1998 announcement (Ref. 1), EPA recently undertook the drafting of a significant proposed test rule for certain high production volume chemicals. The test rule would collect baseline hazard information which, in conjunction with the exposure-related information that would be reported under these IUR amendments, would be critical for chemical screening purposes.

EPA's Existing Chemicals Program is currently evaluating risks from indoor air pollutants, high release chemical substances listed on the Toxics Release Inventory (TRI) (established under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. sections 11001 to 11050), persistent bioaccumulators, and high production volume chemicals. While past approaches to priority setting have been primarily based on relative chemical hazards and production volume as a simple surrogate for exposure, EPA has increased its emphasis on the exposure component of risk screening and assessment. An example of this increased emphasis is reflected in the voluntary effort within EPA called the Use and Exposure Information Project (UEIP), undertaken by EPA and the Chemical Manufacturers Association (CMA), the Chemical Specialty Manufacturers Association (CSMA), the Synthetic Organic Chemical Manufacturers Association (SOCMA), and the American Petroleum Institute (API) (Ref. 2). The UEIP was undertaken cooperatively by government and industry in recognition of the difficulties encountered in obtaining current exposure information on TSCA chemicals. The UEIP, however, provided one-time reporting of information on a small number of selected high production volume chemicals. Given these efforts, the limitations of the data available from past and current information collections that are described in detail in Unit IV.B. of this preamble, and the amount of time it would take to acquire screening-level data for all of the chemical substances on the Inventory otherwise, EPA believes it is appropriate to develop a more systematic and comprehensive approach to the prioritization process. The new exposure-related information that would be reported under this proposed rule is necessary to allow more efficient and effective chemical risk screening.

V. Development of this Proposed Rule

A. Need for Change in the Inventory Update Rule

EPA is proposing to amend the Inventory Update Rule (IUR) for three primary reasons: (1) To tailor the chemical substance reporting requirements to more closely match the Agency's overall information needs; (2) to obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Chemical Substances Inventory (''the TSCA Inventory''); and (3) to improve the utility of the information reported. Changes to the information collected through the IUR, the chemicals covered by the rule, and CBI requirements accomplish these three goals.

These goals are supported by a primary policy underlying TSCA, which is that ''adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures'' (TSCA section 2(b)(1)). EPA believes that, for basic risk screening purposes, the data currently available are inadequate (See Unit IV.B. of this preamble). TSCA section 8(a)(2) authorizes EPA to require manufacturers and processors of chemical substances to report a wide variety of data, including the exposure-related information which would be reported under these amendments to IUR. These amendments would remove certain reporting requirements and add others in an effort by EPA to focus the information reported under IUR on information that is most needed so that EPA and other Federal agencies are better able to screen for risk, and consequently assess and manage risk, and so that public awareness of basic information about a large number of chemical substances is improved.

As discussed in Unit IV.B. of this preamble, any determination of ''risk'' is based on some amount of hazard information in combination with some amount of exposure information. EPA relies on risk screening to indicate which chemical substances may present a risk, and thus warrant a resource-intensive risk assessment. The EPA Science Advisory Board's ''Reducing Risk: Setting Priorities and Strategies for Environmental Protection'' report (Ref. 3) and the National Academy of Public Administration's ''Setting Priorities, Getting Results, A New Direction for EPA'' report (Ref. 4) recognize that EPA's ability to set priorities through risk screening and EPA's ability to allocate its limited resources has been significantly impeded by a lack of exposure data. Screening the potential risks posed by the chemical substances included in the Inventory and setting priorities for more detailed risk assessment and possible risk management is an enormous challenge. The manufacturing, processing, and use of Inventory chemicals result in a wide array of exposure scenarios. By collecting the exposure-related data included in this proposed amendment to the IUR, the Agency would acquire information that would greatly improve EPA's ability to identify, through risk screening, the chemical substances that could pose a risk to human health and to the environment.

1. *Exposure-related data needed for chemical risk screening.* As discussed in Unit IV. of this preamble, EPA must screen thousands of chemical substances for potential risk to determine priorities for follow-up risk assessment and management among the chemical substances included on the TSCA Inventory. Because so many chemical substances and exposure scenarios are involved, it is not practical to devote the extensive resources that would be required to develop more precise exposure data, such as occupational and environmental monitoring data. Instead, EPA must identify and rely on exposure-related data that are more accessible and that are reasonably accurate and useful for identifying potential chemical risks.

EPA has had access to certain types of exposure-related information which it has found to be extremely useful. For example, EPA's New Chemicals Program requires the submission of exposure-related information in Premanufacture Notice (PMN) submissions. This information is used in developing risk estimates to determine the status of the chemical

under evaluation within the New Chemicals Program. Under section 5 of TSCA, companies must submit a PMN to EPA at least 90 days before initiating the manufacture for commercial purposes (including import) of chemical substances that are not included on the TSCA Inventory. Chemical substances included on the TSCA Inventory are often referred to as ''existing chemicals'' and those not included on the TSCA Inventory are often referred to as ''new chemicals.'' EPA reviews the potential risks of new chemicals for which it has received a PMN and may act to restrict certain aspects of the chemicals' manufacture, processing or use. For example, for chemical substances that pose potential risks to workers based on estimates of inhalation exposures, the Agency often requires the use of respiratory protection by workers. EPA requires companies to include information in their PMN submissions that will provide an accurate review of potential exposures and risks. Exposure-related data included in the PMN include estimates of production volume, categories of use, percent production volume in categories of use, releases during manufacture, processing and use, maximum number of workers exposed, and physical form of the chemical. Since the creation of the New Chemicals Program, EPA has successfully reviewed the potential risks of approximately 32,000 chemicals.

The exposure-related information submitted in PMNs is typically developed prior to the manufacture of the chemical and prior to the addition of the chemical to the TSCA Inventory; information submitted through the New Chemicals Program is not sufficient for the future screening of new chemicals once they have been added to the TSCA Inventory (i.e., once they have become existing chemicals). The exposure-related information submitted in a PMN is not necessarily reflective of exposures once a chemical substance is added to the Inventory and is produced commercially by the company that originally submitted the PMN and/or any number of additional companies. Production volume information, for example, is provided only once during the PMN process, whereas production volume information is tracked over time under the IUR. EPA's analysis of the PMN data base is provided in a document entitled, ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening,'' found in the record for this proposal and listed at Unit X.A.2.a. of this preamble.

Another example of EPA's use of available exposure-related information is in the evaluation of chemical risks and establishment of hazard testing priorities in the Agency's New Chemicals and Chemical Testing Programs. These programs rely upon data that are similar to data that would be collected under this proposal. EPA's New Chemicals Program, under the authority of TSCA section 5(e)(1)(A)(ii)(II), has established an exposure-based policy which utilizes various exposure criteria to guide its decisions regarding the issuance of consent orders. These criteria include estimates of production volume, releases, potential dose rates, numbers of potentially exposed workers and consumers, and the size of the potentially exposed general population and are used to determine whether an exposure concern exists (Ref. 5). These decisions are based on the expected use of the new chemical.

Similarly, the Chemical Testing Program relies upon exposure-related information to require testing under TSCA section 4. In order to require testing, EPA must initially make either risk-based findings under TSCA section 4(a)(1)(A) or exposure-based findings under TSCA section 4(a)(1)(B). Risk-based findings are partially based on exposure-related information. Because exposure is a component of risk (see Unit IV.B. of this preamble), risk-based findings require a demonstration that there is some possibility of exposure to a chemical substance. The possibility of exposure must be based on more than theoretical scenarios; some amount of factual information must be demonstrated by EPA. *Chemical Manufacturers Association* v. *EPA*, 859 F.2d 977, 991 (D.C. Cir. 1988). Exposure-based findings, on the other hand, are based entirely on exposure-related information. Generally, EPA relies upon production volume information in addition to chemical release information or human exposure information (i.e., for general population exposure, consumer exposure, or worker exposure) to make exposure-based findings. EPA's interpretation of its legal authority to make the findings necessary to require testing under TSCA section 4(a)(1)(B) is articulated in a Statement of Policy (''B Policy'') (58 FR 28736, May 14, 1993). Many of the exposure data elements included in these proposed amendments to IUR are specifically relevant to the exposure-related findings contained in the B Policy. As a result, the exposure information submitted under the IUR amendments would be integral to the identification of candidate chemicals for inclusion in test rules. For example, the use information reported under the IUR amendments would assist in the selection of chemicals for inclusion in a planned test rule that would collect hazard information on chemicals to which children may be exposed, many of which are present in consumer products.

Other organizations recognize that exposure-related data is useful for screening chemical risks. The Chemical Manufacturers Association (CMA), in a letter to EPA (Ref. 6), noted that data on chemical use volumes, numbers of exposed workers, magnitudes of chemical usage per worker, number of use sites, and environmental releases can supplement production volume data in chemical risk screening. In addition, the exposure-related information that would be reported under these amendments to IUR would support chemical screening by the Consumer Product Safety Commission (CPSC). CPSC has stated that, ''[a]t present, there is no comprehensive source of information on the ingredients of household chemicals and CPSC does not have the authority to obtain this information. The [IUR amendments] would be a first step in obtaining information on product ingredients and provide a more efficient means of screening household chemicals for emerging hazards under the Chemical Hazard Program'' (Ref. 7).

Certain international organizations collect and utilize exposure-related information. The European Union (EU), in a regulation enacted in 1993 regarding the evaluation and control of existing substances (Ref. 8), requires chemical manufacturers and importers to report a variety of hazard and exposure information for the chemical substances they manufacture or import so that the EU can undertake preliminary risk evaluations and identify lists of priority substances which require special attention. Information on reasonably foreseeable uses of chemical substances is included in these reports. The types of use data collected under the EU regulation are similar to the types of use data that would be reported under this proposed rule.

The Organization for Economic Cooperation and Development (OECD) also recognizes the utility of exposure-related information. OECD sponsors an international cooperative effort designed to share the costs of chemical testing among its more than 20 member countries. This effort, called the Screening Information Data Set (SIDS) Program, has focused on securing

ecological and human hazard data for high production volume chemical substances. As this Program has evolved, the member countries have become more aware of the need to consider the contribution of exposure to estimates of potential chemical risks. At times, decisions to pursue followup risk management have been delayed until exposure information could be developed. Without exposure information for use in risk screening and risk assessment, sufficient information did not exist to determine potential risk. To ensure a consistent and accurate evaluation of potential exposures by the various member countries, OECD organized a meeting of designated national experts in occupational and environmental exposure assessment, including experts from the chemical industry and international agencies, to define the exposure-related data needed to support screening level prioritization decisions for chemical testing and risk assessment. The exposure data that are recognized as needed for SIDS screening-level determinations are very similar to the exposure data that would be reported under these amendments to the existing IUR (Ref. 9).

The successful use of exposure-related information in the development of risk estimates in EPA's New Chemicals Program (described in this unit) illustrates that the data reported under this proposed amendment to IUR would support EPA's risk screening of existing chemicals in commerce. EPA is proposing to collect readily obtainable exposure-related data that can be used to better establish priorities for its Existing Chemicals Program. The new IUR data elements included in this proposed rule are related to or are indicative of three components of exposure: The number of ecosystems or size of human populations potentially exposed (for example, data elements regarding number of sites, number of workers, and use in consumer products); the potential routes, magnitudes, and concentrations of exposures experienced by the environment or by humans (for example, data elements regarding function of chemical substances in industrial processes, physical form of chemical substances, industrial sectors where chemical substances are manufactured and used, average concentration, and maximum concentration); and the frequency and duration of potential exposures (for example, data elements regarding industrial function categories and commercial and consumer use categories). EPA intends to supplement the current data collected under IUR with additional data elements that would improve the Agency's ability to evaluate each of these components of exposure.

2. *Need to screen risks of inorganic chemical substances.* In this action, EPA is proposing to remove the IUR reporting exemption for inorganic chemical substances which currently exists at 40 CFR 710.26(a). The exemption exists because EPA believed in the past that the hazard potential of many inorganics was ''relatively well-established'' (50 FR 9944, 9947, March 12, 1985) and that information about these hazards was a sufficient basis for prioritization within inorganic chemical substance risk assessment. EPA now intends to increase the consideration given to exposure, another component of risk, in screening chemicals and in setting priorities for risk assessment and risk management activities due to its belief that chemical hazard information alone is an insufficient basis for prioritization for these purposes. EPA therefore believes that the basis for this exemption is no longer applicable. However, during interagency review it was suggested that EPA first collect the IUR information in Parts I., II., and IV. of the revised Form U on these substances before collecting processing and use information in Part III. of the revised Form U.

The need for additional basic information regarding production volume and other exposure-related data on the ongoing uses of inorganic chemical substances has been shown in a variety of ways. For example, the use of asbestos building materials led to the exposure of workers and other building occupants to asbestos. EPA has worked toward controlling and mitigating this exposure to asbestos. However, there is evidence that builders have unknowingly been incorporating new materials containing asbestos into buildings (Ref. 10). By including inorganic chemicals under the IUR, information needed to control exposure to asbestos in buildings would be made available to EPA. Such examples highlight the importance not only of production volume data, but of the use and other exposure-related data EPA may propose to collect through the IUR in the future.

At this time, EPA is proposing that inorganic chemicals would be subject to only partial IUR reporting. Partial reporting consists of the information in Parts I, II, and IV of revised reporting Form U, whereas full reporting consists of all information on the reporting form (see Unit VI. of this preamble). EPA is choosing to only require partial reporting on inorganic chemicals to allow the Agency to become familiar with information on inorganics; EPA does not generally require reporting of information on inorganics under the existing IUR. Partial reporting would identify inorganic chemicals that are produced in quantities large enough to report to IUR, and would allow EPA to generally become familiar with the production volumes of inorganic chemicals. In addition, limiting IUR reporting for inorganic chemicals to a partial report would allow manufacturers (including importers) of these chemicals, who may never have reported to IUR before, to familiarize themselves with the most basic IUR reporting requirements.

Because EPA and other IUR data users have a need for processing and use information on inorganic substances, EPA will review the need for full IUR reporting, i.e., all parts of revised reporting Form U, from manufacturers (including importers) of inorganic chemicals in the future. Based on EPA's review of the information submitted on inorganic chemicals in the first reporting period under these IUR amendments, EPA may propose to require full IUR reporting on inorganic chemicals by the second reporting period.

3. *Need for procedural reforms to IUR*—a. *Linking IUR data to other reporting.* EPA is undertaking a comprehensive facility identification initiative to improve coordination and comparability among different information reporting mechanisms. To facilitate this effort, EPA is establishing the Facility Registry System (FRS) as a central information resource of definitive facility information, which will link all facilities represented in EPA program data bases through common facility identification data elements. As part of the program, the FRS will include implementation of a new facility numbering system identifying each facility with a unique Facility Registration Identifier (FRI) which will be used for electronic and integrated reporting and central receiving. EPA and the States will develop the business rules for assigning the FRI to each facility and will determine how the number will be used in reporting. EPA anticipates releasing the first version of the FRS and the new numbering system in the fall of 1999.

In line with the FRS initiative, EPA is proposing to amend IUR so that future data collections include the reporting of the submitting plant site's FRI, as well as the county in which the plant site is located. Use of the new FRI number is

important to EPA and others in linking IUR information with information from other data bases, such as the Toxics Release Inventory (TRI).

In the alternative, should the FRS initiative not be underway at the time this proposed rule becomes final, EPA will require submitters to report the plant site's EPA identification number (ID), if it has one. The EPA ID is the 12-character number assigned to sites covered by the hazardous waste regulations under RCRA (40 CFR 262.12). For sites that have not been assigned an EPA ID, submitters would report this item as ''not applicable.'' Section 262.12 states that plant sites that generate hazardous waste can obtain an EPA ID by applying to the EPA Administrator using Form 8700-12 ''Notification of Regulated Activity.'' Upon receipt of such a request, the Administrator assigns an EPA ID number. Plant sites are required to report the EPA ID on RCRA manifests and biennial reports.

EPA also is proposing to amend the reporting basis from a corporate fiscal year basis to a calendar year basis. This amendment would make the information submitted under these amendments more consistent than the information submitted under the existing IUR because all submitters would refer to the same period of time when gathering reportable information. In addition, this amendment would make the IUR reporting schedule more comparable with other EPA reporting requirements, such as TRI, thereby increasing EPA's ability to link information from various data bases.

b. *Improving the process by which CBI claims are made.* IUR submitters currently have the ability to claim much of the information they report under the IUR as CBI. The ability to make CBI claims would continue under these amendments; however, EPA is proposing certain modifications to existing CBI policies in order to ensure that CBI claims are justified, and to facilitate the submission and subsequent release of non-confidential data.

TSCA section 14 provides that certain information may be claimed as confidential. The impact of a confidentiality claim on information is that the information may only be made available to properly trained Federal government employees and contractor employees. Accordingly, under most circumstances, non-Federal entities cannot be authorized for access to CBI data for independent assessment or other purposes. In addition to significantly increasing transaction costs, CBI claims can impact EPA's ability to use IUR data, because it is more difficult to justify risk screening, assessment and management decisions when data driving those decisions are CBI and cannot be publicly shared. While legitimate CBI claims protect valuable proprietary information, invalid claims thwart the Agency's goal of using TSCA data to support a wide variety of chemical management activities as intended by Congress.

Since the enactment of TSCA in 1976, the Agency has grappled with its related, but somewhat conflicting, obligations to protect CBI but also to make information available to the public. In 1990, the Agency initiated a program by which industry's TSCA CBI claims practices were examined and assessed (Refs. 11 and 12). The program revealed that the Agency's transaction costs are increased with CBI claims, the Agency's ability to use CBI data is limited, and CBI claims make it difficult to describe with specificity the facts necessary to justify chemical risk assessment and management decisions. The program also demonstrated that CBI claims prevent state governments engaging in chemical management activities from benefiting from access to TSCA CBI information (Ref. 13).

EPA's review of CBI claims practices also revealed that some CBI claims appeared to be unjustified. In some cases, certain information was claimed as confidential when the same information was available in a variety of publicly available sources such as newspapers, advertisements, and Internet websites. For example, site identity was at times claimed as CBI in IUR filings when that information was available in a variety of public documents. While it was widely accepted that the need for CBI protection for certain information expired over time, there was no mechanism which ensured that older CBI claims would be reviewed by the information submitter. The public increasingly questioned the validity of CBI claims over time as the overall credibility of industry's initial CBI claims was diminished.

One of the purposes of the CBI-specific IUR amendments is to ensure that CBI claims are valid at the time they are filed. Another purpose is to ensure that certain critical information, such as production volume information, is submitted in a way that generally enables the Agency to characterize industry-wide production volume, but that protects the specific CBI information involved. Finally, the new CBI amendments are intended to act as a mechanism that ensures that submitters periodically review older CBI claims and declassify information as their need for confidentiality ends.

Specifically, in an effort to increase the public availability of data and reduce transaction costs, EPA is proposing requirements in addition to those currently in place to require that submitters assert a separate CBI claim for production volume data reported in ranges; submitters substantiate CBI claims for plant site identity at the time the claims are made; and submitters reassert CBI claims for information claimed as CBI in past IUR filings. A detailed discussion of confidentiality issues is included in Unit VIII. of this preamble.

4. *Creating an exemption from IUR reporting for certain forms of natural gas.* EPA is proposing to add an exemption from IUR reporting to 40 CFR 710.26 for certain forms of natural gas. The six chemical substances that would be subject to this exemption are as follows: CAS No. 64741-48-6, Natural gas (petroleum), raw liquid mix; CAS No. 68919-39-1, Natural gas condensates; CAS No. 8006-61-9, Gasoline natural; CAS No. 68425-31-0, Gasoline (natural gas), natural; CAS No. 8006-14-2, Natural gas; and CAS No. 68410-63-9, Natural gas, dried.

EPA currently believes that additional IUR information on these chemical substances would be of limited value in the execution of various assessment and testing programs because EPA believes that adequate IUR information on these chemical substances is available to fulfill EPA's current needs, and the current needs of other IUR information users.

B. Consideration of Alternative Data Sources

TSCA section 8(a)(2) states that, to the extent feasible, the Administrator of EPA shall not impose reporting requirements under TSCA section 8(a)(1) which are unnecessary or duplicative. In order to ensure that the reporting requirements proposed in these amendments are not unnecessary or duplicative, EPA considered the extent to which the data that would be gathered as a result of this rulemaking are available to EPA through existing public data collections.

The data collections considered by EPA include EPA sources such as the current IUR, the TSCA Preliminary Assessment Information Reporting (PAIR) rule (40 CFR part 712), the TRI, and the Use and Exposure Information Project (UEIP), as well as other Federal sources such as the National Occupational Exposure Survey (NOES). EPA has used these sources to support its chemical review program. Although

the sources can provide useful information, EPA has been unable to perform the large-scale screening necessary to screen the chemicals on the TSCA Inventory based on risk because of limitations in the existing data. Some sources are dated, others are narrow in coverage of data elements or limited to certain chemical substances, while others entail procedural complications which limit their effectiveness in meeting EPA's needs. Based on this review, EPA has concluded that these information sources, considered individually or in the aggregate, do not adequately substitute for the information EPA is proposing to collect in this rulemaking. A detailed description of the basis for this conclusion is provided in the several documents provided in the public record for this proposal. These documents are: ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening,'' ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' and ''A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA.'' These documents are listed at Unit X.A.2.a., Unit X.A.2.f., and Unit X.A.2.i. of this preamble respectively.

The following is a brief description of the extent to which each of these data collections includes exposure-related information (e.g., number of plant sites and workers, industrial and consumer uses, etc.), and whether they are sufficient for the risk-based screening of chemical substances listed on the TSCA Inventory. The documents mentioned in the preceding paragraph provide a more comprehensive and detailed discussion of existing exposure information data sources.

1. *The current IUR*. Although certain provisions in the current IUR would be amended by this action, many of its requirements would remain unchanged under these amendments. The existing IUR requires chemical manufacturers (including importers) to provide to EPA every four years the identity of chemical substances manufactured (including imported) in annual quantities of 10,000 lbs. or more at each plant site they own or control. The information required includes company name, plant site location, plant site Dun and Bradstreet number, the identity of the chemical substance, and the production volume of the chemical substance. The IUR has been a reliable source of production volume and site location data for organic chemical substances. Inorganic chemical substances are currently excluded from reporting.

Past approaches to the risk screening of chemical substances have been primarily based on relative chemical substance hazard, coupled with IUR production volume data. EPA has determined that production volume information alone is not typically adequate as a proxy for exposure information for purposes of risk assessment and risk screening (Ref. 14). In the past, the absence in IUR of exposure-related data beyond production volume data has severely limited the utility of IUR in a comprehensive screening program for chemicals in commerce.

2. *PAIR rule*. PAIR, which was promulgated under TSCA section 8(a), requires any person who manufactures (including imports) a particular chemical substance during the indicated reporting year to complete and submit a form that requests a variety of information pertaining to the manufacture and processing of TSCA chemicals. In some ways this information is similar to the information that would be reported under these amendments to IUR, while in other ways the information reported under PAIR is different.

Information reported under PAIR includes, but is not limited to, the following: chemical and company identity, plant site location, annual volume manufactured (including imported), plant site and customer activities (i.e., whether the substance is manufactured or used as a reactant or nonreactant, and whether operations are enclosed, controlled release or open), workers and worker hours, and types of industrial products (i.e., whether the substance is produced in pure form or incorporated into a mixture or article), and whether environmental releases occur (see 40 CFR 712.28). This information, on a per report basis, is both broader and narrower than the proposed IUR amendments information. For instance, release information is collected under PAIR, but would not be collected under the proposed IUR amendments. At the same time, PAIR reporting does not include information which can identify uses by specific consumer groups or NAICS codes, whereas the proposed IUR amendments would require the reporting of such information by certain entities. Duplicative reporting under both PAIR and IUR is avoided under the existing IUR regulations at 40 CFR 710.35, and would be avoided under the proposed IUR amendments as well.

The TSCA Interagency Testing Committee (ITC) determines which chemical substances are included on the TSCA section 4(e) Priority Testing List. PAIR rules are primarily used to collect information on those chemicals the ITC is considering designating for testing under TSCA section 4 (40 CFR 712.30). PAIR reporting is done on a one-time basis in response to the publication of a chemical-specific rule amendment, as opposed to the IUR which, in a single rule, requires recurring reporting for a large group of chemicals. About 458 chemicals have been subject to PAIR reporting as of September 1996, and 360 companies have submitted 1,668 reports (See ''Preliminary Assessment Information Rule (PAIR) Database, Manufacturing Process Type/Release Analysis and Number of Workers/ Production Quantity Analysis,'' available in the public record for this proposal, and listed at Unit X.A.2.b. of this preamble). Other features of PAIR include a reporting threshold of 500 kg/ yr/site and reporting based on a corporate fiscal year.

Both PAIR and IUR could potentially be utilized to require the reporting of data regarding a greater number of chemical substances than the IUR currently covers. For example, the current IUR exemption for polymers and low volume chemicals could be eliminated, or a PAIR rule could be used to collect information for these exempted chemicals.

There are two major differences between reporting under IUR and PAIR other than differences in specific data elements. One of the differences is that IUR requires the reporting of information every 4 years, while PAIR requires the reporting of information on a one-time basis. However, the chemical industry is dynamic, and 30% of the chemicals for which IUR information was reported in 1990 were not reported in 1994. Because the industry is dynamic, the information it would report under the IUR amendments could change from reporting year to reporting year. Therefore, the information collected under these amendments would present a view of exposure to chemical substances that recognizes chemical industry dynamics which PAIR rules are not able to reveal. The other major difference between IUR and PAIR is that IUR requires the reporting of information on a large number of chemical substances during each reporting period, whereas each PAIR rule typically covers only one or a much more limited group of chemical substances. As discussed above, information on a large number of chemicals is necessary for the effective implementation of a chemical screening program.

3. *Toxics Release Inventory (TRI).* EPCRA section 313 and section 6607 of the Pollution Prevention Act (42 U.S.C. 13106(b)) require certain facilities that manufacture, import, process, or ''otherwise use'' EPCRA section 313 listed toxic chemicals at or above specified thresholds to annually report their releases and other waste management activities regarding such substances. The reporting thresholds are generally 25,000 lbs. per year for chemicals that are manufactured (including imported) and processed, and 10,000 lbs. per year for chemicals that are otherwise used. Included in the report is the following information: Chemical identity, facility identity, parent company identity, certain general activities and uses of the chemical at the reporting facility, the maximum amount on-site, releases on-site and quantities sent off-site for disposal, quantities combusted for energy recovery and recycled both on-site and off-site, and on-site waste treatment methods and efficiencies.

Only about 650 chemicals and chemical categories are currently reportable, including chemicals excluded from TSCA jurisdiction such as pesticides, and chemicals currently exempt from the IUR, such as inorganics. This list consists of fewer than 1% of the chemicals listed on the TSCA Inventory. In addition, facilities subject to the reporting requirements of EPCRA section 313 are limited to specific SIC codes and Federal facilities. Only facilities with 10 or more full-time employees are currently required to report. About 22,000 facilities report to TRI.

TRI data are useful for screening and assessing releases from industrial facilities for site-specific assessments of potential general population or environmental exposures to populations near facilities that manufacture, process or use EPCRA section 313 listed toxic chemicals. However, the TRI universe of chemicals is limited to a small portion of the chemicals on the TSCA Inventory. Also, TRI does not contain worker exposure and use data. These data, along with a larger universe of chemicals than is included in the TRI, are needed to accomplish the type of broad based chemical screening process that would be possible under the proposed IUR amendments.

4. *National Occupational Exposure Survey (NOES).* In 1983, NIOSH completed a systematic effort to collect data on potential occupational chemical, physical, and biological exposure agents in a representative sample of businesses. The sample was designed to be representative of virtually all of the non-agricultural, non-mining, and non-governmental businesses covered under the Occupational Safety and Health Act (OSH Act) of 1970. The survey consisted of observational data collected at 4,490 establishments by NIOSH surveyors through field visits, which included walk-through surveys and interviews of employees at the establishments. To develop nationwide samples from the data, the survey results were multiplied by a weighting factor. A description of the survey and the data base can be found in the public record for this proposal (Ref. 15).

The NOES data base includes information on plant site location, plant site SIC code, plant site occupational safety and health programs, occupational titles of workers potentially exposed, number of employees per occupational title, process steps, and product trade names. EPA has frequently used the NOES survey to estimate the total number of workers potentially exposed per chemical per SIC code; to estimate the number of chemical manufacturing, processing, and use sites; to rank potential exposures; and to develop exposure assessments.

Now over 15 years old, the NOES data have become progressively dated, and as a consequence, less representative of current exposure situations. In light of this shortcoming, EPA believes that the NOES data base cannot substitute for the up-to-date data base that EPA would develop with the proposed IUR amendments.

5. *Use and Exposure Information Project (UEIP).* The UEIP is a program developed jointly by EPA and chemical manufacturers. It provides a method for chemical manufacturers to voluntarily send readily obtainable use and exposure information to EPA for chemical substances entering the Existing Chemicals Program's screening assessment process. A sample UEIP data submittal package is included in the public record for this rulemaking (Ref. 2). The program started in the fall of 1992 and was developed after CMA and SOCMA asked EPA what the chemical industry could do to help strengthen EPA's Existing Chemicals Program. EPA explained that accurate use and exposure information was not available and that better information in this area was a key need. A joint industry/EPA workgroup was formed to address this need, to define relevant exposure data, and to develop a data transfer process for industry to effectively transmit data to EPA. More recently, the API and CSMA have endorsed and participated in further development of this project.

In the UEIP, manufacturers (including importers) voluntarily report production volume, site location, environmental releases, number of potentially exposed workers, monitoring data, industrial and consumer uses, and percent of production volume attributed to a given use. For any given chemical substance, the data transmitted to EPA via UEIP are more detailed than the data EPA would receive as a result of these IUR amendments. Upon receipt of UEIP data from manufacturers and importers, EPA prepares an exposure profile. The UEIP program is limited by agreement among the parties to obtaining data on no more than 40 chemical substances per year. The screening information that would be generated by this proposal would assist with the selection of chemical substances for inclusion in the UEIP program.

The UEIP program has yielded important advances for EPA's risk assessment and risk management efforts for several chemical substances. For example, exposure assessments based on the UEIP data have in some instances obviated the need for additional testing or followup risk management action for certain chemical substances under the SIDS program. However, the proposed amendments to IUR would include a wider range of chemicals than the UEIP and therefore would address the need for exposure-related data from across a wider segment of the chemical industry.

6. *Use Cluster Scoring System (UCSS).* EPA has developed the UCSS to identify potential risks of, and to establish regulatory review priorities for, chemical substances used in similar applications, or ''use clusters'' (Ref. 16). For example, instead of evaluating a single chemical used as a paint stripper, the UCSS evaluates the exposures and risks posed by the entire set of chemical substances that are used as paint strippers.

The UCSS evaluates exposure based on information from several sources. Although the UCSS has proven to be a valuable tool in conducting screening level exposure assessments, some of the sources of UCSS data are dated and some of the methods used to further develop the data are not yet validated for accuracy. Some of these data are discussed briefly below.

Use volume estimates are obtained from past EPA studies and commercial market reports. These sources are very limited in the number of uses covered and the detail of use information. Only large volume uses (100,000 kilograms/year or more) of chemical substances are usually captured in commercial market studies. These studies are further discussed in the document entitled, ''A

Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA,'' available in the public record for this rulemaking and listed at Unit X.A.2.i. of this preamble.

Consumer use data are obtained from internal data bases (such as EPA's Indoor Air Chemical Database) and the Hazardous Substances Data Bank (HSDB), a database of Department of Transportation (DOT) information compiled by the National Library of Medicine. Each of these data bases, however, contains limited consumer use information for a small number of chemicals. These data bases are further discussed in the document entitled, ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' and in ''A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA,'' both of which can be found in the public record for this proposal and which are listed at Unit X.A.2.f. and Unit X.A.2.i. of this preamble.

Environmental release estimates are obtained from the TRI. The UCSS is not limited to TRI chemicals; however, no comprehensive sources of release data are available for non-TRI chemical substances. While the UCSS contains data from the Biennial Reporting System (BRS), these data are not used by UCSS to rank potential exposures. BRS, a data base maintained by EPA's Office of Solid Waste, is a collection of information on the quantity, management, and minimization of hazardous solid or liquid wastes from facilities that generate and/or manage these wastes. Information is identified by the RCRA waste codes. These waste codes identify the type of waste and frequently describe mixtures of chemicals; they do not provide information on the waste stream composition. This lack of composition information makes it difficult to determine the quantity of an individual chemical substance in the waste. Therefore, there is little information to use to determine potential exposures.

Estimates of the number of potentially exposed workers and the number of chemical processing and use sites are obtained from the NOES and the Bureau of Census' Census of Manufacturers. As in Unit V.B.4. of this preamble, the NOES data (developed by NIOSH) are over 15 years old and contain uncertainties due to the age of the data as well as sampling errors and systematic biases. The Census of Manufacturers data are not chemical-specific; chemical-specific or use-specific conclusions are therefore based upon data provided by four-and six-digit SIC codes when Census of Manufacturers data are used.

A recent review of the UCSS by EPA's Science Advisory Board (Ref. 17) found that ''the cluster scoring system heavily weights exposure data. . . Unfortunately, there are no easily accessible data on exposure.'' The proposed amendments to the IUR would create a data source that would be used to augment the information in the UCSS, giving EPA a tool for use in prioritizing chemical clusters in a way that is consistent with the Science Advisory Board's suggestions (Ref. 16). Because the exposure information sources used to support many of EPA's existing chemical assessments are essentially the same as those relied upon by the UCSS, this comment is generally applicable to most of EPA's efforts to assess exposure to existing chemical substances.

7. *Other data sources.* Other data sources that have been considered are listed in the ''Inventory of Exposure-Related Data Systems Sponsored by Federal Agencies'' (Ref. 18). This document is a compilation of information on federally managed data systems that contain exposure information. These systems access collections of analytical results that assess environmental media such as air, soil, or water as well as analytical results from food, human samples, or bulk chemicals.

Each of the data bases described in the document is of limited utility due to a small or specialized sample size, the limited number of chemicals, or the age of the data. None of the data bases, either alone or combined, provide the Agency with the full array of screening level data on chemical substances that would be collected by the proposed amendments to IUR.

The information in available data systems does not provide a sufficiently clear picture of the potential for chemical exposure. Some of the systems are regional, rather than national in scope. Several systems cover only a very limited set of chemical substances, or a limited number of chemical uses, or only specific industry sectors. Several systems collect information on categories of pollutants or on waste streams rather than on specific chemical substances, making it difficult to use the data in chemical risk screening. Many of these systems collect monitoring data which are frequently media-specific (e.g., air or water), but do not collect information on the potential sources of chemical releases to the environment. This proposed rule would provide the exposure information needed for screening the chemical substances included on the TSCA Inventory for potential risk.

VI. Amendments Affecting All Manufacturers (Including Importers)

As discussed in detail in Unit VI.B. of this preamble, plant sites that manufacture (including import) a chemical substance in annual quantities of 25,000 lbs. or more would be required to report the information in Parts I., II., and IV. of Revised Reporting Form U. This information relates to basic site identification, manufacturing information, and CBI reassertion. Sites that manufacture (including import) a chemical substance in annual quantities of 300,000 lbs. or more would be required to report the information in Part III. of Reporting Form U in addition to the information in Parts I., II., and IV. This additional information relates to the processing and use of chemical substances.

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(IMPORTANT: Type only, read instructions before completing from)

PAGE 1 of ___

EPA

U.S. Environmental Protection Agency
Washington, DC 20460
Partial Updating of TSCA Inventory Data Base
Production and Site Report
(Section 8(a) Toxic Substances Control Act, 15 U.S.C. 2607)

FORM U 2001

REPORT NUMBER

Mark "X" here if this is a revision to a previous report

Previous Report Number

PART I. FACILITY IDENTIFICATION INFORMATION

SECTION I. CERTIFICATION

Certification Statement: I hereby certify to the best of my knowledge and belief that (1) all information entered on this from is complete and accurate; and (2) the confidentiality statements on the back of this form are true and correct as to that information for which I have asserted a confidentiality claim.

1.1 Signature	1.2 Date	1.3 Name
		1.4 Title

SECTION II. COMPANY INFORMATION

2.1 Company Name	2.2 Company Dun & Bradstreet
2.3 Technical Contact Name	2.4 Telephone (with Area Code)

Company Street Address		Company Mailing Address Check if Same ☐	
2.5 Address (Line 1)		2.10 Address (Line 1)	
2.6 Address (Line 2)		2.11 Address (Line 2)	
2.7 Company City		2.12 City	
2.8 State	2.9 Zip Code	2.13 State	2.14 Zip Code

SECTION III. PLANT SITE IDENTIFICATION

3.1 Plant Site Name	3.2 EPA Facility Identification Number	3.3 Plant Site Dun & Bradstreet

Plant Site Street Address		Plant Site Mailing Address Check if Same ☐	
3.4 Address (Line 1)		3.10 Address (Line1)	
3.5 Address (Line 2)		3.11 Address (Line 2)	
3.6 City	3.7 County	3.12 Address City	
3.8 State	3.9 Zip Code	3.13 State	3.14 Zip Code

EPA Form Number <XXXX-X> (Rev 6/28/99) - Previous editions are obsolete
Form Approved OMB Number: XX/X-XXXX

PAGE ___ of ___

REPORT NUMBER

PART II. MANUFACTURING INFORMATION

SECTION I. CHEMICAL IDENTIFICATION		CBI
1.1 Chemical Identifying Number	1.2 Id Code	
1.3 Chemical Name		

SECTION II. BASIC MANUFACTURING INFORMATION						2.1 Company Information	CBI
2.2 Plant Site CBI	CBI	2.3 Site limited (Y/N)		CBI	2.4 Activity (M or I)		CBI
2.5 Production Volume (LB)				CBI	2.6 Production Volume range		CBI

SECTION III. MANUFACTURING EXPOSURE RELATED DATA											
3.1 Number of workers (code)		CBI	3.2 Physical Form (code)		CBI	3.3 Maximum Concentration (code)		CBI	3.4 Average Concentration (code)		CBI

PART III. PROCESSING AND USE INFORMATION

Complete Part III, section I and II only if the production volume noted in Part II, Section II 2.5 is greater than or equal to 100,000 lb/year

SECTION I. INDUSTRIAL PROCESSING AND USE EXPOSURE RELATED DATA	N/A

	a. Process or Use (code)	CBI	b. 5-digit NAICS Code	CBI	c. Industrial Function Category (code)	CBI	d. % Production Volume	CBI	e. Number of Sites (code)	CBI	f. Number of Workers (code)	CBI
1.1												
1.2												
1.3												
1.4												
1.5												
1.6												
1.7												
1.8												
1.9												
1.10												

PAGE ___ of ___

REPORT NUMBER

SECTION II. CONSUMER AND COMMERCIAL END-USE EXPOSURE RELATED DATA	N/A

	a. Consumer and Commercial Product Category (code)	CBI	b. % Production Volume	CBI	c. Maximum Concentration (code)	CBI		a. Consumer and Commercial Product Category (code)	CBI	b. % Production Volume	CBI	c. Maximum Concentration (code)	CBI
2.1							2.2						
2.3							2.4						
2.5							2.6						
2.7							2.8						
2.9							2.10						

PART IV. REASSERTION OF PAST CBI CLAIMS

1.1 If an IUR report was submitted to EPA for the last reporting cycle for the chemical identified in Part II, Section I, Item 1.1 from the plant site listed in Part I, Section III, enter that report number in the space provided:	Last IUR Report Number

1.2 Do you wish to reassert CBI claims made on your last IUR report?

☐ NO — If you check "**NO,**" all the information you have previously claimed CBI on IUR's for this chemical will be **DECLASSIFIED AND PUBLICLY RELEASED WITHOUT FURTHER NOTICE.** This includes any reassertions made on your last IUR report.

☐ YES, all — ***SEE BELOW**

☐ YES, some — If you check "**YES, some,**" include with this report an amended IUR report indicating the specific changes you wish to make in your CBI claims. ***SEE BELOW**

*** If you checked either of the "YES" boxes above, any data which you continue to claim CBI must qualify for this protection per 40 CFR 710.38. If any of your answers to the substantiation questions listed in 40 CFR 710.38 and submitted with your original CBI claim (which you now wish to re-assert) have changed, please submit amended answers together with this Part IV.**

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EPA will make available detailed instructions for completing the reporting form before the effective date of the final rule. EPA also intends to encourage electronic submissions of the final form. The procedures for electronic submissions will be made available before the effective date of the final reporting rule.

A. Amendments to Substances Covered by IUR

1. *Inorganics*. EPA is proposing to require partial reporting for inorganic chemical substances (i.e., Parts I., II., and IV. of revised Reporting Form U, but not Part III.), most of which are presently excluded under the current IUR regulations at 40 CFR 710.26(a). As discussed in Unit V.A.2. of this preamble, EPA intends to screen potential risks associated with inorganic chemical substances to set priorities for testing, more detailed risk assessment and potential risk management. The removal of the IUR reporting exemption for inorganic chemical substances would allow EPA to gather information important for effective risk screening and priority setting.

2. *Petroleum process streams*. EPA is proposing to exempt as a class certain chemical substances termed ''petroleum process streams'' from a portion of the amended IUR's reporting requirements. For purposes of this proposed rule, the petroleum process streams included in the exemption would be the multi-component complex chemical substances listed by Chemical Abstracts Service (CAS) Registry Number in the proposed regulatory text at § 710.26(d). The reporting excluded by this exemption would be the exposure-related data contained in Part III. of Revised Reporting Form U. The chemical substances listed as petroleum process streams in the proposed regulatory text were derived from the 1983 publication of the API entitled ''Petroleum Process Stream Terms Included in the Chemical Substances Inventory Under the Toxic Substances Control Act (TSCA)'' (Ref. 19). Chemical substances listed in the API document consisting of a single component chemical, except for water, would not be considered petroleum process streams for IUR reporting purposes.

This exemption is not being proposed because these streams are of known low toxicity. In fact, EPA believes that several petroleum process streams are toxicologically active; however, EPA believes that it, as well as other IUR information users, will not have a need in the near future for full IUR reporting on petroleum process streams. EPA will take action to revoke this exemption if its needs change. About 5,850 of the about 24,000 IUR reports submitted to EPA during the 1994 reporting period were for chemical substances that fit the definition of petroleum process streams. Therefore, this proposed exemption is expected to significantly reduce submitters' reporting burdens from the burden that would exist without the exemption.

3. *Natural gas*. EPA is proposing to exempt certain forms of natural gas from IUR reporting. The chemical substances that would be covered by this exemption are the following: CAS No. 64741-48-6, Natural gas (petroleum), raw liquid mix; CAS No. 68919-39-1, Natural gas condensates; CAS No. 8006-61-9, Gasoline natural; CAS No. 68425-31-0, Gasoline (natural gas), natural; CAS No. 8006-14-2, Natural gas; and CAS No. 68410-63-9, Natural gas, dried.

EPA believes that adequate IUR information collected on these chemical substances to date is available to fulfill EPA's current needs, and the current needs of other IUR information users. EPA specifically requests comment on whether IUR reporting for these six natural gas substances should be required in upcoming reporting periods, and whether the six CAS numbers identified are the appropriate natural gas substances for inclusion in this exemption. EPA will take action to revoke this exemption if its needs change in the future. Approximately 1,225 of the 24,000 IUR reports submitted to EPA during the 1994 reporting period were for the six chemical substances included in this proposed exemption. Therefore, this proposed exemption would likely result in a beneficial burden reduction for IUR submitters.

B. Amendments to Reporting Thresholds

EPA is proposing to raise the IUR reporting threshold from a production volume of 10,000 lbs. per year to 25,000 lbs. per year. Every person manufacturing (including importing) a non-excluded substance at or above the threshold would be required to report the information in Parts I., II., and IV. of Revised Reporting Form U. The increased IUR reporting threshold would make the IUR and TRI reporting thresholds equivalent at 25,000 lbs. per year for manufacturers (including importers). These thresholds are also approximately equal to the recently amended PMN low volume exemption threshold of 10,000 kg (approximately 22,000 lbs.). EPA is proposing to raise this reporting threshold in order to reduce the number of reports filed, thus reducing industry burden. The new reporting threshold does not represent a finding of low exposure or low risk.

EPA is also proposing a second, higher-volume threshold of 300,000 lbs. per year. Persons who manufacture (including import) a non-excluded substance at or above this level would be required to report the information in Part III. of Revised Reporting Form U in addition to the information in Parts I., II., and IV. The information reported under Part III. relates to the processing and use of chemical substances. EPA recognizes that the requirement that processing and use information be reported would impose a burden on industry. EPA originally considered proposing a higher-volume threshold of 100,000 lbs. per year; however, in the interest of further reducing the paperwork burden imposed on industry, EPA is proposing a higher-volume threshold of 300,000 lbs. per year. EPA is proposing this separate threshold to limit exposure data reporting to a subset of a few thousand IUR reportable chemicals.

The new, higher thresholds proposed in this action are consistent with a report from the General Accounting Office (Ref. 20), which recommended that, ''. . .the inventory could be more useful to EPA and other interested parties if it initially focused on a smaller number of the highest-priority chemicals known to present risks to health and the environment and was expanded as necessary.'' EPA considered a number of different thresholds between 10,000 lbs. and 50,000 lbs. for basic IUR information and between 10,000 lbs. and 10,000,000 lbs. for processing and use information (See ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' available in the public record for this rulemaking and listed in this preamble at Unit X.A.2.f.). EPA examined each of these options in light of the benefits that would be obtained from the information collected, EPA's ability to utilize that information, and the burden imposed on the public to provide the information. EPA concluded that processing and use information would be highly valuable (see Ref. 14), but that EPA would likely focus initially on larger volume chemical substances.

In order to retain information on potential substitutes for the larger volume chemical substances, but at the same time reduce the public reporting burden, EPA initially considered proposing a 100,000 lb. higher-volume reporting threshold for processing and use information to reduce the paperwork burden on industry. Although EPA believes a 100,000 lbs.

higher-volume threshold would provide valuable information, EPA is proposing that this threshold be set at 300,000 lbs. in an attempt to further reduce paperwork burden on submitters. EPA believes that this effort to further reduce the paperwork burden, as well as the Agency's other efforts to minimize burden in this proposed rule, is consistent with the Paperwork Reduction Act. EPA seeks public comment on the proposed threshold and on the other alternative thresholds analyzed in the Economic Analysis (listed in Unit X.A.2.f. of this preamble).

EPA still believes that information concerning lower production volume chemical substances is valuable, especially for identifying trends and additional substitute chemicals, but EPA also recognizes the importance of limiting the reporting burden when the need for the data is generally less great. In the future, EPA may find it necessary to collect information on chemicals at reporting thresholds below the thresholds proposed in this action. Although both proposed thresholds are significantly higher than the current IUR 10,000 lbs. threshold, EPA believes that the enhanced information it would receive under this rule at the proposed thresholds would enable the Agency to more efficiently identify those chemical substances warranting further, more in-depth regulatory review (see Ref. 14).

The new, higher reporting thresholds would result in a reduction in the number of currently reportable chemicals. However, this reduction would be partially offset by the elimination of the exemption for inorganic chemical substances. Under the current IUR, EPA receives reports on about 8,900 chemical substances. The Agency estimates that raising the reporting threshold from 10,000 lbs. to 25,000 lbs. reduces the number of reportable chemicals to about 7,800, while deleting the exemption for inorganic chemical substances would increase the number of reportable chemicals by about 1,200. Of the approximately 8,900 reportable chemical substances expected under the IUR amendments, about 4,050 would likely be produced in volumes of 300,000 lbs. or more and would require the completion of the entire revised reporting form.

C. Amendments to Reporting Period and Frequency

Under the current IUR regulations at 40 CFR 710.33(b), submitters are required to report on a recurring basis between August 25 and December 23 every 4 years (''the reporting period''). EPA is not proposing to change this requirement. However, the current IUR regulations indicate that the information reported during each reporting period is from the submitter's latest complete corporate fiscal year prior to the reporting period. In order to standardize reporting time frames across IUR submitters and across various other reporting programs, such as the TRI program, the Agency is proposing to change this IUR reporting scheme from a fiscal year reporting basis to a calendar year reporting basis. This would mean, for example, that the information that would be reported during the reporting period from August 25 to December 23 in the year 2002 would be from calendar year 2001.

D. Amendments to Recordkeeping Requirements

Currently, the Inventory regulations at 40 CFR 710.37 require submitters to retain records on IUR reports for 4 years. In these amendments to IUR, EPA is proposing that persons subject to the rule be required to retain records that document information reported for 5 years after the end of the relevant reporting period. For example, if a person submits an IUR report in the reporting year 2002, that person would be required to retain the records on which the report is based until December 31, 2007. This change, which would assist EPA's enforcement of the IUR, would result in the requirement that submitters maintain records that span successive reporting periods, which would continue to occur every 4 years as under the existing IUR.

Persons who are not required to report under the existing IUR because they manufacture less than the 10,000 lb. reporting threshold are required to retain volume records as evidence to support a decision not to submit a report. In this rulemaking, EPA is proposing that this provision be eliminated because EPA believes that this information is of the type that companies would routinely retain in the normal course of business.

E. Amendments to Reportable Data Elements

The new and revised data elements that would be reported under the rule are discussed in this section. Data elements that are currently reported under IUR but that would not be revised by these amendments (such as company information, Part I., Section II. of Revised Reporting Form U; site-limited activity, Part II., Section II.; and manufacturer/importer activity, Part II., Section II.) are not generally discussed because EPA is not reopening these data elements for comment. Although certain CBI issues are mentioned in this section (see Unit VI.E.3. of this preamble, for example), changes to CBI procedures are discussed more completely in Unit VIII. of this preamble.

1. *Plant site identification (Part I., Section III. of Revised Reporting Form U)*. EPA currently requires the following information to be reported for each plant site at which a reportable chemical substance is manufactured (including imported) in amounts greater than the reporting threshold: the plant site name, Dun and Bradstreet number, street address, city, state, and zip code. The site for a chemical substance importer is the site of the operating unit within the importer's organization that is directly responsible for importing the substance and that controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.

EPA believes additional plant site identifiers would allow for full integration of IUR data with other ''place-based'' environmental data collected by EPA or states under other regulatory authorities into multi-source and function data bases. By facilitating this integration, the Agency would be better able to address its obligations under TSCA section 10, and would thereby achieve the intended TSCA goal that information collected under the Act be made easily accessible to a wide variety of governmental and nongovernmental entities. With data integrations, TSCA data could be fully utilized as a ''feedstock'' for a wide variety of chemical management activities.

Providing linkages and achieving integration for environmental data across various data bases are important EPA goals under TSCA. While it was always intended that TSCA data be made available to chemical managers, until relatively recently, the primary user of TSCA data has been OPPT and the TSCA data systems were designed with this user in mind. Over the last several years, however, TSCA data has been sought by a wide variety of Federal, State and private organizations. For example, several States routinely contact the Agency to gain access to TSCA data that might be useful for their implementation of both State laws and Federally delegated laws. As demand has increased, EPA has recognized that the existing TSCA data systems do not always efficiently address the needs of the non-OPPT user.

Another benefit associated with fully integrating TSCA data into multi-source and function data bases is that duplicative information collections would be more easily identified and

eliminated. Finally, improved linkages among data bases would provide the public with access to additional information at little or no burden to the regulated community.

EPA is proposing to require the reporting of two identifiers for each plant site reporting under IUR:

a. The Facility Registration Identifier (FRI) (if the plant site has one).

b. The county or parish (or other jurisdictional indicator) in which the plant site is located.

EPA is establishing the Facility Registry System (FRS) as a central resource of facility information, which will link all facilities represented in EPA program data bases through common facility identification data elements. The FRS will include a new facility numbering system identifying each facility with a unique Facility Registration Identifier (FRI) which will be used for electronic and integrated reporting and central receiving. The business rules for assigning an FRI to each facility will be developed by EPA and the States. EPA anticipates releasing the first version of the FRS and the new numbering system in the fall of 1999. The first reporting year under the final IUR amendments should occur after this system is in effect. For sites that have not been assigned an FRI, submitters would report this item as ''not applicable.''

In the alternative, should the FRS initiative not be underway at the time this rule becomes final, EPA will require submitters to report the plant site's EPA identification number (ID), if it has one. The EPA ID is described by the 12-character number assigned to sites covered by the hazardous waste regulations under RCRA (40 CFR 262.12). This number is further described in Unit V.A.3.a. of this preamble. For sites that have not been assigned an EPA ID, submitters would report this item as ''not applicable.''

The TRI program has demonstrated that many public and private sector organizations find it useful to aggregate release data by county or parish of reporting plant sites when evaluating chemical risks. EPA believes that there is merit to including similar geographic identifiers in future IUR reporting so that similar aggregations of IUR data can be generated. The two proposed plant site identifiers will facilitate improved linkages of the IUR information to other data bases, enabling the Agency to perform more comprehensive risk screening, assessment, and management activities.

2. *Chemical identification (Part II., Section I. of Revised Reporting Form U).* The IUR currently requires manufacturers (including importers) to report both the specific chemical substance name and the Chemical Abstracts Service (CAS) Registry Number of each reportable chemical substance manufactured (including imported) in amounts over 10,000 lbs. per year. EPA is proposing to require that chemicals be identified only by EPA Accession Number, PMN case number or Inventory reporting form number when the CAS Registry Number is unknown to the submitter. Other previously used substitute identifying numbers (such as EPA-assigned numbers for Test Market Exemption applications) would not be allowed because they cannot be efficiently cross-referenced to CAS Registry Numbers.

3. *Confidentiality of production volume range.* In addition to the requirement that specific production volume be reported, EPA is proposing to amend the IUR to allow submitters to claim a pre-determined production volume range corresponding to the reported production volume number as CBI. This claim would be separate from a CBI claim for the specific production volume. Production volume range reporting is included in these amendments because EPA believes that the availability of range information is less likely to raise CBI concerns than the availability of specific production volume figures. Accordingly, EPA expects that the confidentiality claim rates will be roughly 50% lower for the reporting of volume ranges than for the reporting of specific volumes. EPA's expectation of reduced CBI claims for production volume ranges is based on the CBI claim statistics associated with the development of the original TSCA Inventory (See ''Inventory Update Rule (IUR) Technical Support Document: Evaluation of Likelihood of Confidential Business Information Claims for Production Volume Information,'' available in the public record for this rulemaking and listed at Unit X.A.2.g. of this preamble) as well as comments received from industry (Ref. 21). If this expectation is correct, the public would have greater access to data on chemical production volumes, and the Agency would be better equipped to publicly release more data relevant to its risk screening decisions.

EPA is proposing to use the following production volume ranges for future CBI determinations:

- At least 25,000 but less than 100,000 lbs.
- At least 100,000 but less than 1,000,000 lbs.
- At least 1,000,000 but less than 10,000,000 lbs.
- At least 10,000,000 but less than 50,000,000 lbs.
- At least 50,000,000 but less than 100,000,000 lbs.
- At least 100,000,000 but less than 500,000,000 lbs.
- At least 500,000,000 but less than 1,000,000,000 lbs.
- At least 1,000,000,000 lbs.

These ranges were first used in the development of the original TSCA Inventory, except that the proposed ranges start at the proposed IUR reporting threshold of 25,000 lbs. rather than the existing 10,000 lb. threshold.

4. *Number of potentially exposed workers (Part II., Section III. of Revised Reporting Form U).* Workers involved in chemical manufacturing (including importing), processing and use are a subpopulation of concern to EPA, the Occupational Safety and Health Administration (OSHA) (Ref. 22), the National Institute of Occupational Safety and Health (NIOSH) (Ref. 23), and other organizations. Workers may often be exposed to chemical substances in higher doses and with greater frequency than the general population, and so are potentially at greater risk of adverse health effects. Accordingly, EPA and other organizations believe that it is important to be able to estimate the number of workers potentially exposed to specific chemical substances when developing priorities for testing, more detailed risk assessment, and risk management.

EPA is proposing to use ranges for the reporting of certain quantitative estimates, including number of workers and number of processing sites (see Unit VII.A. of this preamble), instead of requiring the reporting of specific values. In general, EPA believes that reporting these estimates in ranges has two advantages over requiring the reporting of specific values:

a. Range reporting would reduce the potential burden to submitters of developing a precise point estimate for the data element.

b. Range reporting should reduce CBI claims because ranges tend to reveal less sensitive information than specific estimates while still conveying information useful to more effectively screen chemical risks.

Submitters would be permitted to claim the reported ranges as confidential if even revealing this general information would disclose CBI.

EPA is proposing to require reporting of the range code that corresponds to the submitter's estimate of the total number of workers reasonably likely to be exposed to each reportable chemical substance at each reporting plant site. EPA is proposing to define ''reasonably

likely to be exposed'' as an exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use of the chemical substance, is more likely to occur than to not occur. Such exposures would normally include, but not be limited to, exposure during activities such as charging reactor vessels; drumming; bulk loading; cleaning equipment; maintenance operations; materials handling and transfers; and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact or absorption, contact with personal protective equipment, etc.), but excludes accidental or theoretical exposures. The use of protective equipment or engineering controls to minimize worker exposures cannot be used by submitters as a rationale for lowering their estimates of the total number of exposed workers.

EPA has considered using the OSHA hazard communication standard's (29 CFR 1910.1200) definition of exposed worker for amended IUR reporting. The Hazard Communication Standard defines ''employee'' as a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered. The Standard also defines ''exposure'' or ''exposed'' as the subjection of an employee to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.) and includes potential (e.g. accidental or possible) exposure. In EPA's view, this definition is overly broad for IUR purposes and for use in exposure assessments. The definition, for OSHA's purposes, was intended to be protective in order to ensure that all workers that could conceivably be exposed to a chemical substance would receive hazard communication. EPA solicits comment on the definition of ''reasonably likely to be exposed'' that the Agency has selected for this proposed rule.

The proposed ranges for reporting the estimated number of potentially exposed workers are as follows:

- Less than 10.
- At least 10 but less than 25.
- At least 25 but less than 50.
- At least 50 but less than 100.
- At least 100 but less than 250.
- At least 250 but less than 500.
- At least 500 but less than 1,000.
- At least 1,000 but less than 10,000
- At least 10,000.

5. *Physical Form (Part II., Section III. of Revised Reporting Form U).* EPA is proposing to require submitters to report the physical form of each reportable chemical substance as it leaves their sites. EPA believes that the physical form of a chemical is an important factor to consider when estimating magnitudes and concentrations of potential exposures. Two technical documents that support this proposed rule, entitled, ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening,'' and ''Preliminary Assessment Information Rule (PAIR) Database, Manufacturing Process Type/Release Analysis and Number of Workers/ Production Quantity Analysis,'' both available in the public record for this proposal (listed at Unit X.A.2.a. and Unit X.A.2.b. of this preamble), state that an EPA data analysis demonstrated that information regarding the physical form of chemical substances provides an indication of potential chemical exposures to the environment or to humans. EPA is proposing that submitters would select the category that best describes the physical form of the chemical as it leaves their site. In the event the submitter ships a chemical in more than one physical form, the submitter must report the code corresponding to the physical form of the majority of the chemical manufactured (including imported). The proposed categories for reporting the physical form are as follows:

- Dry powder.
- Pellets or large crystals.
- Water- or solvent-wet solid.
- Other solid.
- Gas or vapor.
- Liquid.

The Agency recognizes that, for some chemical substances, the physical form of the substance at the time it leaves the submitter's site may not be the same physical form of the substance during processing and use; the Agency believes that such substances constitute a minority of all reportable chemical substances, and that it can, based on its knowledge of work practices in many industrial sectors, successfully identify many of the substances that undergo changes in physical form during processing and use. Therefore, to limit submitters' reporting burdens, EPA is proposing that physical form reporting be limited to the physical form of the substance at the time it leaves a submitter's site. Comments are invited on this proposed approach.

6. *Average and maximum concentration in commercial products (Part II., Section III. of Revised Reporting Form U).* EPA is proposing to require submitters to report the average and maximum concentration, measured by weight, of the reportable chemical substance as it leaves their sites in a commercial product. EPA believes that concentration is an important factor to consider when estimating magnitudes of potential exposures. Information related to average concentration is valuable when estimating the potential for concerns due to chronic exposures, while information related to maximum concentration is useful when estimating the potential for concerns due to acute exposures. EPA frequently uses models to estimate potential human inhalation and dermal exposures (Ref. 24). In the absence of concentration data, EPA often assumes that human inhalation and dermal exposures are the result of exposures to undiluted chemicals. Chemical substance concentration data would allow EPA to generate less conservative exposure estimates for chemicals that are diluted prior to processing or use.

Information about the average and maximum concentration of a chemical substance present at processing and use sites is used in chemical risk screening in EPA's New Chemicals Program. Estimates of maximum concentration assist EPA in establishing the maximum concentrations to which the environment and workers might be exposed by releases from industrial settings. For example, EPA has developed standard methods to estimate dermal exposures that workers may experience while performing common industrial operations such as sampling and loading chemicals into drums. If EPA is aware that a chemical substance is not processed or used at concentrations above a certain level, exposure estimates may be adjusted accordingly.

The following is the list of proposed concentration codes for use in IUR reporting under the proposed rule:

- Less than 1% by weight.
- 1 - 30% by weight.
- 31 - 60% by weight.
- 61 - 90% by weight.
- Greater than 90% by weight.

The Agency is proposing that reporting on concentrations be limited to concentrations at the time the chemical substance leaves the submitter's site, for the reasons discussed in Unit V.E.6. of this preamble.

VII. Amendments Affecting Larger Volume Manufacturers (Including Larger Volume Importers)

As discussed in Unit VI.B. of this preamble, EPA is proposing to replace

the current IUR reporting threshold of 10,000 lbs. per year with two new reporting thresholds of 25,000 lbs. per year and 300,000 lbs. per year. Every person manufacturing (including importing) a reportable substance at or above the 25,000 lbs. threshold would be required to report the information in Parts I., II., and IV. of Revised Reporting Form U. Persons who manufacture (including import) a reportable substance at or above the 300,000 lbs. threshold would be required to report the information in Part III. of Revised Reporting Form U in addition to the information in Parts I., II., and IV. Part III. relates to the processing and use of chemical substances.

Process is defined in 40 CFR 710.2 as ''the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.''

Process for commercial purposes means ''to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.''

Based on these definitions, processing includes incorporating a reportable chemical substance into a formulation, an article, or a product. EPA is proposing to define ''use'' as ''any utilization of a chemical substance or mixture that is not otherwise covered by the terms manufacture or process. Relabeling or redistributing a container holding a chemical substance or mixture where no repackaging of the chemical substance or mixture occurs does not constitute use or processing of the chemical substance or mixture.''

TSCA section 8(a) authorizes EPA to require persons to report information that is ''known to or reasonably ascertainable by'' them (see proposed regulatory text § 710.2). Under the proposed amendment, the submitter would be required to report processing and use information only to the extent that such information is ''readily obtainable'' by the submitter's management and supervisory employees responsible for manufacturing, processing, distributing, technical services, and marketing (see proposed regulatory text § 710.2). Extensive file searches would not be required. The ''readily obtainable'' standard proposed for processing and use information requires less effort on the part of the submitter than the ''known to or reasonably ascertainable by'' standard that applies to all other IUR reporting. The Agency believes that the ''readily obtainable'' reporting standard would provide processing and use information of a sufficient precision for use in screening level reviews. Reducing the precision to ''readily obtainable'' from ''known to or reasonably ascertainable by'' for processing and use information also lowers the reporting burdens for many submitters. Moreover, the proposed reporting standard for processing and use information under these IUR amendments is the same standard currently in effect under PAIR (See 40 CFR 712.7).

Much of the additional information required under Part III. of Revised Reporting Form U would be provided in ranges, rather than discrete values, as described in more detail in this unit. EPA preliminarily determined that the planned use of information such as percent production volume, number of sites, number of potentially exposed workers, average concentration, and maximum concentration does not warrant the reporting of discrete values. In addition, the use of ranges for certain data elements would reduce reporting burdens, yet provide sufficient information for screening level analyses. EPA also believes that the use of ranges would greatly diminish CBI claims for information reported.

EPA considered the option of requiring processing and use reporting by larger volume manufacturers (i.e., those manufacturers that reach the 300,000 lbs. threshold) based upon submitter owned or controlled sites alone versus customer owned or controlled sites in addition to submitter owned or controlled sites. EPA preliminarily determined that manufacture, processing, and end use of the chemical substance were important to examining the potential exposure scenarios for a chemical substance, but that it did not matter if the processing or use site was submitter controlled or not. In addition, restricting the reporting of this information to submitter owned or controlled sites alone would not capture much of the information needed regarding the processing and use of reportable chemicals. Therefore, EPA decided to require the reporting of processing and use information readily obtainable by the submitter, including information based upon submitters' sites as well as their customers' sites.

The two general types of information that would be reported under Part III. of Revised Reporting Form U are industrial processing and use information and commercial and consumer use information.

A. Processing and Use Information (Part III. of Revised Reporting Form U)

EPA is proposing to require submitters to report the information described in Unit VII.A.1-5. of this preamble concerning the processing and use of each reportable chemical substance that are conducted both at sites the submitter controls and at sites that receive a reportable chemical substance from the submitter either directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.).

1. *Industrial process or use code (Part III., Section I.a. of Revised Reporting Form U).* The first item of reportable information under this proposed section is the industrial process or use code. The proposed categories for reporting the industrial processing and use are:

- Processing - as a reactant.
- Processing - incorporation into a formulation or mixture.
- Processing - incorporation into an article.
- Processing - repackaging.
- Use - non-incorporative activities.

Repackaging would be defined for purposes of IUR reporting under the proposed rule as the physical transfer of a chemical substance or mixture, as is, from one container to another container or containers in preparation for distribution of the chemical substance or mixture in commerce. This definition, therefore, would not include sites which only relabel or redistribute the reportable chemical substance without removing the chemical substance from the container in which it is received or purchased.

2. *The North American Industrial Classification System (NAICS) Code and Industrial Function Category (Part III., Section I.b. and c. of Revised Reporting Form U).* EPA is proposing to require submitters to report the five-digit NAICS code(s) that best describe(s) the industrial activities at the sites under the control of the submitter, as well as at the sites that receive a reportable chemical substance from the submitter either directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.), and that process and use the reportable chemical substance (Ref. 25). The NAICS codes, published by the Office of Management and Budget (OMB), have superseded OMB's prior system of Standard Industrial Classification (SIC) Codes. EPA is proposing that, to the extent the information is readily obtainable, submitters will report on industrial processing and use of chemical substances they manufacture after the chemical substances have passed

through distributors or other distribution or shipping systems. EPA does not intend for manufacturers (including importers) to survey their customers or distributors to precisely identify the appropriate NAICS codes at their ''downstream'' sites.

The NAICS code classification system is being used in this application solely to describe the industrial setting in which there may be chemical exposures associated with the industrial processing or use of a chemical substance. The submitter would be required to report all known and readily obtainable NAICS codes for the reportable chemical substances it manufactures (including imports). If the submitter is aware of more than 10 NAICS codes that describe the industrial activities at sites that process and use the reportable chemical substance, the submitter would be required under this proposed rule to report only the 10 NAICS codes that cumulatively represent the largest percentage of production volume, measured by weight. This limitation on reporting is intended to minimize submitters' reporting burdens.

EPA is also proposing to require submitters to report the industrial function categories associated with each NAICS code for each reportable chemical substance that is processed or used for industrial purposes. EPA believes that a NAICS code and industrial function category combination sufficiently define a potential exposure scenario for risk screening and priority-setting purposes. Two technical documents that support this proposed rule, entitled ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening,'' and ''Preliminary Assessment Information Rule (PAIR) Database, Manufacturing Process Type/Release Analysis and Number of Workers/Production Quantity Analysis,'' both found in the public record for this rulemaking (listed at Unit X.A.2.a and X.A.2.b. of this preamble), describe studies that demonstrate that information regarding the industrial sectors where a chemical substance is produced and used and information regarding the function that a chemical substance performs within industrial processes provide indications of the route, magnitude, and concentration of potential chemical exposures to the environment and to humans.

Industrial function categories are helpful in estimating the frequency and duration of chemical substance exposures. For example, EPA has found that the relationship between industrial function categories and the frequency and duration of exposure to chemical substances is particularly useful in developing exposure assessments for the New Chemicals Program. Similarly, data elements such as the number of sites and the number of workers enable the Agency to better estimate the scope of potential exposure. These data elements are important pieces in developing the most accurate exposure scenarios possible. In the absence of this data, EPA often assumes, for chemical risk screening purposes, that workers are exposed to chemical substances for full 8–hour work days for the duration of their careers. The data that would be obtained under these proposed amendments to IUR would enable EPA to make more realistic characterizations of exposure, instead of ''worst case'' assumptions.

Industrial function categories would be reported by selecting from the following list of proposed industrial function category codes for chemical processing and use:

- Adhesives and binding agents.
- Adsorbents and absorbents.
- Aerosol propellants.
- Agricultural chemicals (non-pesticidal).
- Anti-adhesive agents.
- Bleaching agents.
- Coloring agents, dyes.
- Coloring agents, pigments.
- Corrosion inhibitors and anti-scaling agents.
- Fillers.
- Fixing agents.
- Flame retardants.
- Flotation agents.
- Fuels.
- Functional fluids.
- Intermediates.
- Lubricants.
- Odor agents.
- Oxidizing agents.
- pH-regulating agents.
- Photosensitive chemicals.
- Plating agents and metal surface treating agents.
- Process regulators, used in vulcanization or polymerization processes.
- Process regulators, other than polymerization or vulcanization processes.
- Processing aid, not otherwise listed.
- Reducing agents.
- Solvents (for chemical manufacture and processing and are not part of the end product at greater than one percent by weight).
- Solvents (for cleaning or degreasing).
- Solvents (that become part of product formulation or mixture).
- Stabilizers.
- Surface active agents.
- Viscosity adjustors.
- Other.

As described in the document entitled, ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening'' (listed at Unit X.A.2.a. of this preamble), these industrial function categories have been developed and defined based on a review of different chemical function classification systems (including the systems used in the Premanufacture Notification, UCSS, UEIP, and EU programs), as well as development of data pertinent to the potential media of releases, potential quantities released, potential worker exposures, and potential incorporation into commercial and consumer products for each industrial function category. This list of specific categories is not meant to be exhaustive, therefore, an ''other'' category is provided for miscellaneous uses not captured in the listed categories. These categories address a wide range of industrial chemical processing and use functions, and are likely to be revised as analysis of reported IUR data is further refined over time.

3. *Percentage of production volume attributable to each combination of NAICS code and industrial function category (Part III., Section I.d. of Revised Reporting Form U).* EPA is proposing to require submitters to estimate the percentage of production volume that is attributable to each reported combination of NAICS code estimate and industrial function category, to the extent that such information is readily obtainable. Estimates must be rounded off to the nearest 10% of production volume. However, under the proposed rule, a particular NAICS code/industrial function category (NAICS/IFC) combination which accounts for 5% or less of the total production volume of a reportable chemical substance would not be permitted to be rounded off to zero if the production volume attributable to that NAICS/IFC combination is greater than or equal to 300,000 lbs. In such cases, submitters must report the percentage of production volume attributable to that NAICS/IFC combination to the nearest 1% of production volume. This exception to the general rounding off rule is being proposed to ensure that adequate use information is reported for the very large production volume chemical substances. The 300,000 lbs. level was selected for consistency with the proposed threshold for reporting exposure and use data.

4. *Number of sites (Part III., Section I.e. of Revised Reporting Form U).* For risk screening purposes, the number of sites at which chemical substances are manufactured (including imported), processed and used is a useful indicator of the number of ecosystems and the size of the general population potentially exposed to the chemical substances. EPA is proposing to require submitters to report an estimate of the total number of industrial sites, including those beyond the submitter's control, that process or use each reported chemical substance manufactured (including imported) by the submitter, as described by each combination of NAICS code estimate and industrial function category.

The ranges that would be used for reporting the number of sites are as follows:

- Less than 10.
- At least 10 but less than 25.
- At least 25 but less than 100.
- At least 100 but less than 250.
- At least 250 but less than 1,000.
- At least 1,000 but less than 10,000.
- At least 10,000.

EPA recognizes that there is a possibility of double-counting sites, for example, where two or more submitters manufacture (including import) the same reportable chemical substance and each sends the chemical substance to the same industrial processing or use site. However, because the Agency is proposing that the number of sites be reported in the specified ranges, it believes the impact of double-counting sites will not significantly affect the use of these estimates for screening purposes. In the event a submitter both manufactures (including imports) and processes or uses the same reportable chemical substance at the reporting plant site, the site should be counted as both a manufacturing site in Part II. of Revised Reporting Form U, and as a processing or use site reported in Part III. of Revised Reporting Form U.

5. *Number of workers (Part III., Section I.f. of Revised Reporting Form U).* As discussed in Unit V.A. of this preamble, information related to the exposure of workers to chemical substances is of particular interest to EPA and other organizations. EPA is proposing to require submitters to report an estimate of the total number of workers reasonably likely to be exposed while processing or using the reportable chemical substance as described by each combination of NAICS code estimate and industrial function category. These combinations relate to sites under the control of the submitter as well as sites that receive a reportable chemical substance from the submitter either directly or indirectly (see Unit VII.A.2. of this preamble). The approximate number of workers reasonably likely to be exposed during processing and use would be reported using the same definitions and codes described under Unit VI.E.4. of this preamble. The only difference in reporting worker exposure information under this section is that such information need be reported only to the extent that it is readily obtainable.

EPA recognizes that there is also a possibility of double-counting workers at industrial processing and use sites, for example, when two or more submitters manufacture the same reportable chemical substance and each ships the chemical substance to the same processing or use site. Because EPA is proposing that the number of workers be reported through the use of broad ranges, EPA believes the impact of double-counting workers will not significantly affect the use of the estimates for risk screening purposes. In addition, it will be possible to estimate the maximum potential magnitude of double counted workers at processing and use sites because the total number of manufacturers (including importers) will be known to EPA.

B. Commercial and Consumer Use Information (Part III., Section II. of Revised Reporting Form U)

EPA is proposing to require submitters to report the information described in Unit VII.B.1-3. of this preamble concerning the commercial and consumer uses of each reportable chemical substance that is manufactured (including imported) at sites the submitter controls and at sites controlled by persons to whom the submitter has either directly or indirectly (including through a broker/distributor or from a customer of the submitter, etc.) distributed the reportable chemical substance. As with the industrial processing and use information described in Unit VII.A. of this preamble, this requirement would apply only to each chemical substance manufactured (including imported) in annual quantities of 300,000 lbs. or more and submitters would only be required to report information to the extent that it is readily obtainable.

For purposes of IUR reporting, a commercial use means the use of a chemical substance or mixture in a commercial enterprise providing saleable goods or a service, such as painting contractors using paint products. A consumer use, on the other hand, means the use of a chemical substance that is directly, or as part of a mixture, sold to or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas. Exposures to commercial and consumer products are similar for risk screening purposes because existing assessment methods are not sophisticated enough to distinguish between these exposures.

Consumers comprise a subpopulation of particular concern to EPA, the Consumer Products Safety Commission (CPSC), and other organizations. Information from submitters on whether the chemical substances they manufacture (including import) are used in consumer products is useful in estimating the potential risks to consumers that result from chemical exposures. EPA often assumes, for risk screening purposes, that large, unprotected populations may potentially be exposed to the chemical substances in consumer products. EPA plans to propose a test rule to develop hazard data regarding chemicals in consumer products to which children are exposed. The consumer product information that would be reported under these IUR amendments would be used by EPA in the identification of chemicals that might be included in the test rule.

1. *Commercial and consumer product categories (Part III., Section II.a. of Revised Reporting Form U).* Commercial and consumer product categories are helpful in estimating the frequency and duration of chemical substance exposures. In the absence of other information, consumers are often assumed to experience less controlled, but less frequent exposures than workers. The data that would be obtained under these proposed amendments to IUR would enable EPA to make more realistic characterizations of exposure, instead of ''worst case,'' overly conservative assumptions.

The proposed commercial and consumer product categories were developed based on a review of various data sources including national usage surveys of consumer products, product emissions testing, and exposure monitoring data (See ''Technical Support Document: Technical Approach for the Selection of Consumer End-Use Categories for the Inventory Update Rule,'' available in the public record for this proposal and listed at Unit X.A.2.h. of this preamble). This review identified an extensive list of consumer products and provided subsequent categorization of these products by common characteristics, such as use scenarios, into major groupings of commercial and consumer products. The list is not meant to be comprehensive, therefore, an ''other'' category is provided for

miscellaneous commercial and consumer products not captured in the categorization system. Further details about the categories, including their development and definitions, are provided in the technical support document described in this paragraph.

The proposed categories for reporting commercial and consumer products are:

- Adhesives and sealants.
- Artists' supplies.
- Automotive care products.
- Electrical and electronic products.
- Fabrics, textiles and apparel.
- Glass and ceramic products.
- Lawn and garden products (non-pesticidal).
- Leather products.
- Lubricants, greases and fuel additives.
- Metal products.
- Paints and coatings.
- Paper products.
- Photographic chemicals.
- Polishes and sanitation goods.
- Rubber and plastic products.
- Soaps and detergents.
- Transportation products.
- Wood and wood furniture.
- Other.

2. *Percentage of production volume attributable to each commercial and consumer product category (Part III., Section II.b. of Revised Reporting Form U).* EPA is proposing to require submitters to estimate the percentage of their production volume for each reportable chemical substance that is attributable to each specific commercial and consumer end-use carried out at sites under the control of the submitter, as well as at sites that receive a reportable chemical substance from the submitter either directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.), to the extent that such information is readily obtainable. Estimates must be rounded off to the nearest 10% of production volume. However, under the proposed rule, a commercial and consumer product (CCP) category which accounts for 5% or less of the total production volume of a reportable chemical substance would not be permitted to be rounded off to zero if the production volume attributable to that CCP category is greater than or equal to 300,000 lbs. In such cases, submitters must report the percentage of production volume attributable to that CCP category to the nearest 1% of production volume. This exception to the general rounding off rule is being proposed to ensure that adequate use information is reported for the very large production volume chemical substances. The 300,000 lbs. level was selected for consistency with the proposed threshold for reporting processing and use data (see Unit VI.B. of this preamble).

3. *Maximum concentration, measured by weight in commercial and consumer products (Part III., Section II.c. of Revised Reporting Form U).* EPA is proposing to require each submitter to report estimates, in ranges, of the maximum concentration (measured by weight) of each reportable chemical substance likely to be present in commercial and consumer products manufactured (including imported) at sites under the submitter's control and at sites where the submitter's commercial and consumer products are distributed directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.). As with the other information in this section, such information would be required only to the extent that it is readily obtainable by the submitter. The proposed reporting range codes are the same as those listed in Unit VI.E.6. of this preamble.

VIII. Confidentiality

A. Asserting Claims

Submitters are able to claim certain information submitted to EPA under this proposed rule as confidential if they have reason to believe that release of the information would reveal trade secrets or confidential commercial or financial information, as provided by section 14 of TSCA and 40 CFR part 2. Claims of confidentiality must be asserted at the time information is submitted to EPA. EPA's procedures for processing and reviewing confidentiality claims are set forth at 40 CFR part 2, subpart B. EPA strongly encourages submitters to review confidentiality claims carefully to ensure that the information in question falls within the protection of TSCA section 14 and to limit confidentiality claims as much as possible.

To claim information as confidential, a submitter must check the appropriate box and sign the certification statement on the reporting form. If a submitter failed to do so, EPA could release the information to the public without further notice to the submitter. As in the last three TSCA Inventory Update collections and the initial TSCA Inventory collection and as reflected in the regulations, by signing the certification statement the submitter certifies that its claims of confidentiality are made in good faith. Procedures for claiming information submitted electronically (such as a submission on diskette) as confidential will be specified in the reporting rule instruction manual. CBI should not be submitted by e-mail. A discussion on proposed procedures and policies for making CBI claims in the context of this proposed rule is provided in this unit.

B. Chemical Identity

Under the existing IUR, confidentiality claims for chemical identity can only be made for those chemicals listed on the confidential portion of the Inventory. A submitter must currently assert a separate claim of confidentiality for specific chemical identity when submitting an IUR report. To assert a claim of confidentiality for the identity of a chemical substance which is confidential on the TSCA Inventory, submitters are currently, and would continue to be, required to indicate the claim on the IUR reporting form and provide a detailed substantiation of the claim as specified in 40 CFR 710.38. If a submitter fails to substantiate the chemical identity CBI claims in accordance with the applicable regulations, EPA may make the information available to the public without further notice to the submitter. EPA is not proposing to change these requirements.

C. Manufacturing Plant and Plant Site Information

Under IUR, a submitter may assert a claim of confidentiality for the specific manufacturing plant and plant site information if it is believed that release of that identity would reveal trade secrets or confidential commercial or financial information as provided by TSCA section 14. In past IUR information collections, in excess of 15% of IUR information submitters have claimed plant site name as CBI. While the Agency does not question the occasional need for this claim, it believes that these claims should be limited to only those circumstances in which it is absolutely necessary. The Agency has identified instances in which submitters have claimed plant site name as confidential yet this same information was found in such public filings as material safety data sheets and State and Federal permits. Overall, approximately 20% of the 1994 IUR reports contained CBI claims for plant site information. The IUR does not currently require upfront substantiation of CBI claims for plant site information. In these amendments to IUR, EPA is proposing a new upfront substantiation requirement for CBI claims for plant site information.

EPA has observed that, on occasion, plant site information has been claimed as confidential even though it was revealed in filings required under

sections 311, 312 and 313 of EPCRA. EPA believes that many of these CBI claims are inappropriate and that the new substantiation requirement would reduce the occurrence of inappropriate claims. A decrease in the number of CBI claims under the new substantiation requirement would facilitate EPA's ability to make current plant site information available to other Federal agencies and the public because more information submitted under IUR could be released publicly.

Under this proposed rule, in order to assert a claim of confidentiality for plant site information, the submitter would be required to both check the appropriate box on the reporting form indicating a confidentiality claim for plant site information, and to substantiate the claim in writing by answering certain questions provided in § 710.38(d)(1) of the proposed rule. If a submitter fails to substantiate the plant site CBI claim in accordance with the applicable regulations, EPA may make the information available to the public without further notice to the submitter.

D. Chemical Production Volume Information

Under IUR, a submitter may assert a claim of confidentiality for production volume information if the release of that information would reveal trade secrets or confidential commercial or financial information as provided by section 14 of TSCA. EPA is not proposing to change this.

EPA observed that, in the last three IUR reporting periods when EPA sought actual production volume information, over 65% of the information was claimed as confidential. In contrast, overall CBI claims for production volume information in the original TSCA Inventory collection were 35%; this information, however, was collected in ranges. This high proportion of CBI claims in IUR reports has limited EPA's ability to convey to the public plant site production volume information. Because over 95% of the chemicals reported under IUR are manufactured at three plant sites or less, these CBI claims also greatly hinder EPA's ability to create national aggregate statistics on overall chemical production for specific chemical substances. For example, if EPA publishes a national aggregate production volume for a chemical substance that is manufactured at three plant sites and one site claims its production volume CBI and the other two do not, it might be possible to calculate the CBI production volume by difference. In such a case, EPA would not release aggregate data because of its responsibility to protect the CBI claim of the one submitter. However, EPA needs to be able to convey chemical substance production volume information to the public to explain its chemical risk assessment and risk management decisions. Effective communication of this information is vital to EPA's overall mission. To address this problem and yet acknowledge industry's legitimate concerns about this data element, EPA is proposing to require submitters to report both actual plant site chemical production volume information and a corresponding production volume range. Separate CBI claims could be made for each.

EPA is proposing to use the production volume ranges that are similar to those that were successfully used in the implementation of the original TSCA Inventory collection. Proposed production volume ranges for use in this action are listed in Unit VI.E.3. of this preamble. EPA anticipates that the CBI claim rates will be around 50% lower for the reporting of volume ranges than for the reporting of specific claims (See ''Inventory Update Rule (IUR) Technical Support Document: Evaluation of Likelihood of Confidential Business Information Claims for Production Volume Information,'' available in the public record for this proposal and listed at Unit X.A.2.g. of this preamble).

EPA is seeking to develop and use ranged chemical production volume information at the suggestion of industry representatives following a dialogue with the public about TSCA CBI claims. In correspondence, an industry representative noted that manufacturers were less sensitive about ranged production volume information than specific numbers (Ref. 21). The representative suggested that collecting information on ranges similar to those used under the original TSCA Inventory might reduce the incidence of CBI claims for production volume information and facilitate EPA information dissemination goals. In this proposed rule, EPA would seek chemical production volume information and would use that information to make a production volume range assignment. EPA intends to use the production volume information in the creation of national statistics, whereas the ranged production volume data may be most useful in the creation of information products conveying site-specific chemical information.

E. Reasserting Claims

Submitters would use Part IV. of Revised Reporting Form U to reassert CBI claims made in their previous IUR reporting. CBI claims made in IUR submissions prior to 2002 (the first IUR reporting year under these amendments) would be not be subject to this reassertion requirement.

Since 1990, EPA has been engaged in a dialogue with the public on issues associated with TSCA CBI. During this dialogue, industry has confirmed EPA understanding that the need for certain confidentiality claims is reduced or eliminated over time. What was considered CBI to a submitter during one reporting cycle may not be considered CBI in subsequent years. Some information submitted to EPA with CBI claims is subsequently released by the submitter to the public because the submitter no longer believes that the claims are necessary. The result is that some information submitted to EPA is withheld by EPA from the public for long periods, at additional cost to the Agency and with no appreciable advantage to the submitter. This situation complicates EPA's efforts to make information available to potential users, including other Federal agencies, State and local chemical management authorities and local communities, secure the participation of the public in EPA's chemical management efforts, and in other ways allow for the effective EPA implementation of TSCA.

EPA is proposing new procedures to ensure that there is an ongoing need by the submitter for continued CBI protection. Under the proposed procedures, manufacturers (including importers) would be required, in subsequent reporting periods, to affirmatively represent the need for the continued CBI protection of the claims made in previous IUR reporting periods. To illustrate, for data submitted to EPA in the year 2010, a manufacturer (including importer) would be required to affirmatively represent on the reporting form that: (1) The specific CBI claims made for the first time in reporting year 2006 and (2) the specific CBI claims reasserted in reporting year 2006 continue to be necessary in order to protect trade secrets or confidential commercial or financial information as provided by TSCA section 14. The CBI certification statements would be contained in Part IV. of Revised Reporting Form U for the convenience of the submitter. If either certification is not provided by the submitter, EPA would assume that the submitter is waiving those claims of confidentiality to the underlying information contained in the earlier filings and the information would be subject to public disclosure without further notice.

This policy would be applied even if the submitter is not required to report in the present reporting period due to low production volume or other applicable exclusions. In other words, if a submitter who asserts a CBI claim in a prior reporting period is not required to report under the current IUR reporting period, that submitter must file a certification regarding its prior CBI claim during the current reporting period if it wishes to retain the claim. Again, CBI claims made in IUR submissions prior to 2002 (the first IUR reporting year under these amendments) would not be subject to this reassertion requirement.

EPA will undertake certain precautions in order to ensure that persons that make CBI claims in IUR submissions in the 2002 reporting period and subsequent reporting periods are aware of the requirement that these claims be reasserted, as appropriate, in subsequent reporting periods in order to retain CBI protections. Prior to each IUR reporting period, EPA will send an IUR reporting package to each person who submitted an IUR report or CBI reassertion in the previous reporting period. This package will contain a cover letter which will: (1) Remind the submitters of the reassertion requirements and (2) advise that failure to affirmatively reassert prior CBI claims will result in the removal of CBI protections for this information. The package will also contain a reporting form and reporting instructions which will reiterate these reminders. In addition, EPA will publish a **Federal Register** notice at least 2 weeks before the end of each reporting period which will remind members of the public who have not reasserted their prior CBI claims of the pending declassification of these claims if they do not reassert by the end of the reporting period.

In addition to the reminders related to CBI reassertion that are specifically proposed in this document, EPA also intends to publicize the need to reexamine and reassert past CBI claims via the EPA/OPPT Homepage on the Internet, and in communications with trade association publications.

It has been suggested that EPA additionally send a followup certified letter to persons who were sent IUR reporting packages, but who fail to indicate their intention to reassert/not reassert previous CBI claims by the end of the reporting period. The intent of the letter would be to further notify submitters that they need to reevaluate their past CBI claims and reassert them, as appropriate. EPA believes that this additional step would be costly and would result in an inefficient use of Agency resources. For example, if a submitter does not receive the reporting package mailed by EPA because the submitter's address was changed between the last IUR reporting period and the current reporting period (EPA sends packages to the addresses submitted during the previous reporting period), the submitter likewise would not receive a followup letter from EPA sent to the same incorrect address. As discussed above, before each reporting period ends, EPA is proposing to publish a **Federal Register** notice which EPA believes would reach a far broader audience than individual letters would. EPA seeks comment on the issue of whether means beyond those proposed in this action are needed to better inform submitters of the requirement that they reexamine their past CBI claims and reassert them, as appropriate, in order to retain CBI protections.

IX. Request for Comment and Notice of Public Meeting

The comment period for this proposed rule will extend until October 25, 1999. EPA will hold a public meeting on Monday, October 4, 1999, from 9 a.m. to noon at the EPA Auditorium, 401 M St., SW., Washington, DC 20460 to provide an opportunity for the public to present oral comments.

The following is a list of issues on which the Agency is specifically requesting public comment. EPA encourages all interested persons to submit comments on these issues, and to identify any other relevant issues as well. This input will assist the Agency in developing a rule that successfully addresses information needs while minimizing potential reporting burdens associated with the rule. EPA requests that commenters making specific recommendations include supporting documentation where appropriate.

1. What (if any) specific mechanisms or sources of data could EPA use to acquire the exposure-related information sought in this proposed rule with greater ease and less burden to industry?

2. EPA initially considered proposing a larger-volume threshold for the reporting of processing and use information of 100,000 lbs. per year per site, rather than the 300,000 lbs. per year per site threshold proposed in this document. EPA analyzed a number of alternative thresholds in the Economic Analysis (listed in Unit X.A.2.f. of this preamble). EPA is specifically seeking comment on the question of whether this threshold should be modified.

3. During the interagency review process, it was suggested that EPA consider proposing a partial reporting exemption for ''low priority'' chemicals. Manufacturers of these chemicals could be exempt from reporting the exposure-related data contained in Part III. of the reporting form. At one point during the development of this proposal, EPA considered developing such an exemption, but was unable to develop a satisfactory rationale for the exemption. Therefore, EPA seeks comment on the criteria the Agency might use to establish such an exemption. EPA also solicits comment on the specific chemicals that would qualify for such an exemption.

During the interagency review process, various lists of chemicals were suggested as candidates for such a ''low priority'' partial exemption. EPA would be interested in comments on the alternative lists described below, as well as any other suggested set of chemicals.

One set consists of those chemical substances that: (1) EPA has previously determined to be of low concern under the Existing Chemicals Program and (2) for which EPA has a minimum set of hazard and exposure data. This could include chemicals for which the following exist: (1) A complete set of basic test data as specified in the OECD's Screening Information Data Set (SIDS) Manual; (2) the UEIP data set (submitted by at least two-thirds of the manufacturers of the subject chemical substance based on the most recent IUR report); and (3) a determination by EPA's Existing Chemicals Program that the chemical substance is a ''low priority.''

An alternative set is the list of chemical substances that the European Union exempted from its reporting requirements for existing substances (Ref. 8, Annex II).

A third option for a ''low priority substances'' partial exemption is the list of high production volume chemical substances that are not considered candidates for testing under the HPV Challenge Program (Ref. 26). This list currently consists of the following 41 chemicals:

CAS Number	Chemical Name
50–70–4	Glucitol, D-
50–99–7	D-Glucose
56–81–5	Glycerol
57–50–1	Sucrose
69–65–8	Mannitol, D-
124–38–9	Carbon dioxide
1592–23–0	Stearic acid, calcium salt
7440–44–0	Carbon
8001–21–6	Sunflower oil
8001–22–7	Soybean oil
8001–26–1	Linseed oil
8001–29–4	Cottonseed oil
8001–30–7	Corn oil
8001–31–8	Coconut oil
8001–78–3	Castor oil, hydrogenated
8001–79–4	Castor oil
8002–03–7	Peanut oil
8002–75–3	Palm oil
8006–54–0	Lanolin
8016–28–2	Lard oil
8016–70–4	Soybean oil, hydrogenated
8021–99–6	Charcoal, bone
8029–43–4	Syrups, hydrolyzed starch
9050–36–6	Maltodextrin
16291–96–6	Charcoal
61788–61–2	Fatty acids, tallow, Me esters
61789–97–7	Tallow
61789–99–9	Lard
64147–40–6	Castor oil, dehydrated
64755–01–7	Fatty acids, tallow, calcium salts
68188–81–8	Grease, poultry
68334–00–9	Cottonseed oil, hydrogenated
68409–76–7	Bone meal, steamed
68425–17–2	Syrups, hydrolyzed starch, hydrogenated
68439–86–1	Bone, ash
68476–78–8	Molasses
68514–27–2	Grease, catch basin
68514–74–9	Palm oil, hydrogenated
68525–87–1	Corn oil, hydrogenated
68952–94–3	Soaps, stocks, vegetable-oil
73138–67–7	Lard, hydrogenated

Alternatively, it was suggested that EPA create a ''low priority chemicals'' list by identifying chemicals that are present on both the European Union list and the HPV Challenge Program list. Currently, the following chemicals are included on both of these lists:

CAS Number	Chemical Name
50–70–4	Glucitol, D-
50–99–7	D-Glucose
57–50–1	Sucrose
69–65–8	Mannitol, D-
124–38–9	Carbon dioxide
1592–23–0	Stearic acid, calcium salt
7440–44–0	Carbon
8001–21–6	Sunflower oil
8001–22–7	Soybean oil
8001–26–1	Linseed oil
8001–30–7	Corn oil
8001–79–4	Castor oil

CAS Number	Chemical Name
9050–36–6	Maltodextrin
61788–61–2	Fatty acids, tallow, Me esters

4. During the interagency review process, it was suggested that the information the Agency would collect under the IUR amendments might be duplicative of existing reporting for manufacturers and importers of petroleum chemicals, who may also be required to report to the Department of Energy's (DOE) Energy Information Administration. Under the existing IUR 4 year reporting cycle, if a manufacturer or importer of a petroleum chemical meets the 10,000 lbs. reporting threshold, they must complete EPA Form U to report to EPA. Under the proposed IUR amendments, if a manufacturer or importer of a petroleum chemical meets the proposed 25,000 lbs. reporting threshold, they must complete Parts I., II., and IV. of Revised Reporting Form U. The proposed IUR amendments exempt these entities from reporting the proposed processing and use information in Part III. of revised reporting Form U (see Unit VI.A.2. of this preamble). In addition, EPA is proposing to fully exempt certain forms of natural gas from IUR reporting (see Unit VI.A.3. of this preamble).

It has been suggested that information provided to DOE in forms EIA 810, EIA 816, and EIA 64A might duplicate the information that would be provided to EPA under the proposed IUR amendments. Operators of domestic natural gas processing plants must complete form EIA 64A to provide an annual report of the origin of natural gas liquids production to DOE. Operators of all operating and idle petroleum refineries, blending plants or blending terminals must complete form EIA 810 to provide a monthly refinery report on their operations to DOE. Operators that extract liquid hydrocarbons from a natural gas stream and/or separate a liquid hydrocarbon stream into its component products must complete form EIA 816 to provide a monthly natural gas liquids report to DOE.

EPA is concerned about potential reporting duplication and is specifically requesting comments on whether such duplication exists, what specific information may be duplicated, and whether the information collected by DOE would satisfy the proposed IUR reporting requirements. EPA will also work with DOE to identify potential duplication, and investigate the potential utility of the information reporting to DOE in fulfilling EPA's statutory obligations under TSCA. Your comments will further inform EPA's evaluation of this issue.

5. EPA is proposing to require only partial IUR reporting for inorganic chemicals, i.e. only the information in Parts I., II., and IV. of Form U would be reported by manufacturers of inorganic chemicals. Full IUR reporting for inorganic chemicals, i.e. all parts of Form U, including the processing and use-related data elements in Part III., would be considered for a future amendments to the IUR regulations. Alternatively, EPA could adopt a phased-in approach to full reporting for inorganics, e.g., partial reporting for inorganic chemicals could be required in the first reporting year, followed by full reporting in subsequent reporting years. EPA solicits public comment on the proposed and alternate approaches.

6. During the interagency review process, it was suggested that the Agency limit the reporting of processing and use information on Part III. of Revised Reporting Form U to manufacturers and importers of high production volume (HPV) chemicals in the U.S. (i.e., are produced in amounts equal to or greater than 1 million pounds), chemicals that are currently subject to testing under TSCA section 4 (i.e., test rules and enforceable consent agreements (ECAs)), chemicals identified for voluntary testing, chemicals designated for testing by the ITC, and chemicals listed in the Agency's Master Testing List (the current edition is available at http://www.epa.gov/opptintr/chemtest/mtl.htm). This would mean that, for example, in order to determine whether or not a chemical is an HPV chemical, a manufacturer or importer would not only need to know their own production volume, but also whether the chemical is produced nationally in amounts equal to or greater than 1 million pounds. In order to determine whether a chemical is subject to testing under TSCA section 4, identified for voluntary testing, or designated for testing by the ITC during a particular reporting period, a manufacturer or importer would be required to review the regulations and the most recent Master Testing List. Therefore, EPA is specifically requesting comment on whether manufacturers and importers will be able to make these determinations for the universe of chemicals potentially subject to IUR reporting, including any suggestions for ways in which to make these determinations.

EPA believes that for an HPV determination procedure to be effective, it must be able to accommodate the frequency with which individual chemicals may rise above or fall below the HPV threshold criteria of a U.S. aggregate production volume of 1 million lbs. or more per year. For example, 17% of the chemicals which were HPVs according to data submitted under the 1990 IUR were not HPVs according to data submitted under the 1994 IUR. To address this issue, EPA is proposing in these IUR amendments to use a submitter-specific processing and use production volume threshold of 300,000 lbs. or more per site per year to ensure that reporting is captured for a great majority of HPVs (as defined on the basis of national aggregate production volume). EPA seeks comments on alternative approaches for identifying HPVs for IUR reporting purposes that similarly account for the dynamic nature of the set of HPV chemicals.

EPA is also specifically interested in receiving comments on the additional burden imposed on manufacturers and importers associated with the reporting of processing and use information under the IUR amendments to manufacturers and imports of HPV chemicals. Under EPA's current proposal, in order to determine whether a chemical is subject to IUR reporting during a particular reporting period, a manufacturer or importer would first determine the production volume of the chemicals they produced during the year for which reporting is required (i.e., was the chemical produced in an amount of 25,000 lbs. or more, or in an amount of 300,000 lbs. or more for processing and use information). They would then determine if the chemical is otherwise exempt from IUR reporting. The Agency is concerned that limiting reporting to the HPV chemicals would require a manufacturer or importer to make additional determinations, as described in the beginning of this request for

comment, in order to ascertain whether they must report under IUR.

In addition, EPA is interested in receiving comment on whether this suggestion would limit the utility of the information that would be collected, because it would change the focus and purpose of the proposed IUR amendments related to the collection of processing and use information. As discussed previously, EPA believes that the basic processing and use information that EPA is proposing to collect on less than 3,500 of the 76,000 chemicals on the TSCA Inventory, is critical for EPA to more effectively and efficiently fulfill its obligations under TSCA, e.g., to assess the risks of chemicals in commerce, and to promote pollution prevention by encouraging the development of safer substitutes and alternatives. In developing its proposal, the Agency has taken steps to minimize burden and costs, and believes that the information that the Agency is proposing to collect is essential to the Agency's chemical screening process. The basic processing and use information that EPA is proposing to collect will allow the Agency and other users of IUR information to better prioritize their efforts based on a chemical's potential risks. The Agency therefore believes that the burden and costs associated with providing the information proposed in this document will assist the Agency and others to avoid the imposition of additional burden and costs related to further actions, such as more in-depth assessments and regulations.

7. Are the industrial function categories listed in this proposed rule the most appropriate ones?

8. Are the commercial and consumer product categories in this proposed rule the most appropriate ones?

9. Are there better alternatives to the definition of ''potentially exposed worker'' contained in this proposed rule (i.e., § 710.2), ''reasonably likely to be exposed'')? Is the OSHA hazard communication standard's definition (i.e., 29 CFR 1910.1200(c), ''employee'') more appropriate for this proposed rule?

10. Should EPA require the reporting of TRI facility identification numbers, where available?

11. Is the reporting of production volume ranges, as proposed, likely to result in fewer confidentiality claims than when specific production volumes are reported? What else could be done to the reporting process and data elements included in the final rule to reduce CBI claims of submitters to allow better public access to data?

12. Should the Agency collect information on the use of personal protective equipment during the manufacture or import of chemicals reported on the IUR? During the interagency review process, it was suggested that the Agency consider collecting information on the use of personal protective equipment (PPE). Generic PPE recommendations exist from Material Safety Data Sheets (MSDS), and may be available from other sources. As described in this preamble, EPA plans to use the information collected through these proposed amendments mainly for initial screening level assessments. EPA is interested in receiving comment on whether the Agency should collect information on PPE, what kind of specific PPE information should be collected, and whether such additional data reporting requirements would result in a significant burden increase to industry.

13. Are the data sought in this proposed rule related to industrial processing and use and commercial and consumer products ''readily obtainable'' by those who are required to report?

14. What alternatives are available to the procedures proposed in this document that will protect submitters' right to reassert their CBI claims? Can you identify means other than those discussed in this proposed rule which the Agency might use to better inform submitters of the requirement to reexamine past CBI claims and to reassert CBI claims, as appropriate, in order to retain CBI protections?

15. Should EPA require data to be reported using the metric system?

X. Materials in the Public Docket

The official record for this rulemaking has been established under docket control number OPPTS–82053. The following is a listing of the documents that have already been placed in the official record for this proposal.

A. Supporting Documentation

1. **Federal Register** notices/EPA documents/court opinions pertaining to this proposed rule consisting of:

a. ''TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure,'' (58 FR 28736, May 14, 1993).

b. 29 CFR 1910.1200 (OSHA hazard communication standards for toxic and hazardous substances).

c. *Chemical Manufacturers Association* v. *EPA*, 859 F.2d 977, 991 (D.C. Cir. 1988).

2. Technical support documents and studies consisting of:

a. EPA/OPPT, ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening,'' Volumes 1 and 2, July 19, 1996.

b. Eastern Research Group, Inc., ''Preliminary Assessment Information Rule (PAIR) Database, Manufacturing Process Type/Release Analysis and Number of Workers/Production Quantity Analysis,'' prepared for EPA/OPPT, September 26, 1996.

c. Environmental Business Strategies, ''U.S. Chemical Production, Use, and Exposure Data: A Study of Existing Information Sources,'' on behalf of Chemical Manufacturers Association, October 1997.

d. GE Plastics, ''IUR Reporting Frequency and EPA's Existing Chemicals Program,'' 1996.

e. NIOSH, National Occupational Exposure Survey (NOES), 1981.

f. EPA/OPPT/EETD/EPAB, ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' March 1, 1999.

g. EPA/OPPT, ''Inventory Update Rule (IUR) Technical Support Document: Evaluation of Likelihood of Confidential Business Information Claims for Production Volume Information,'' Final Draft, August 26, 1996.

h. EPA/OPPT, ''Technical Support Document: Technical Approach for the Selection of Consumer End-Use Categories for the Inventory Update Rule,'' 1996.

i. EPA/OPPT, ''A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA,'' March 1999.

3. Minutes or summaries of public meetings:

a. American Chemical Society Roundtable Forum, ''A Pollution Prevention Strategy for Toxic Chemicals,'' July 28, 1993.

b. EPA, ''Chemical Use Inventory (CUI) Meeting With Environmental and Right-to-Know Groups,'' September 29, 1993.

c. EPA, ''The EPA Office of Pollution Prevention and Toxics (OPPT) Meeting on the Chemical Use Inventory,''' October 6, 1993.

d. EPA, ''Chemical Use Inventory (CUI) Meeting With Industry,'' October 12, 1993.

e. EPA, ''OPPT's Chemical Use Inventory Project: Presentation to FOSTTA Chemical Management and Chemical Information Project Members,'' October 19, 1993.

f. EPA, ''Meeting with Labor Constituents,'' November 10, 1993.

g. EPA, ''CUI Multi-stakeholder Meeting,'' January 5, 1994.

h. EPA, ''Statement of Lynn R. Goldman, M.D. Before the

Subcommittee on Toxic Substances, Research and Development, Committee on Environment and Public Works, U.S. Senate,'' May 17, 1994.

i. U.S. Senate Committee on Environment and Public Works, Subcommittee on Toxic Substances, Research and Development, ''Hearing to discuss reauthorization of the Toxic Substances and Control Act (TSCA),'' July 13, 1994.

j. Clean Sites, ''CUI/IUR Amendments Workshop, Meeting Summary,'' April 13, 1995.

k. EPA, ''Discussion Paper [for April 13, 1995 meeting], Amendments to the TSCA Inventory Update Rule Needed to Create A Chemical Use Inventory,'' April 1995.

l. Mary Ellen Weber, EPA, ''TSCA Chemical Use Inventory, Inventory Update Rule Amendments,'' presented to Chemical Manufacturers Association, TSCA Information Forum, May 15, 1996.

m. Mary Ellen Weber, EPA, ''Chemical Use Inventory, TSCA Inventory Update Rule Amendments,'' presented to Organization Resources Counselors, Inc., Environmental Group, June 26, 1996.

4. Communications consisting of:

a. Memorandum from Mark V. Stanga and Patricia A. Franco, Electronic Industries Association to EPA, May 5, 1993.

b. Letter from Claudette M. Cofta, CMA to Mark A. Greenwood, EPA, September 8, 1993.

c. Letter from Albert K. Langley, Jr., Georgia Department of Natural Resources to Wardner G. Penberthy, EPA, October 25, 1993.

d. Letter from Michael A. Babich, Consumer Product Safety Commission to Wardner G. Penberthy, EPA, October 26, 1993.

e. Letter from Stephen S. Kellner, Chemical Specialties Manufacturers Association to Mark Greenwood, EPA, October 29, 1993.

f. Letter from Stephen D. Hanna, California EPA to Mary Ellen Weber, EPA, November 8, 1993.

g. Letter from Public Interest Groups to Mark Greenwood, EPA, November 17, 1993 (with attachments).

h. Letter from Hillel Gray, National Environmental Law Center, to Wardner G. Penberthy, EPA, November 22, 1993.

i. Letter from Roger A. Kanerva, State of Illinois EPA to Wardner G. Penberthy, EPA, November 22, 1993.

j. Letter from F. David Petke, Eastman Chemical Co. to Mary Ellen Weber, EPA, November 23, 1993.

k. Letter from Stephen S. Kellner, Chemical Specialties Manufacturers Association to Tim Hunt, OMB, November 30, 1993.

l. Letter from Andy Opperman, New Jersey Dept. of Environmental Protection and Energy to Wardner G. Penberthy, December 6, 1993.

m. Letter from Claudette M. Cofta, CMA to Mark A. Greenwood, EPA, December 7, 1993.

n. Letter from Cheryl O. Morton, SOCMA to Mark A. Greenwood, EPA, December 10, 1993.

o. Letter from Jeanne Herb, State of New Jersey Department of Environmental Protection and Energy, to Wardner G. Penberthy, EPA, December 8, 1993.

p. Letter from Robert D. Bullard, University of California, Los Angeles, to Wardner G. Penberthy, EPA, December 14, 1993.

q. Letter from Stephen R. Sides and H. Allen Irish, National Paint Coatings Association to Wardner G. Penberthy, EPA, January 11, 1994.

r. Letter from Mark V. Stanga, Litton Corporate, to Wardner G. Penberthy, EPA, January 17, 1994.

s. Letter from Stephen S. Kellner, Chemical Specialties Manufacturers Association to Lynn R. Goldman, EPA, January 19, 1994.

t. Letter from Claudette M. Cofta, CMA to Mark A. Greenwood, EPA, January 25, 1994.

u. Letter from Hillel Gray, National Environmental Law Center to Lynn R. Goldman, EPA, February 11, 1994.

v. Letter from Richard I. Sedlak, The Soap and Detergent Association to Wardner G. Penberthy, EPA, February 24, 1994.

w. Letter from Lawrence E. Slimak, American Automobile Manufacturers Association to Mark Greenwood, EPA, March 8, 1994.

x. Letter from Mark A. Greenwood, EPA to Lawrence E. Slimak, American Automobile Manufacturers Association, March 28, 1994.

y. Letter from Sarah Doelp, CMA to Mark Greenwood, EPA, June 20, 1994.

z. Report from Ken Geiser, Toxics Use Reduction Institute, University of Massachussetts, October 1994.

aa. Letter from Sarah Doelp, CMA to Wardner G. Penberthy, EPA, February 2, 1995.

bb. Letter from Stephen S. Kellner, Chemical Specialties Manufacturers Association to Tim Hunt, OMB, March 23, 1995.

cc. Letter from Walter L. McLeod, API to Allan Abramson, EPA, April 21, 1995.

dd. Letter from Lynn R. Goldman, EPA to Steve Tiber, Office of Administration and Resources Management, August 18, 1995.

ee. Letter from Donald D. Helin, Chemical Manufacturers Association to William H. Sanders III, EPA, March 26, 1997.

ff. Letter from Larry Rampy, Chemical Manufacturers Association to Arthur G. Fraas, Office of Management and Budget, May 26, 1999.

gg. Letter from Pamela Gilbert, Consumer Product Safety Commission, to Donald R. Arbuckle, Office of Management and Budget, June 14, 1999.

hh. Letter from John D. Walter, TSCA Interagency Testing Committee, to Mary Ellen Weber, EPA, June 15, 1999.

B. References

1. Vice President Albert Gore, ''EPA Right-to-Know Announcement,'' April 21, 1998.

2. Chemical Manufacturers Association, Synthetic Organic Chemical Manufacturers Association, U.S. EPA, Chemical Specialties Manufacturing Association, American Petroleum Institute, ''Round 3 of the UEIP (Use and Exposure Information Project),'' June 3, 1996.

3. U.S. EPA, ''Reducing Risk: Setting Priorities and Strategies for Environmental Protection,'' Science Advisory Board, (SAB-EC-90-021), 1990.

4. National Academy of Public Administration, ''Setting Priorities, Getting Results - A New Direction for EPA,'' 1995.

5. U.S. EPA, ''Decision Guidelines Manual,'' OPPT/CCD/NCB, December 1992.

6. Letter from M.L. Mullins, Chemical Manufacturers Association, to EPA, ''Proposed Alternative to Anticipated Rule to Amend TSCA for the Creation of a Chemical Use Inventory,'' May 20, 1996.

7. Letter from Michael A. Babich, U.S. Consumer Product Safety Commission, to Wardner G. Penberthy, EPA, June 24, 1996.

8. Official Journal of the European Communities, ''Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances,'' L84, Volume 36, April 5, 1993.

9. Organization of Economic Cooperation and Development, ''SIDS Manual (Second Revision) Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals,'' May 1996.

10. Memorandum from Norman R. Niedergang, EPA to Dr. Lynn R. Goldman, EPA, ''Continuing Sources of Asbestos Exposure,'' June 26, 1998.

11. U.S. EPA, ''Influence of CBI Requirements on TSCA Implementation,'' OPPT, March 1992.

12. U.S. EPA, ''Final Action Plan: TSCA Confidential Business

Information Reform,'' OPPT, June 20, 1994.

13. U.S. EPA, ''TSCA CBI Reform Program: State Access to TSCA Data, Including CBI, Project; Forum on State, Tribal Toxics Action Meeting'' OPPT/IMD, June 24, 1996.

14. U.S. EPA, ''EPA Needs Exposure-Related Data: A Discussion of the Justification for Collecting Exposure-Related Data Through the IUR Amendments,'' OPPT/EETD/EPAB, 1998.

15. Griefe, A. et al., ''National Institute for Occupational Safety and Health General Industry Occupational Exposure Databases: Their Structure, Capabilities and Limitations,'' Applied Occupational and Environmental Hygiene 10(4), April 1995.

16. U.S. EPA, ''Chemical Use Clusters Scoring Methodology,'' Draft Report, OPPT/EETD/CEB, July 23, 1994.

17. U.S. EPA, ''An SAB Report: Improving the Use Cluster Scoring System, Recommendations for the Use Cluster Scoring System Prepared by the Environmental Engineering Committee,'' Science Advisory Board, SAB-EEC-95-017, September 1995.

18. U.S. EPA, ''Inventory of Exposure-Related Data Systems Sponsored by Federal Agencies,'' EPA/600/R-92/078, http://www.epa.gov/ncepihom/nepishom/index.html, 1992.

19. American Petroleum Institute, ''Petroleum Process Stream Terms Included in the Chemical Substances Inventory Under the Toxic Substances Control Act (TSCA),'' Health and Safety Regulation Committee Task Force on Toxic Substances Control, February 1985.

20. General Accounting Office, ''EPA Should Focus Its Chemical Use Inventory on Suspected Harmful Substances,'' GAO/RCED-95-165, July 7, 1995.

21. Letter from Mark N. Duvall, Union Carbide, to EPA, ''Additional Comments of Union Carbide Corporation on EPA's Preliminary Actions to Reform TSCA Confidential Business Information, Docket No. OPPTS-00125,'' August 31, 1993.

22. Letter from Stephen A. Newell, Occupational Safety and Health Administration, to Wardner G. Penberthy, EPA, October 15, 1996.

23. Letter from Paul A. Schulte, National Institute for Occupational Safety and Health, to Wardner G. Penberthy, EPA, October 8, 1996.

24. U.S. EPA, ''Preparation of Engineering Assessments,'' Vol. 1, Ch. 4, pp. 1-33, OPPT/EETD/CEB, February 28, 1991.

25. U.S. Census Bureau, North American Industrial Classification System (NAICS), http://www.census.gov/epcd/www/naics.html, 1999.

26. U.S. EPA, ''Chemical Right-to-Know Initiative,'' http://www.epa.gov/chemrtk/index.htm, June 8, 1999.

XI. Regulatory Assessment Requirements

A. Executive Order 12866

Pursuant to Executive Order 12866 (58 FR 51735, October 4, 1993), entitled ''Regulatory Planning and Review,'' the Office of Management and Budget (OMB) has determined that this is a ''significant regulatory action'' because this action may raise novel policy issues related to the collection of information. This action was submitted to OMB for review, and any comments or changes made during that review have been documented in the public record.

In addition, the Agency has prepared an economic assessment of the estimated costs and benefits attributable to this proposed rule. This document, entitled ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule,'' is available in the public version of the official record for this proposal, at the address listed in Unit I.B.2. of this preamble. EPA estimates the proposed amendments would cost between $36 to $51 million for the first year of reporting and $27 to $41 million for future years of reporting, resulting in an annualized cost of $10 to $14 million over the next 20 years.

Under the proposed amendments, approximately 8,900 chemicals would be subject to reporting, and the Agency expects that it would receive approximately 25,500 submissions during the first reporting cycle. Approximately 10,000 of those submissions (providing information on about 4,000 chemicals) would be full reports which include information found in Part III. of Revised Reporting Form U, with the remainder reporting only company, site and chemical identification and manufacturing information (Parts I., II., and IV. of Revised Reporting Form U). In order to keep the reporting burden as low as possible, EPA is proposing to require that certain information be reported in ranges, that only the top 10 NAICS codes be accounted for when reporting industrial processing and use information, and that only readily obtainable information in Part III be reported.

EPA analyzed the effects of a number of different alternatives for the proposed rule, including variations in exemptions, different thresholds for both partial- (i.e. Parts I., II., and IV. of Revised Reporting Form U) and full-form (i.e. all parts of Revised Reporting Form U), and various frequencies of collection. These options are explored further in the Economic Analysis.

In addition to the proposed option, EPA considered continuing the exemption from IUR reporting for inorganic chemicals and adding an exemption for site-limited petroleum streams. EPA examined the effects of keeping the partial-form threshold at 10,000 pounds and considered full-form thresholds of 10,000, 25,000, 100,000, 500,000, 1,000,000 and 10,000,000 pounds, as well as a phased-in 100,000/500,000 full-form threshold. EPA also considered changes in the reporting cycle, such as a one-time collection, a 2-year cycle, and an option that would have collected partial forms every 2 years and full forms every 4 years.

During the interagency review process, EPA also considered a 50,000 lb. threshold for the partial form (see Addendum to the economic analysis referenced in Unit X.A.2.f. of this preamble). While this threshold would indeed reduce industry burden by $2-3 million when compared to the proposed 25,000 lb. threshold, EPA feels that the benefit of the information obtained on chemicals produced between 25,000 and 50,000 lbs. yearly, far outweighs the costs. By increasing the threshold from 25,000 to 50,000 lbs., EPA would lose data on roughly 880 discrete chemicals from roughly 1,750 reports. Forgoing this information would exclude a large portion of the chemical industry from oversight under TSCA, which requires EPA to regulate the entire industry. In addition, EPA feels that the data collected at a 50,000 lb. threshold would be insufficient to meet the TSCA statutory requirement to update and keep current the TSCA Inventory of Chemical Substances.

During the interagency review process, EPA altered its proposal to include a natural gas exemption, an inorganics partial exemption, and an upper threshold of 300,000 lbs. These options are also analyzed in the addendum to the economic analysis referenced in Unit X.A.2.f. of this preamble. While the natural gas exemption affects only six chemicals, it reduces the number of reports by over 1,200. The inorganics partial exemption reduces the number of chemicals requiring full reports by about 1,200. The increase in the upper threshold from 100,000 to 300,000 pounds reduces the number of chemicals reporting processing and use information (Part III. of Form U) to about 3,400.

The costs of the proposed amendments would be borne by two groups: the chemical industry and EPA. Industry costs are associated with complying with the regulation, while EPA costs are associated with administering the regulation and maintaining the collected data. In this rulemaking effort, EPA has made every attempt to balance data needs with collection costs and burden. Wherever possible, EPA has used exemptions or partial exemptions to reduce the number of reports filed by industry. EPA has provided an upper threshold for reporting use information required in Part III of Revised Reporting Form U, reducing the per report burden for submitters. Recognizing that this information would be used for screening-level purposes, EPA has reduced the specificity of the information that would be required in three ways:

- By requiring the reporting of only readily obtainable information for the use and non-manufacturing exposure-related data.
- By requiring that submitters report much of the information in ranges, reducing the need to generate precise estimates.
- By requiring processing and use-related information on only the top 10 NAICS codes, as determined by percent of the chemical's volume.

These steps limit the amount of information required, reducing the time and effort spent by the chemical industry in complying with the amendments.

First-year costs of the proposed rule are estimated to be between $36 million and $51 million, with subsequent annual costs in future reporting years of $27 to $41 million. This results in an annualized cost of between $10 million and $14 million over the first 20 years. EPA assumes that the burden associated with reporting under the IUR amendments would decrease over time as the industry's familiarity with the reporting rule increases and to the extent that the information being reported remains somewhat constant from one reporting period to the next. Projected costs to EPA are relatively small and are estimated to be $525,000 in the first reporting year, and $275,000 in subsequent reporting years.

During the interagency review process, EPA added the collection of the data element for average concentration (not included in the Economic Analysis) to Part II. of the revised Reporting Form U. EPA expects the addition of this data element to result in only a negligible increase in burden because similar information is needed in order to report both the maximum concentration as well as the average concentration. EPA therefore did not find a reason to adjust the Economic Analysis to reflect this change.

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this proposed rule, if promulgated as proposed, will not have a significant impact on a substantial number of small entities. This certification is based on the Agency's analysis of potential impacts on small entities, which is included in the Economic Analysis summarized in section A. of this Unit.

Small entities include small businesses, small not-for-profit organizations, and small governmental jurisdictions (5 U.S.C. 601(6)). Because not-for-profit organizations and governmental jurisdictions will not be affected by this proposed rule, ''small entity'' for purposes of this proposed rule is synonymous with ''small business.''

Section 601(3) of the RFA establishes as the default definition of small business the definition used in section 3 of the Small Business Act (15 U.S.C. 632) under which the SBA establishes small business size standards (13 CFR 121.201). The RFA recognizes, however, that it may be appropriate at times for Federal agencies to use an alternate definition of small business. As a result, RFA section 601(3) provides that an agency may establish a different definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. EPA established a different definition of small business, found in the existing IUR at 40 CFR 704.3, in accordance with these requirements. Manufacturers and importers who meet the 40 CFR 704.3 definition of small business are generally exempted from IUR reporting in 40 CFR 710.29. This exemption is retained under these amendments and is not being reopened for comment.

Despite the fact that small manufacturers and importers that fully meet the 40 CFR 704.3 definition of small manufacturers and importers are generally exempt from reporting under IUR, and thus are not significantly impacted by these amendments to IUR, EPA conducted an analysis of the potential impact for submitters that meet only part of the 40 CFR 704.3 definition. Specifically, an analysis of the potential impact was conducted only for those submitters that meet the first criterion in the 40 CFR 704.3 definition of ''small manufacturer or importer,'' i.e. total annual sales of less than $40 million, but that do not meet the second criterion, i.e. production or import volume of less than 100,000 pounds at all sites.

For small entities manufacturing (including importing) organic chemicals subject to reporting, the Agency estimates the impact to be 0.13% to 0.16% of sales. For small entities manufacturing (including importing) inorganic chemicals subject to reporting, the Agency estimates the impact to be 0.15% to 0.20% of sales. These estimates are based upon the Agency's belief that most small businesses reporting will complete the full Form U, unless the business is eligible for one of the partial exemptions. These small entity impacts are based on EPA's original proposal for the IUR amendments. The revised proposal, which has reduced industry cost and burden even further, is expected to have even less impact on small entities.

Information relating to this determination has been provided to the Chief Counsel for Advocacy of the Small Business Administration, and is included in the docket for this rulemaking. Any comments regarding the economic impacts that this proposed regulatory action may impose on small entities should be submitted to the Agency according to the procedures identified in the ''ADDRESSES'' section at the beginning of this preamble.

C. Paperwork Reduction Act

The information collection requirements contained in this proposed rule have been submitted to OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and in accordance with the procedures at 5 CFR 1320.11. An Information Collection Request (ICR) document has been prepared by EPA (EPA ICR No. 1884.01), and included in the public version of the official record that is described in Unit I.B.3. of this preamble. In addition to viewing the ICR document as described in Unit I.B.3. of this preamble, you may obtain a copy of the ICR by mail from Sandy Farmer, OP Regulatory Information Division; Environmental Protection Agency (2137), 401 M St., SW., Washington, DC 20460, by calling (202) 260-2740, or by e-mail to ''farmer.sandy@epa.gov.'' An electronic copy has also been posted on EPA's World Wide Website (http://www.epa.gov/) with other information related to this action.

The information requirements contained in this proposal are not effective until OMB approves them. An Agency may not conduct or sponsor,

and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register**, are displayed in a list at 40 CFR part 9.

The information that would be reported under these amendments to IUR would better enable EPA to screen thousands of chemical substances for potential risk. Risk screening is necessary in order to conserve limited Agency resources by focusing risk assessment work on chemical substances for which some level of potential risk has been indicated. The new information that would be reported under this rule is critical to the risk screening process and is unavailable through other sources. Responses to this collection of information would be mandatory, pursuant to TSCA section 8(a).

CBI claims may be made for all of the new information that would be reported under these amendments to IUR. This action proposes new substantiation procedures for CBI claims regarding plant site identity. (See § 710.38(d) of the regulatory text). In addition, a new provision for the reassertion of CBI claims would be added. This provision states that all CBI claims made in one reporting period would be valid only until the beginning of the reporting period immediately following the reporting period in which the information was claimed as confidential. To maintain the confidential status of information, the submitter would need to certify during every reporting period following the one in which the original claim of confidentiality was made, that the information should continue to be treated as confidential by EPA. Reassertions must be made to maintain confidentiality even if the submitter is not required to report during a given reporting period. If a submitter fails in a reporting period to reassert the confidentiality claims made in the previous reporting period, the claims are presumed to be waived and EPA will make the information available to the public without further notice to the submitter. (See § 710.39 of the regulatory text).

The following annual burden and cost figures represent the cost of a 4–year reporting cycle, spread over 4 years. Most or all of the burden would fall in the first year of the cycle. The public reporting burden for this collection of information is estimated to be 150,000 to 210,000 hours for each of the 4 years in the first reporting cycle for approximately 3,050 respondents. The average annual reporting burden per response is 6 to 8 hours, with the average company reporting 8.4 times per collection and each information collection occurring every 4 years. The annual public reporting cost burden for operation and maintenance expenses is estimated to be $11 to $15 million annually for the first four year reporting cycle, and decreasing after that. The total capital and start-up costs, as well as the purchase of services, are estimated to be zero.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing burden, including through the use of automated collection techniques. Send comments on the ICR to the EPA according to the instructions provided in Unit I.C. of this preamble. Please remember to include the docket control number OPPTS–82053, or the ICR number in any correspondence. The final rule will respond to any comments on the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), EPA has determined that this proposed regulatory action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector in any 1 year. The analysis of the costs associated with this proposed action are described in Unit XI.A. of this preamble. In addition, EPA has determined that this proposed rule does not significantly or uniquely affect small governments. Accordingly, today's proposed rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing Intergovernmental Partnerships* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12857 requires EPA to provide to the OMB a description of the extent of EPA's prior consultations with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's notice does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule. Nevertheless, EPA has sought the active participation of State, local and tribal governments who might be interested in this proposal. The Agency has had several informal consultations regarding the proposed rule with some States through the EPA regional offices and at regularly scheduled State meetings. No significant issues or information were identified as a result of EPA's discussion with the States, who are primarily interested in CBI issues and whether they will have access to the information EPA collects under these proposed amendments.

F. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communitiies, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with

those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

G. Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, the Agency has considered environmental justice-related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. The Agency believes that the information collected under this proposed rule would assist the Agency in determining the risks and exposures associated with these chemicals. Although not directly impacting environmental justice-related concerns, this information would enable the Agency to protect human health and the environment by being better able to prioritize chemical substances of concern.

H. Executive Order 13045

This rulemaking does not require special consideration pursuant to the terms of Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it is not likely to have an annual effect on the economy of $100 million or more and it does not have a potential effect or impact on children. As discussed in this preamble, this proposed rule would provide the Agency with information needed to screen and prioritize chemical substances. This information will allow the Agency and others to determine which chemical substances have potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

I. National Technology Transfer and Advancement Act

This proposed regulatory action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) of NTTAA directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. EPA invites public comment on the Agency's determination that this regulatory action does not require the consideration of voluntary consensus standards.

List of Subjects in 40 CFR Part 710

Environmental protection, Chemicals, Hazardous materials, Reporting and recordkeeping requirements.

Dated: August 2, 1999.

Susan H. Wayland,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR part 710 be amended as follows:

PART 710—[AMENDED]

1. The authority citation for part 710 would continue to read as follows:

Authority: 15 U.S.C. 2607(a).

2. By revising § 710.2 to read as follows:

§ 710.2 Definitions.

In addition to the definitions in § 704.3 in this chapter, the following definitions apply to this part:

(a) The following terms shall have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under such Act: *Cosmetic*, *device*, *drug*, *food*, and *food additive*. In addition, the term *food* includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.*; *meats* and *meat food products*, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.*; and *eggs* and *egg products*, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

(b) The term *pesticide* shall have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.*, and the regulations issued thereunder.

(c) The following terms shall have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 *et seq.*, and the regulations issued thereunder: *byproduct material*, *source material*, and *special nuclear material*.

(d) The following definitions also apply to this part:

Act means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

Administrator means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any other person who shall by operation of law be authorized to carry out such functions.

An article is a manufactured item: (1) Which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without separate commercial intent during the manufacture or processing of another chemical substance(s) or mixture(s).

Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that ''chemical substance'' does *not* include:

(1) Any mixture,

(2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide,

(3) Tobacco or any tobacco product, but not including any derivative products,

(4) Any source material, special nuclear material, or byproduct material,

(5) Any pistol, firearm, revolver, shells, and cartridges, and

(6) Any food, food additive, drug, cosmetic, or device, when

manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Commerce means trade, traffic, transportation, or other commerce:

(1) Between a place in a State and any place outside of such State, or

(2) Which affects trade, traffic, transportation, or commerce described in paragraph (1) of this definition.

Commercial use means the use of a chemical substance or mixture in a commercial enterprise providing saleable goods or services (e.g., dry cleaning establishment, painting contractor).

Consumer use means the use of a chemical substance that is directly, or as part of a mixture, sold to or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas.

Distribute in commerce and distribution in commerce when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture, mean to sell or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

EPA means the U.S. Environmental Protection Agency.

Importer means any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the U.S. and includes:

(1) The person primarily liable for the payment of any duties on the merchandise, or

(2) An authorized agent acting on his behalf (as defined in 19 CFR 1.11).

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Industrial use means use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.

Intermediate means any chemical substance:

(1) Which is intentionally removed from the equipment in which it is manufactured, and

(2) Which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).

Note: The *equipment in which it was manufactured* includes the reaction vessel in which the chemical substance was manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical substance may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Manufacture means to manufacture or import for commercial purposes.

Manufacture or import ''for commercial purposes'' means: To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage, and includes, for example, the manufacture or import of any amount of a chemical substance or mixture:

(1) For commercial distribution, including for test marketing, or

(2) For use by the manufacturer, including use for product research and development, or as an intermediate.

Master Inventory File means EPA's comprehensive list of chemical substances which constitute the Chemical Substances Inventory compiled under section 8(b) of the Act. It includes substances reported under subpart A of this part and substances reported under part 720 of this chapter for which a Notice of Commencement of Manufacture or Import has been received under § 720.120 of this chapter.

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that ''mixture'' does include:

(1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined and if, after the effective date or premanufacture notification requirements, none of the chemical substances comprising the combination is a new chemical substance, and

(2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.

New chemical substance means any chemical substance which is not included in the inventory compiled and published under subsection 8(b) of the Act.

Nonisolated intermediate means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

Person means any natural or juridicial person including any individual, corporation, partnership, or association, any State or political subdivision thereof, or any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

Process means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

Process for ''commercial purposes'' means to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.

Processor means any person who processes a chemical substance or mixture.

Readily obtainable information means information which is known by management and supervisory employees of the submitter company who are associated with research, development, distribution, technical services, or marketing of the reportable chemical substance. Extensive file searches are not required.

Reasonably likely to be exposed means an exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use of the chemical substance, is more likely to occur than not to occur. Such exposures would normally include, but not be limited to, activities such as charging reactor vessels, drumming, bulk loading, cleaning equipment, maintenance operations, materials handling, and transfers, and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact, absorption, etc.), but excludes accidental or theoretical exposures.

Repackaging means the physical transfer of a chemical substance or mixture, as is, from one container to another container or containers in preparation for distribution of the chemical substance or mixture in commerce.

Reportable chemical substance means a chemical substance described in § 710.25.

Site means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site. For the purposes of imported chemical substances, the site shall be the business address of the importer.

Site-limited means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited.

Small maufacturer or importer means a manufacturer or importer whose total annual sales are less than $5,000,000, based upon the manufacturer's or importer's latest complete fiscal year as of January 1, 1978, except that no manufacturer or importer is a ''small manufacturer or importer'' with respect to any chemical substance which such person manufactured at one site or imported in quantities greater than 100,000 pounds during calendar year 1977. In the case of a company which is owned or controlled by another company, total annual sales shall be based on the total annual sales of the owned or controlled company, the parent company, and all companies owned or controlled by the parent company taken together.

Note: The purpose of the exception to the definition is to ensure that manufacturing and importers report production volumes for all chemical substances which they manufactured at one site or imported in quantities equal to or greater than 100,000 pounds during calendar year 1977.

Small quantities for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product (hereinafter sometimes shortened to *small quantities for research and development*) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that:

(1) Are no greater than reasonably necessary for such purposes, and

(2) After the publication of the revised inventory, are used by, or directly under the supervision of, a technically qualified individual(s).

Note: Any chemical substances manufactured, imported, or processed in quantities less than 1,000 pounds annually shall be presumed to be manufactured, imported, or processed for research and development purposes. No person may report for the inventory any chemical substance in such quantities unless that person can certify, that the substance was not manufactured, imported, or processed solely in small quantities for research and development, as defined in this section.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Technically qualified individual means a person:

(1) Who because of his/her education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his supervision,

(2) Who is responsible for enforcing appropriated methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and

(3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in this paragrah may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (1) of this definition.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture or article in commerce.

United States, when used in the geographic sense, means all of the States, territories, and possessions of the United States.

Use means any utilization of a chemical substance or mixture that is not otherwise covered by the terms manufacture or process. Relabeling or redistributing a container holding a chemical substance or mixture where no repackaging of the chemical substance or mixture occurs does not constitute use or processing of the chemical substance or mixture.

3. In § 710.26, by revising the introductory text and paragraphs (a) and (c) and adding paragraph (e) to read as follows:

§ 710.26 Chemical substances for which information is not required.

The following categories of chemical substances are excluded from the reporting requirements of this part, with two exceptions: a chemical substance described in paragraph (a) only qualifies for a partial reporting exemption, as described in paragraph (a), and a chemical substance described in paragraph (a), (b), (c), or (e) of this section is not excluded from the reporting requirements of this part if that substance is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Act, or is the subject of an order issued under section 5(e) or 5(f) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act.

(a) *Petroleum process streams.* All chemical substances listed by Chemical Abstract Service Registry Number (CAS Number) in this paragraph are excluded only from paragraphs (c)(4) and (5) of § 710.32. Such chemical substances are not excluded from the other reporting requirements under 40 CFR part 710. The chemical substances included in the list in this paragraph may be modified and, if modified, a new list will be published through direct final rulemaking in the **Federal Register** by EPA prior to the upcoming reporting period. If a new list is not published prior to a given reporting period, the list in effect for the previous reporting period is still in effect for the current reporting period.

CAS Numbers of Partially Exempt Chemical Substances Termed ''Petroleum Process Streams''

63231-60-7
64741-41-9
64741-42-0
64741-43-1
64741-44-2
64741-45-3
64741-46-4
64741-47-5
64741-48-6
64741-49-7
64741-50-0
64741-51-1
64741-52-2
64741-53-3
64741-54-4
64741-55-5

64741-56-6
64741-57-7
64741-58-8
64741-59-9
64741-60-2
64741-61-3
64741-62-4
64741-63-5
64741-64-6
64741-65-7
64741-66-8
64741-67-9
64741-68-0
64741-69-1
64741-70-4
64741-71-5
64741-72-6
64741-73-7
64741-74-8
64741-75-9
64741-76-0
64741-77-1
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64741-99-7
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68606-09-7
68606-10-0
68606-11-1
68606-24-6
68606-25-7
68606-26-8
68606-27-9
68606-28-0
68606-31-5
68606-34-8
68606-35-9
68606-36-0
68607-11-4
68607-30-7
68608-56-0
68647-60-9
68647-61-0
68647-62-1
68650-36-2
68650-37-3
68650-78-2
68741-41-9
68782-97-8
68782-98-9
68782-99-0
68783-00-6
68783-01-7
68783-02-8
68783-04-0
68783-05-1
68783-06-2
68783-07-3
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68783-15-3
68783-61-9
68783-62-0
68783-61-9
68783-64-2
68783-65-3
68783-66-4
68814-47-1
68814-67-5
68814-89-1
68814-87-9
68814-90-4
68814-91-5
68855-57-2
68855-58-3
68855-59-4
68855-60-7
68911-58-0
68911-59-1
68915-96-8
68915-97-9
68918-69-4
68918-73-0
68918-93-4
68918-99-0
68919-00-6
68919-01-7
68919-02-8
68919-03-9
68919-04-0
68919-05-1
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68919-12-0
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68919-39-1
68920-06-9
68920-07-0
68920-73-0
68920-64-9
68921-07-3
68921-09-5
68921-08-4
68921-67-5
68952-76-1
68952-77-2
68952-78-3
68952-79-4
68952-80-7
68952-81-8
68952-82-9
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68956-54-7
68956-55-8
68956-70-7
68988-99-8
68989-88-8
68990-35-2
68991-49-1
68991-50-4
68991-51-5
68991-52-6
69013-21-4
69029-75-0
69430-33-7
70024-88-3
70528-71-1
70528-72-2
70528-73-3
70592-76-6
70592-77-7
70592-78-8
70592-79-9
70693-00-4
70913-85-8
70913-86-9
70955-08-7
70955-09-8
70955-10-1
70955-17-8
71243-66-8
71302-82-4
71329-37-8
71808-30-5
72230-71-8
72623-83-7
72623-84-8
72623-85-9
72623-86-0
72623-87-1
7732-18-5
8002-05-9
8002-74-2
8006-14-2

8006-20-2
8006-61-9
8007-45-2
8008-20-6
8008-20-6
8009-03-8
8012-95-1
8030-30-6
8032-32-4
8042-47-5
8052-42-4
10024-97-2
* * * * *

(c) *Microorganisms.* Any combination of chemical substances that is a living organism, and that meets the definition of ''microorganism'' at 40 CFR 725.3 of this chapter. Any chemical substance produced from a living microorganism is reportable under this part unless otherwise excluded.

* * * * *

(e) *Certain forms of natural gas.* Chemical substances with the following CAS Numbers: CAS No. 64741-48-6, Natural gas (petroleum), raw liquid mix; CAS No. 68919-39-1, Natural gas condensates; CAS No. 8006-61-9, Gasoline natural; CAS No. 68425-31-0, Gasoline (natural gas), natural; CAS No. 8006-14-2, Natural gas; and CAS No. 68410-63-9, Natural gas, dried.

4. By revising § 710.28 to read as follows:

§ 710.28 Persons who must report.

Except as provided in §§ 710.29 and 710.30, the following persons are subject to the requirements of this part. Persons must determine whether they must report under this section for each chemical substance that they manufacture (including import) at an individual site.

(a) *Persons subject to recurring reporting.* Any person who manufactured (including imported) for commercial purposes 25,000 lbs. (11,350 kg) or more of a chemical substance described in § 710.25 at any single site owned or controlled by that person at any time during calendar year 1999 or during the calendar year at 4–year intervals thereafter is subject to reporting. A person who does not manufacture (including import) at least 25,000 lbs. of a chemical substance described in § 710.25 at any single site owned or controlled by that person at any time during 1999 or during any year in 4–year intervals thereafter, but who chooses to reassert [a] confidentiality claim[s] made in [a] previous reporting period[s], as described in § 710.39, must make the reassertion in each reporting period even if the person is not required to report the information described in § 710.32(c).

(b) *Special provisions for importers.* For purposes of this section, the site for a person who imports a chemical substance described in § 710.25 is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction. The import site may in some cases be the organization's headquarters in the United States (see also § 710.35(b)).

5. By revising § 710.32 to read as follows:

§ 710.32 Reporting information to EPA.

Any person who must report under this part, as described in § 710.28, must submit the information described in this section for each chemical substance described in § 710.25 that the person manufactured (including imported) for commercial purposes in an amount of 25,000 lbs. (11,350 kg) or more at any one site during calendar year 2001 or during the calendar year at 4–year intervals thereafter. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization that is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the United States) Except as otherwise noted, a submitter of information under this part must report information in writing or by magnetic media as prescribed in this section, to the extent that such information is known to or reasonably ascertainable by that person. A submitter under this part must report information that applies to the calendar year for which the person is required to report (i.e., calendar year 2001 and the calendar year at 4–year intervals thereafter).

(a) *Reporting in writing.* Any person who chooses to report information to EPA in writing must do so by completing the reporting form available from EPA at the address set forth in § 710.40(b). The form must include all information prescribed in paragraph (c) of this section. Persons reporting in writing must submit a separate form for each site for which the person is required to report.

(b) *Reporting by magnetic media.* Any person who chooses to report information to EPA by means of magnetic media must submit the information prescribed in paragraph (c) of this section. Magnetic media submitted in response to this subpart must meet EPA specifications, as described in the instruction booklet available from EPA at the address set forth in § 710.40(b).

(c) *Information to be reported.* Manufacturers (including importers) of a chemical substance described in § 710.25 in an amount equal to or greater than 25,000 lbs. (11,350 kg) during a calendar year for which reporting is required must report the information described in paragraphs (c)(1), (c)(2), and (c)(3) of this section. Manufacturers (including importers) of an organic chemical substance described in § 710.25 in an amount equal to or greater than 300,000 lbs. (136,200 kg) during a calendar year for which reporting is required must report the information described in paragraphs (c)(4) and (c)(5) of this section in addition to the information described in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(1) *A certification statement signed and dated by an authorized official of the submitter company.* Persons reporting by means of magnetic media must submit this information on the reporting form available from EPA at the address set forth in § 710.40.

(2) *Company and plant site information.* The following company and plant site information must be reported:

(i) The name, company, address, city, State, zip code, and telephone number of a person who will serve as technical contact for the submitter company, and who will be able to answer questions about the information submitted by the company to EPA. Persons reporting by means of magnetic media must submit this information on the reporting form available from EPA at the address set forth in § 710.40.

(ii) The name, street address, city, State, and zip code of each site at which at least 25,000 lbs. (11,350 kg) or more of a chemical substance for which reporting is required under this part is manufactured (including imported). (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.) A submitter under this part must include the appropriate Dun and Bradstreet Number and any EPA Facility Registration Identifier (FRI) (once an FRI has been assigned to the facility) for each plant site reported. In addition, the county or parish (or other jurisdictional indicator) in which the plant site is located must be provided.

(3) *Chemical specific information.* The following chemical-specific information must be reported:

(i) The specific chemical name and Chemical Abstracts Service (CAS) Registry Number of each chemical

substance for which reporting is required under this part (''reportable chemical substance''). As provided in the instruction booklet identified in § 710.40(b), a submitter under this part may use an EPA-Designated Accession Number, a premanufacture notice (PMN) case number (see § 720.65 of this chapter), or a TSCA Chemical Inventory reporting form number (see § 710.40) in lieu of a CAS Registry Number when a CAS Registry Number is not known to the submitter.

(ii) A statement indicating, for each reportable chemical substance, whether the substance is manufactured in the United States, imported into the United States, or both manufactured in the United States and imported into the United States.

(iii) A designation indicating, for each reportable chemical substance, whether the substance is site-limited.

(iv) The total volume (in pounds) of each reportable chemical substance manufactured (including imported) at each site. This amount must be reported to two significant figures of accuracy provided that the reported figures are within plus or minus 10% of the actual volume.

(v) Any person claiming the volume reported under paragraph (c)(3)(iv) of this section is confidential business information under § 710.38 must provide a statement indicating, for each reportable chemical substance, whether the total volume range (in pounds) which corresponds to the volume reported in response to paragraph (c)(3)(iv) of this section of each reportable chemical substance manufactured (including imported) at each site is claimed confidential. Volume ranges are listed in the following table:

Volume Ranges for Non-Confidential Reporting Purposes

From 25,000 to 100,000 lbs.
From 100,000 to 1,000,000 lbs.
From 1,000,000 to 10,000,000 lbs.
From 10,000,000 to 50,000,000 lbs.
From 50,000,000 to 100,000,000 lbs.
From 100,000,000 to 500,000,000 lbs.
From 500,000,000 to 1,000,000,000 lbs.
Greater than 1,000,000,000 lbs.

(vi) The total number of workers reasonably likely to be exposed to each reportable chemical substance at each site where the substance is manufactured (including imported). For each substance, the submitter shall report the code that corresponds to the appropriate number of workers according to the range codes in the following table:

Codes for Reporting Number of Workers Exposed

Codes	Range
W1	Less than 10
W2	At least 10 but less than 25
W3	At least 25 but less than 50
W4	At least 50 but less than 100
W5	At least 100 but less than 500
W6	At least 500 but less than 1,000
W7	At least 1,000 but less than 10,000
W8	At least 10,000

(vii) The physical form of the reportable chemical substance as it is sent off-site. If the reportable chemical substance is sent in more than one physical form, the submitter shall report whichever physical form constitutes the largest portion of its total volume, measured by weight. For each substance, the submitter shall report the code that corresponds with the appropriate physical form code according to the following table.

Codes for Reporting Physical Form of Chemical Substance

Codes	Physical Form
F1	Dry powder
F2	Pellets or large crystals
F3	Water- or solvent-wet solid
F4	Other solid
F5	Gas or vapor
F6	Liquid

(viii) The average concentration and maximum concentration, measured by percentage of weight, of the reportable chemical substance at the time it is sent off-site. For each chemical substance, report the code that corresponds to the appropriate average concentration and maximum concentration according to the following table:

Codes for Reporting Average Concentration and Maximum Concentration of Chemical Substance

Codes	Concentration Range (% weight)
M1	Less than 1% by weight
M2	Between 1 and 30% by weight
M3	Between 31 and 60% by weight
M4	Between 61 and 90% by weight
M5	Greater than 90% by weight

(4) *Industrial processing and use information*—(i) The following information must be be reported only for reportable chemical substances manufactured (including imported) for commercial purposes in an amount of 300,000 lbs. (136,200 kg) or more at any one site during calendar year 1999 or during the calendar year at 4-year intervals thereafter. Persons subject to this paragraph must report industrial processing and use information for each reportable chemical substance at sites under their control and at sites that receive a reportable chemical substance from the submitter directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.). Information regarding processing or use activities occurring at sites not under the control of the submitter must be reported only to the extent that it is readily obtainable by the submitter. If the required information is not readily obtainable by the submitter, the submitter shall provide estimates, using the submitter's best professional judgment, based upon the submitter's past experience for similar chemical substances in the same or similar markets, and/or any reasonable projections of likely processing and use scenarios for the chemical substance. The following items must be reported under this paragraph:

(A) A designation indicating the type of industrial processing or use operation at each site subject to the industrial processing and use information reporting under this paragraph. For each reportable chemical substance, report the letters which correspond to the appropriate processing or use operation[s]:

Designation	Operation
PC	Processing as a reactant
PF	Processing - incorporation into formulation, mixture or reaction product
PA	Processing - incorporation into article
PK	Processing - repackaging
U	Use - non-incorporative activities

(B) The five-digit North American Industrial Classification System (NAICS) codes which best describe the industrial activities associated with each industrial processing or use operation reported under paragraph (c)(4)(i)(A) in this section. If more than 10 NAICS codes apply to a reportable chemical substance, submitters need only report the NAICS codes for the reportable chemical substance that cumulatively represent the largest percentage of production volume, measured by weight.

(C) For each NAICS code reported under paragraph (c)(4)(i)(B) in this section, a code from the following list must be selected to designate the industrial function category that best represents the specific manner in which the reportable chemical substance is used:

Codes for Reporting Industrial Function Categories

Codes	Categories
U01	Adsorbents and absorbents
U02	Adhesives and binding agents
U03	Aerosol propellants
U04	Agricultural chemicals (non-pesticidal)
U05	Anti-adhesive agents
U06	Bleaching agents
U07	Coloring agents, dyes
U08	Coloring agents, pigments
U09	Corrosion inhibitors and anti-scaling agents
U10	Fillers
U11	Fixing agents
U12	Flame retardants
U13	Flotation agents
U14	Fuels
U15	Functional fluids
U16	Intermediates
U17	Lubricants
U18	Odor agents
U19	Oxidizing agents
U20	pH-regulating agents
U21	Photosensitive chemicals
U22	Plating agents and metal surface treating agents
U23	Processing aid, not otherwise listed
U24	Process regulators, used in vulcanization or polymerization processes
U25	Process regulators, other than polymerization or vulcanization processes
U26	Reducing agents
U27	Solvents (for cleaning or degreasing)
U28	Solvents (which become part of product formulation or mixture)
U29	Solvents (for chemical manufacture and processing and are not part of product at greater than one percent by weight)
U30	Stabilizers
U31	Surface active agents
U32	Viscosity adjustors
U33	Other

(D) The percentage, rounded off to the closest 10%, of total production volume of the reportable chemical substance associated with each combination of NAICS code and industrial function category. Where a particular combination of NAICS code and industrial function category accounts for 5% or less of the total production volume of a reportable chemical substance, the percentage shall not be rounded off to zero % if the production volume attributable to that NAICS code and industrial function category combination is equal to or greater than 300,000 lbs. during the calendar year for which data must be reported. Instead, in such a case, submitters shall report the percentage, rounded off to the closest 1%, of total production volume of the reportable chemical substance associated with the particular combination of NAICS code and industrial function category.

(E) The number of processing and use sites, by number range, of each subject chemical substance for each combination of NAICS code and industrial function category. For each substance, report the code (e.g., 0 through 9) that corresponds to the appropriate number range according to the following table:

Codes for Reporting Numbers of Sites

Codes	Range
S1	Less than 10
S2	From 10 to 25
S3	From 25 to 100
S4	From 100 to 250
S5	From 250 to 1,000
S6	From 1,000 to 10,000
S7	Greater than 10,000

(F) An estimate of the number range of workers reasonably likely to be exposed to each reportable chemical substance at the site(s) where the chemical substance is processed or used. For each substance, report the code (e.g., W1 through W8) which corresponds to the appropriate worker range according to the table in paragraph (c)(3)(vi) of this section.

(ii) [Reserved]

(5) *Commercial and consumer use information.*—(i) The following information must be reported only for reportable chemical substances manufactured (including imported) for commercial purposes in an amount of 300,000 lbs. (136,200 kg) or more at any one site during calendar year 1999 or during the calendar year at 4–year intervals thereafter. Persons subject to this paragraph must report information for each reportable chemical substance at sites under their control and at sites that receive a reportable chemical substance from the submitter directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.). Information regarding use activities occurring at sites beyond the control of the submitter must be reported only to the extent that it is readily obtainable by the submitter. If the required information is not readily obtainable by the submitter, the submitter shall provide estimates, using the submitter's best professional judgment, based upon the submitter's past experience for similar chemical substances in the same or similar market, and/or any reasonable projections on likely use scenarios for the chemical substance. The following information must be reported under this paragraph:

(A) Using the codes listed, submitters must designate each commercial and consumer product category for which the reportable chemical substance is used:

Codes for Reporting Commercial and Consumer Product Categories

Codes	Category
C01	Artists' supplies
C02	Adhesives and sealants
C03	Automotive care products
C04	Electrical and electronic products
C05	Glass and ceramic products
C06	Fabrics, textiles and apparel
C07	Lawn and garden products (non-pesticidal)
C08	Leather products
C09	Lubricants, greases and fuel additives
C10	Metal products
C11	Paper products
C12	Paints and coatings
C13	Photographic chemicals
C14	Polishes and sanitation goods
C15	Rubber and plastic products
C16	Soaps and detergents
C17	Transportation products
C18	Wood and wood furniture
C19	Other

(B) The percentage, rounded off to the closest 10%, of total production volume of the reportable chemical substance associated with each commercial and consumer product category. Where a particular commercial and consumer product category accounts for 5% or less of the total production volume of a reportable chemical substance, the percentage shall not be rounded off to zero % if the production volume attributable to that commercial and consumer product category is equal to or greater than 300,000 lbs. during the calendar year for which data must be reported. Instead, in such a case, submitters shall report the percentage, rounded off to the closest 1%, of total production volume of the reportable chemical substance associated with the particular commercial and consumer product category.

(C) Where the reportable chemical substance is used in commercial or consumer products, the typical maximum concentration, measured by

weight, of the chemical substance in each commercial and consumer product category reported under paragraph (c)(5)(i)(A) of this section.

(ii) [Reserved]

6. By revising § 710.33 to read as follows:

§ 710.33 When to report.

All information reported to EPA in response to the requirements of this part must be submitted during an applicable reporting period. The first reporting period is from August 25, 2002, to December 23, 2002. Subsequent recurring reporting periods are from August 25 to December 23 at 4-year intervals after the first reporting period. Any person described in § 710.28(a) must report during each reporting period for each chemical substance described in § 710.25 that the person manufactured (including imported) during the preceding calendar year.

7. By revising § 710.37 to read as follows:

§ 710.37 Recordkeeping requirements.

Each person who is subject to the reporting requirements of this part must maintain records that document any information reported to EPA. Records relevant to reporting during a reporting period described in § 710.33 must be retained for a period of 5 years beginning with the effective date of that reporting period.

8. By revising § 710.38 to read as follows:

§ 710.38 Confidentiality.

(a) Any person submitting information under this part may assert a business confidentiality claim for the information at the time it is submitted. These claims will apply only to the information submitted with the claim. New confidentiality claims, if necessary, must be asserted with regard to information submitted during the next reporting period. Guidance for asserting confidentiality claims is provided in the instruction booklet identified in § 710.40. Information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in part 2 of this chapter.

(b) A person may assert a claim of confidentiality for the chemical identity of a specific chemical substance only if the identity of that substance is treated as confidential in the Master Inventory File as of the time the report is submitted for that substance under this part.

(c) *Chemical identity*. The following steps must be taken to assert a claim of confidentiality for the identity of a reportable chemical substance:

(1) The person must submit with the report detailed written answers to the following questions signed and dated by an authorized official.

(i) What harmful effects to your competitive position, if any, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(ii) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(iii) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

(iv) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?

(v) Is the fact that the chemical substance is being manufactured (including imported) for a commercial purpose available to the public, for example in technical journals, libraries, or State, local, or Federal agency public files?

(vi) What measures have been taken to prevent undesired disclosure of the fact that the chemical substance is being manufactured (including imported) for a commercial purpose?

(vii) To what extent has the fact that this chemical substance is manufactured (including imported) for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

(viii) Does this particular chemical substance leave the site of manufacture (including import) in any form, e.g. as product, effluent, emission, etc.? If so, what measures have been taken to guard against the discovery of its identity?

(ix) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the substance be identified by analysis of the product?

(x) For what purpose do you manufacture (including import) the substance?

(xi) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

(2) If any of the information contained in the answers to the questions is asserted to contain confidential business information, the person must mark that information as ''trade secret,'' ''confidential,'' or other appropriate designation.

(d) *Site identity*. A person may assert a claim of confidentiality for a submitter site only if the linkage of the site with a chemical submitted in this rule is confidential and not publicly available. The following steps must be taken to assert a claim of confidentiality for a site identity:

(1) The person must submit with the report detailed written answers to the following questions signed and dated by an authorized official:

(i) Has site information been linked with a chemical identity in any other Federal, state or local reporting scheme? For example, is the chemical identity linked to a facility in a filing under the Emergency Planning and Community Right-To-Know Act (EPCRA) section 311, namely through a Material Safety Data Sheet (MSDS)? If so, identify all such schemes. Was the linkage claimed as confidential in any of these instances?

(ii) What harmful effect, if any to your competitive position do you think would result from the identity of the site and the chemical substance? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(2) If any of the information contained in the answers to the questions is asserted to contain confidential business information, the person must mark that information as ''trade secret,'' ''confidential,'' or another appropriate designation.

(e) If no claim of confidentiality is indicated on the reporting form submitted to EPA under this part, or if confidentiality claim substantiation required under paragraphs (c) and (d) of this section is not submitted with the reporting form, EPA may make the information available to the public without further notice to the submitter.

9. By revising § 710.39 to read as follows:

§ 710.39 Reassertion of past confidentiality claims.

(a) Any claim of confidentiality under § 710.38 is valid only until the end of the reporting period immediately following the reporting period in which the information was claimed as confidential. To maintain the

confidential status of information, the submitter must certify during every reporting period following the one in which the original claim of confidentiality was made, that the information should continue to be treated as confidential by EPA. Reassertions must be made to maintain confidentiality even if the submitter is not required to report the information in § 710.32(c) during a given reporting period.

(b) If the submitter fails in a reporting period to reassert the confidentiality claims made in the previous reporting period, the claims are presumed to be waived and EPA will make the information available to the public without further notice to the submitter. EPA will publish a Federal Register notice at least 2 weeks before the end of each reporting period, which will remind persons who made or reasserted CBI claims in the previous reporting period of the need to examine these claims and reassert them, as appropriate, in the current reporting period. Claims not reasserted by the end of a reporting period will be declassified after the reporting period ends.

(c) CBI claims made in IUR submissions prior to 2002 will not be subject to this reassertion requirement. CBI claims made in IUR submissions beginning with the 2002 reporting year will need to be reasserted in subsequent reporting years in order to retain CBI protections.

10. By adding § 710.40 to read as follows:

§ 710.40 Availability of reporting form and instructions.

(a) Use the proper EPA form. You must use the EPA form identified as ''Form U'' to submit written information in response to the requirements of this subpart. Copies of Form U are available from EPA at the address set forth in paragraph (c) of this section, from the EPA Internet Home Page at http://www.epa.gov/opptintr, or via fax on demand by using a faxphone to call (202) 401-0527 and selecting item 5119. You may also follow the automated menus.

(b) Guidance for completing the reporting form and preparing a magnetic media report is available in the EPA publication entitled ''Instructions for Reporting for Partial Updating of the TSCA Chemical Inventory Data Base.''

(c) EPA will mail a reporting package (consisting of a copy of Form U and a copy of the ''Instructions for Reporting for Partial Updating of the TSCA Chemical Inventory Data Base'') to those companies that reported in the IUR reporting period that occurred immediately prior to the current reporting period. If you did not receive a reporting package, but are required to report, you may obtain a copy of the reporting package from EPA by submitting a request for this information as follows:

(1) By phone. Call the EPA TSCA Hotline at 202-554-1404, or TDD 202-554-0551.

(2) By e-mail. Send an e-mail request for this information to the EPA TSCA Hotline at TSCA-Hotline@epa.gov.

(3) By mail. Send a written request for this information to the following address: TSCA Hotline, Mail Code 7408, ATTN: Inventory Update Rule, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

(d) Submit the completed reports. You must submit your completed reporting form(s) and/or magnetic media to EPA at the following address: Document Control Officer, Mail Code 7407, ATTN: Inventory Update Rule, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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