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Part II

Environmental Protection Agency

40 CFR Parts 9, 710, and 723
TSCA Inventory Update Rule Amendments

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 710, and 723

[OPPT–2002–0054; FRL–6767–4]

RIN 2070–AC61

TSCA Inventory Update Rule Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating amendments to the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Rule (IUR). The IUR currently requires manufacturers (including importers) of certain chemical substances on the TSCA Chemical Substances Inventory to report data on each chemical's current production volume, site–limited status, and plant site information every 4 years. Through these IUR amendments (IURA), EPA is requiring the reporting of additional data for certain chemicals to assist EPA and others in screening potential exposures and risks resulting from industrial chemical operations and commercial and consumer uses of TSCA chemical substances. EPA is also modifying the IUR reporting and recordkeeping requirements, removing one reporting exemption and creating others, and modifying its procedures for making Confidential Business Information claims. EPA is also making certain non–substantive technical corrections.

DATES: This final rule is effective February 6, 2003. For purposes of judicial review, this rule shall be promulgated at 1 p.m. eastern daylight/standard time on January 21, 2003.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7401M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–8170; e–mail address: TSCA–Hotline@epa.gov.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you manufacture (defined by statute to include import) chemical substances currently subject to reporting under the Inventory Update Rule (IUR) at 40 CFR part 710 or if you manufacture inorganic chemical substances. Any use of the term ''manufacture'' in this document will encompass ''import,'' unless otherwise stated. In the past, persons that only are processors of chemical substances have not been required to comply with the requirements of 40 CFR part 710. These 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:

Chemical manufacturers and importers currently subject to IUR reporting, and chemical manufacturers and importers of inorganic chemical substances (NAICS codes 325, 32411).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in § 710.48 in the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPPT–2002–0054. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102–Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket identification number.

II. Background

A. What Action is the Agency Taking?

1. *Substantive changes to the CFR*. EPA is promulgating amendments to the IUR (IURA) which were proposed on August 26, 1999 (64 FR 46772) (FRL–6097–4), taking into consideration comments received on the proposal. The amendments to the IUR that are contained in this final rule, as well as the inventory update provisions of 40 CFR part 710 that are unchanged by these amendments, appear in a new subpart C to 40 CFR part 710. The inventory update provisions that apply to the 2002 update remain unchanged although the Agency has added subpart headings in order to distinguish the provisions that apply to the 2002 update (i.e., the existing IUR) and the new and revised provisions promulgated in this rule. The following is a brief listing of the primary changes to the IUR, which do not affect the regulations in place for IUR reporting in 2002. These changes are described in more detail in this document, along with a summary of the comments received and the Agency's summary response to those comments.

First, EPA is amending the existing IUR regulations, 40 CFR 710.28 and 710.32, which appear in the new subpart C as §§ 710.48 and 710.52, to raise the production volume basic

reporting threshold from the current 10,000 pounds (lbs.) per year 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.

Second, EPA is amending 40 CFR 710.32, which appears in the new subpart C as § 710.52, to add exposure–related information to the existing reporting requirements for chemical substances covered by the IUR. Specifically, the Agency is requiring that manufacturers subject to the amended rule (''submitters'') report, in ranges: (1) The number of workers reasonably likely to be exposed to the chemical substance at the site of manufacture; (2) the physical form(s) in which the chemical substance is sent off–site; (3) the percentage of total reported production volume associated with each physical form; and (4) the maximum concentration of the chemical substance at the time it leaves the submitter's manufacturing site or, if the chemical substance is site–limited, the maximum concentration at the time it is reacted on–site to produce a different chemical substance.

Third, EPA is amending 40 CFR 710.32, which appears in the new subpart C as § 710.52, to require chemical manufacturers of chemical substances with production volumes of 300,000 lbs. or greater to report certain exposure–related information concerning the processing and use of each reportable chemical substance that is conducted at sites that receive the reportable chemical substance from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not) (including through a broker/distributor, from a customer of the submitter, etc.). Specifically, manufacturers of these larger–production volume chemical substances will be required to report, to the extent the information is readily obtainable:

- The type of industrial processing or use operation(s) at each site, including downstream sites.
- The five–digit NAICS codes that best describe the industrial activities during the processing or use operation.
- The industrial function of each chemical substance during the processing or use operation, for each NAICS code reported.
- The percentages of the submitter's production volume used in each industrial function category.
- The number of sites where the various processing or use operations occur.
- The number of workers reasonably likely to be exposed to the chemical substance in each processing or use operation.
- The categories of commercial and consumer uses of the reportable chemical substance.
- An indication of the presence of the reportable chemical substance in or on consumer products intended for use by children.
- The percentages of the submitter's production volume associated with each commercial and consumer product category.
- The maximum concentration of the reportable chemical substance in each commercial and consumer product category.

Fourth, EPA is revoking the current full exemption from IUR reporting at 40 CFR 710.26(a) for inorganic chemical substances, and is phasing in reporting for these substances, which appears in the new subpart C as § 710.46(b)(3). For the first submission period following promulgation of IURA (i.e., the 2006 submission period), EPA is requiring partial reporting for these substances (i.e., inorganic chemical substances will not be subject to the reporting of processing and use information). In subsequent submission periods, manufacturers of an inorganic substance will be subject to full reporting (i.e., including the processing and use information reporting requirements), to the extent that they manufacture at least 300,000 lbs. of the substance at a site during a given reporting year.

Fifth, EPA is amending 40 CFR 710.26, which appears in the new subpart C as § 710.46(b)(1), to create a partial reporting exemption for certain chemical substances termed ''petroleum process streams'' for purposes of reporting under the IURA (i.e., these chemical substances are not subject to the reporting of processing and use information).

Sixth, EPA is providing, in 40 CFR 710.46(b)(2), a partial exemption for specific chemical substances (i.e., these chemical substances are not subject to the reporting of processing and use information) where EPA has identified that there is a low current interest in the IURA processing and use information related to the chemical. EPA has identified a list of chemicals that are covered by this partial exemption, and provides a process for revising this list over time because interest in the IURA processing and use information for a particular chemical can change.

Seventh, EPA is amending 40 CFR 710.26, which appears in the new subpart C as § 710.46(a)(4), to provide a full exemption from IUR reporting for certain forms of natural gas.

Eighth, EPA is amending 40 CFR 710.32, which appears in the new subpart C as § 710.52, to require the reporting of more specific information to assist in the accurate identification of plant sites reporting under IUR.

Ninth, EPA is amending 40 CFR 710.28, 710.32, and 710.33, which appear in the new subpart C as §§ 710.48, 710.52, and 710.53, to change the period for which reporting is required from a corporate fiscal year to a calendar year basis.

Tenth, EPA is amending 40 CFR 710.32, which appears in the new subpart C as § 710.52, to allow submitters to claim their production volume range as CBI, in addition to the existing requirement that submitters report a specific production volume number and the CBI status of that specific number. Under the IURA, some submitters may choose to assert a confidentiality claim for specific production volume information while releasing the more general production volume range as public information.

Eleventh, EPA is amending 40 CFR 710.38, which appears in the new subpart C as § 710.58, to require substantiation of plant site confidentiality claims at the time such claims are made in IUR submissions to EPA (i.e., ''upfront substantiation''), in a manner similar to the upfront substantiation of chemical identity, which will continue to be required under 40 CFR 710.38, which appears in the new subpart C as § 710.58.

Finally, EPA is amending 40 CFR 710.37, which appears in the new subpart C as § 710.57, to extend the records retention period from 4 years to 5 years.

2. *Technical changes to the CFR.* The amendments that are contained in this final rule, as well as the parts of 40 CFR part 710 that are unchanged by these amendments, are codified in a new subpart C in 40 CFR part 710. Because promulgation of IURA will overlap a current IUR reporting cycle, EPA must maintain the existing IUR provisions in 40 CFR part 710 in effect throughout the 2002 submission period for the existing IUR. Submitters filing IUR reports in 2002 must follow the regulations currently contained in 40 CFR part 710, which will now appear under the new heading as subpart B. On January 1, 2003, the regulations in this final rule that are promulgated in subpart C of 40 CFR part 710 will become effective for use by submitters filing IURA reports in 2006 and beyond. (See § 710.1(b) of the regulatory text) Since the Agency has duplicated in subpart C those provisions from subpart B (i.e., the existing part 710) that are unchanged by these

amendments, once the current reporting cycle is complete, subpart B will no longer be applicable and the Agency will issue a technical amendment to remove it from the CFR. The creation of subparts in 40 CFR part 710 does not make any substantive changes other than those that have been presented in this final rule.

Although there are no substantive changes to the provisions from existing 40 CFR part 710 that have been incorporated into the new subpart C, the Agency has made minor technical corrections to those provisions, as well as technical changes to the existing provisions that now appear in subpart A. Specifically, the Agency is correcting several typographical errors that appear in the existing 40 CFR part 710, and is making other minor non–substantive edits to that text. These technical corrections include the following. (Note wherever a change is being made to a new regulatory text provision, a regulatory text citation to the corresponding existing 40 CFR part 710 provision is provided in parentheses, e.g., § 710.59 (§ 710.39). This parenthesized citation is provided in order to identify where the new regulatory text originated.)

In accordance with plain language principles, EPA has substituted ''will'' or ''must'' for ''shall.'' These three terms are considered to be equivalent, and delineate requirements to be followed or met. Corrections were made in the following sections: § 710.1(d) (§ 710.1(c)); § 710.3(a) (§ 710.2(a)); § 710.3(b) (§ 710.2(b)); § 710.3(c) (§ 710.2(c)); § 710.3(d) in the definition for ''Administrator'' (§ 710.2(e)); § 710.3(d) in the definition for ''site'' (§ 710.2(w)); § 710.3(d) in the note following the definition for ''small quantities for research and development'' (§ 710.2(y)); and § 710.4(b)(2) (§ 710.4(b)(2)).

EPA has corrected some punctuation and spelling errors: commas were added in § 710.1(a) (§ 710.1(a)), in § 710.3(d) in the definition for ''distribute in commerce'' (§ 710.2(j)) and in the definition for ''small quantities for research and development'' and in the note following the same definition (§ 710.2(y)); commas were removed in the definition for ''distribute in commerce'' (§ 710.2(j)) and in the note following the definition for ''distribute in commerce'' (§ 710.2(y)); in § 710.3(d) ''Process 'for commercial purposes''' was substituted for ''Process for 'commercial purposes''' in the definition for ''Process 'for commercial purposes''' (§ 710.2(u)); in § 710.3(d) ''juridical'' was substituted for ''juridicial'' in the definition for ''person'' (§ 710.2(s)) and ''appropriate'' was substituted for ''appropriated'' in the definition for ''technically qualified person'' (§ 710.2(aa)(2)); in § 710.4(d)(2) ''premanufacture'' was substituted for ''premanufacturing'' (§ 710.4(d)(2)); and in § 710.4(d)(5) ''photographic films'' was substituted for ''photographic, films'' (§ 710.4(d)(5)).

EPA has made certain additional non–substantive changes. In § 710.3(d), EPA substituted ''1,000 lbs. (454 kg)'' for ''1,000 pounds'' in the note following the definition for ''small quantities for research and development'' (§ 710.2(y)). EPA has substituted ''his/her'' for ''his'' in sections where the word ''his'' was used: in two instances in § 710.3(d) in the definition for ''Administrator'' (§ 710.2(e)); in § 710.3(d) in the definition for importer (§ 710.2(l)(2)); and in § 710.3(d) in the definition for ''technically qualified person'' (§ 710.2(aa)).

EPA has made certain additional non-substantive changes and updated information submission information in § 710.59 by substituting ''Availability of reporting form and instructions'' for ''How do I submit the required information for the 1998 reporting cycle?'' (§ 710.39); in § 710.59(a) by substituting ''http://www.epa.gov/oppt/iur'' for ''http://www.epa.gov/opptintr/iur98'' and by removing ''or Fax-on-Demand by using a faxphone to call (202) 401–0527 and selecting item 5119'' as Fax-on-Demand is no longer available (§ 710.39(a)); in § 710.59(b) by substituting ''Guidance for completing the reporting form and preparing an electronic (magnetic media) report will be made available prior to each submission period.'' for the existing paragraph after the heading (§ 710.39(b)); in § 710.59(c) by substituting ''will send'' for ''is mailing'' and ''reporting package (consisting of a copy of Form U and a copy of the reporting instructions) to those submitters that reported in the IUR submission period that occurred immediately prior to the current submission period.'' for ''reporting package to those companies that reported in 1994. '' (§ 710.39(c)); in § 710.59(c)(1), EPA substituted ''By telephone'' for ''By phone'' and removed ''or TDD 202–554–0551'' as the TDD number is no longer available (§ 710.39(c)(1)); in § 710.59(c)(2), EPA substituted ''TSCA-Hotline@epa.gov'' for ''TSCA-Hotline@epamail.epa.gov'' (§ 710.39(c)(2)); and in § 710.59(c) and (d) EPA substituted ''7408M'' for ''7408,'' ''OPPT Document Control Officer (DCO)'' for ''Document Control Officer,'' and ''Environmental Protection Agency'' for ''U.S. Environmental Protection Agency'' (§ 710.39(c)(3)); and by adding § 710.59(c)(4) to state that the reporting form and instructions will additionally be available via the Internet.

EPA has also made minor technical corrections to the existing provisions in § 710.39 that now appear in subpart B. EPA removed ''for the 1998 reporting cycle'' from the section heading to clarify that the section applies to the current reporting cycle. In § 710.39(a), EPA replaced the website address with the current address, www.epa.gov/oppt/iur/iur02/index.htm, and removed the Fax-on-Demand information, which is no longer available. In § 710.39(c)(1), EPA removed the TDD number, which is no longer available. The Agency corrected dates and addresses in § 710.39(c), (c)(3), and (d) by replacing ''1994'' with ''1998,'' ''Mail Code 7408'' with ''Mail Code 7408M,'' and inserting ''OPPT'' before ''Document Control Officer.''

EPA made minor revisions to clarify the meaning of certain provisions. In § 710.1(a) ''and recordkeeping'' was inserted after ''governing reporting,'' ''(TSCA)'' was inserted after ''(15 U.S.C. 2607(a)),'' and ''and keeping current'' was inserted after ''purpose of compiling'' (§ 710.1(a)); in § 710.1(d), the note following the paragraph was added to the end of the paragraph and ''Note: As a matter of traditional Agency policy,'' was removed (§ 710.1(b)); in § 710.52(c)(1) ''submitter'' was substituted for ''respondent'' and ''as described in § 710.59'' for ''from EPA at the address set forth in § 710.39'' (§ 710.32(c)(1)); in § 710.52(c)3(ii) ''indicating, for each reportable chemical substance at each site,'' was substituted for ''for each substance for which information is being submitted indicating'' and added '', or both manufactured in the United States and imported in the United States'' (§ 710.32(c)(5)); in § 710.52(c)(3)(iii) ''designation indicating, for each reportable chemical substance at each site,'' was substituted for ''statement for each substance for which information is being submitted indicating'' (§ 710.32(c)(6)); in §§ 710.45 and 710.55(a) ''submission period'' was substituted for ''reporting period'' (§§ 710.25 and 710.35(a)); in § 710.48 ''section'' was substituted for ''§ 710.28'' (§ 710.28); in § 710.48(b) ''paragraphs (a) and (b)'' were deleted (§ 710.28(c)); in § 710.52(c)(3)(iv) ''reportable'' was substituted for ''subject'' (§ 710.32(c)(7)); in § 710.58(b) ''Chemical identity.'' was added as a section header to more clearly identify the topic of the section, and ''The following steps must be taken to assert'' was substituted for ''To

assert,'' and ''reportable'' was substituted for ''specific'' (§ 710.38(c)(b) and (c)); in § 710.58(b)(1) ''submitter'' was substituted for ''person'' (§ 710.38(c)(1)); in § 710.58(b)(1)(i) ''subpart'' was substituted for ''part'' (§ 710.58(c)(1)(i)); in § 710.58(b)(1)(vi) substituted ''have been taken'' for ''have you taken'' and ''the'' for ''this'' (§ 710.38(c)(1)(vi)); in § 710.58(c)(2) ''listed in paragraph (c)(1) of this section'' was added for clarification purposes, ''submitter'' was substituted for ''person'' and ''clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as 'confidential business information,' 'proprietary,' or 'trade secret.'" was substituted for ''mark that information as 'trade secret,' 'confidential,' or other appropriate designation.'' (§ 710.38(c)(2)); and in § 710.58(d) ''is indicated on the reporting form'' was substituted for ''accompanies information at the time it is'' and ''confidentiality claim substantiation'' was substituted for ''substantiation'' (§ 710.38(d)).

EPA replaced ''manufactured or imported'' with ''manufactured (including imported)'' to provide consistency and clarification. EPA made this change in: § 710.52(c)(3)(iv) (§ 710.32(c)(7)); § 710.58(c)(1)(v) (§ 710.38(c)(1)(v)); § 710.58(c)(1)(vi) (§ 710.38(c)(1)(vi)); § 710.58(c)(1)(vii) (§ 710.38(c)(1)(vii)); § 710.58(c)(1)(viii) (§ 710.38(c)(1)(viii)); § 710.58(c)(1)(x) (§ 710.38(c)(1)(x)); and § 710.48 (§ 710.28).

EPA moved three definitions that currently appear in § 710.2 to § 710.23, to clarify that they apply to the existing IUR. In § 710.3(d), three changes were made in recognition that the definitions are no longer separated into sections, but are contained within paragraph (d): in the § 710.3(d) definition for ''Commerce,'' ''paragraph (1) of this definition'' was substituted for ''paragraph (1) of this section'' (§ 710.2(i)), and in the § 710.3(d) definition for ''Technically qualified individual,'' ''this paragraph'' was substituted for ''paragraph (aa)(3) of this section'' and ''paragraph (1) of this definition'' was substituted for ''paragraph (aa)(1) of this section'' (§ 710.2(aa)(3)).

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may promulgate a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making these minor regulatory changes in this final rule without prior notice and opportunity for comment because these minor corrections are non–substantive and do not affect the meaning or legal effect of the provisions affected, which remains the same as it was when the provision appeared in 40 CFR part 710. Thus, notice and public procedure are unnecessary for these minor changes to the existing or new provisions in 40 CFR part 710. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

B. What is the Agency's Authority for Taking this Action?

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. This inventory is known as the TSCA Chemical Substances Inventory (the TSCA Inventory). 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 commerce at that time. In 1986, EPA promulgated the initial IUR at 40 CFR part 710 (51 FR 21447, June 12, 1986), also under TSCA section 8(a), to facilitate the periodic updating of the TSCA Inventory and to support activities associated with the implementation of TSCA.

TSCA section 8(a)(1) authorizes the EPA Administrator to promulgate rules under which manufacturers and processors of chemical substances and mixtures (referred to hereinafter 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 associated with chemical substances to the extent that it is known to or reasonably ascertainable by the submitter. TSCA section 8(a) gives EPA broad discretion in determining the information for which reporting can be required. 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 in their places of employment; and the duration of such exposure.

TSCA section 8(a) generally excludes small manufacturers and processors of chemical substances from the 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 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 section 5 or 7. The standard for determining whether an entity qualifies as a ''small manufacturer'' for purposes of 40 CFR 710.29, and for 40 CFR part 710 generally, is defined in 40 CFR 704.3. Processors are not currently subject to the regulations at 40 CFR part 710.

This document promulgates the IURA as subpart C in 40 CFR part 710, which includes provisions copied from the existing IUR regulations in 40 CFR part 710 that are not substantively changed as a part of this rulemaking, and the new IURA provisions in this final rule. Failure to comply fully with any provision of this final rule will be a violation of TSCA section 15 and will subject the violator to the penalties of TSCA sections 16 and 17.

C. What is the Inventory Update Rule (IUR)?

The IUR requires U.S. manufacturers of organic chemicals to report to EPA every 4 years the identity of chemical substances manufactured annually during the reporting year in quantities of 10,000 lbs. or more at each plant site they own or control. The current IUR generally excludes several categories of substances from its reporting requirements, i.e., 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 each reportable chemical substance. Data were reported to EPA under the IUR in 1986, 1990, 1994, and 1998, and a collection is occurring in 2002.

The data reported under IUR are used to update the information maintained 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 II.E. for

further explanation of some of these activities).

D. Why is EPA amending the IUR?

EPA is amending the IUR for three primary reasons: (1) To tailor the chemical substance reporting requirements to more closely match the Agency's information needs; (2) to obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory; and (3) to improve the utility of the information reported. These amendments will enhance the information collected through the IUR, improve the scope of chemicals covered by the rule, and improve CBI claims, thereby accomplishing these three goals.

These goals are supported by the policy in section 2(b)(1) of TSCA, 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.'' The data currently available to EPA are generally inadequate for risk screening purposes. TSCA section 8(a)(2) authorizes EPA to require manufacturers and processors of chemical substances to report a wide variety of data, including exposure–related information which will be reported for certain chemical substances under IURA. These amendments remove certain reporting requirements and add others to focus reporting under the IUR on that information which is most needed by EPA and other Federal agencies for screening, assessing, and managing risk. Additionally, the availability of these data will enhance public awareness of basic information about chemical substances.

Any evaluation of potential ''risk'' is generally based on a combination of hazard information and exposure information. EPA relies on risk screening to indicate which chemical substances pose a potential risk to human health or the environment, and thus warrant a more detailed, resource intensive analysis. The EPA Science Advisory Board's report ''Reducing Risk: Setting Priorities and Strategies for Environmental Protection'' (Ref. 1) and the National Academy of Public Administration's report ''Setting Priorities, Getting Results, A New Direction for EPA'' (Ref. 2) recognize that EPA's ability to use risk screening to set priorities and allocate its limited resources has been significantly impeded by a lack of exposure data. The manufacturing, processing, and use of chemicals on the TSCA Inventory result in a wide array of exposure scenarios. The exposure-related data included in IURA will greatly improve EPA's ability to conduct risk screening to identify chemical substances that could pose an unreasonable risk to human health or to the environment, or that otherwise warrant further investigation.

E. What are EPA's TSCA-Related Chemical Screening and Assessment Activities?

TSCA authorizes EPA to gather chemical hazard and exposure data, as well as related information such as production volume, to determine whether a chemical may pose an unreasonable risk of injury to human health or the environment. The Agency is able to institute risk management actions when necessary to mitigate or avoid unreasonable risk. Important elements in a successful chemical risk management program include identifying the chemical substances, manufacturing sites, and exposure scenarios of greatest potential concern, and using that information to set priorities for more detailed risk assessment, further research, advisory notices, or other appropriate actions. To help fulfill its TSCA responsibilities, EPA has established the IUR and other regulations to collect information on commercial chemicals.

The TSCA Inventory currently includes more than 76,000 chemical substances. Approximately 8,900 of these chemical substances are non-polymer, organic chemical substances manufactured at at least one site in quantities of 10,000 lbs. or more per year, as reported under the 1998 IUR data collection. EPA estimates that IURA will continue to collect information on approximately 8,900 chemical substances. However, the set of substances that will be reported under IURA will be somewhat different than the set of substances that was reported under the previous IUR collections primarily because of two changes: Raising the basic reporting threshold (see Unit II.F.2.) and adding reporting on the manufacture of inorganic chemical substances (see Unit II.F.1.a.). Data collected under IURA will enable EPA to more effectively conduct initial risk screening on a subset of the chemical substances within its purview, as described in the remaining part of this section and in Unit III.A.1.

EPA conducted tiered risk evaluations of chemical substances even prior to the enactment of TSCA in 1976. A tiered approach allows EPA to sort through many chemicals, focus on those chemical substances of greatest concern, and take appropriate actions. The Agency is thus able to optimize resources while limiting overall regulatory burdens. The essential steps of the tiered risk evaluation generally include: An initial evaluation (sometimes preceded by a prescreen of candidate chemicals); basic risk management decisions resulting from the initial screening; more detailed risk assessment when appropriate; and resulting risk management actions, such as regulatory or voluntary efforts to reduce risk. Each of these steps is only as effective as the available data inputs--if little data exist to inform the process, each step suffers as a result.

Exposure-related information collected through the IURA will inform the initial risk screening step. Initial risk screening is conducted using readily accessible information from the scientific literature, as well as other data readily available to the Agency, such as those provided by manufacturers and processors. This information set often is incomplete or of insufficient quality to allow the Agency to reach definitive conclusions about the set of chemicals under review, but may be sufficient to decide which chemicals appear to warrant further evaluation, or conversely, appear to be low priority and therefore do not currently warrant further review. These initial reviews are often more qualitative than quantitative. Also, continual updates to these data, such as the recurring reporting of exposure-related data under IURA, will ensure that the most serious concerns will be addressed even as chemical quantities and exposure potentials change between submission periods.

The effectiveness of risk screening, risk assessment, and risk management is dependent upon the quality as well as the availability of both hazard and exposure information. While past approaches to priority setting have emphasized relative chemical hazards and used production volume as a simple surrogate for exposure, EPA must increase its emphasis on the exposure component of risk screening and assessment. EPA no longer believes that reporting under the current IUR is adequate for these purposes. The IURA will provide EPA with data that will more accurately and realistically gauge potential exposures. The exposure-related information reported under IURA will be used in combination with hazard information developed under TSCA section 4 test rules and enforceable consent agreements/orders, through voluntary efforts such as the High Production Volume (HPV) Challenge Program (see www.epa.gov/opptintr/chemrtk/volchall.htm), and

other sources. These more current and complete data from the IURA will allow the Agency and others to screen and prioritize chemicals based on potential risk more effectively than it is currently able to do.

Although the inherent hazard associated with a chemical substance will generally remain the same over time, exposure of workers and affected populations can change significantly. If the amount of a chemical substance produced increases significantly, releases to the environment and human exposures would also be expected to increase. Conversely, if the amount produced remains constant, environmental releases and human exposures may decline as engineering controls are added and pollution prevention practices are implemented. Although the hazard associated with a chemical generally remains constant, the risk associated with the manufacturing, processing, and use of a chemical substance will change as exposure increases or changes. The Agency needs to be able to identify changes in exposures as well as specific exposure scenarios, making it important to collect exposure data on a regular basis. Chemicals that present low hazard may still pose a risk if they are produced in large amounts and have high exposure potential, are released into the environment at high volumes and/or concentrations, or involve exposures to particularly sensitive subpopulations.

A voluntary effort called the Use and Exposure Information Project (UEIP) demonstrated that useful screening level exposure information is available to and can be reported by industry. The UEIP was a cooperative effort begun in the fall of 1992 between government and industry in recognition of the difficulties encountered in obtaining accurate and up-to-date exposure information on HPV TSCA chemicals. Participants included EPA, the Chemical Manufacturers Association (CMA) (now the American Chemistry Council, or ACC), the Chemical Specialty Manufacturers Association (CSMA), the Synthetic Organic Chemical Manufacturers Association (SOCMA), and the American Petroleum Institute (API) (Ref. 3). Data collected by EPA under the UEIP were similar to those now being required under IURA, and included the following: Production volume, site location, percentage of production volume for a given use, environmental releases, number of workers, worker activities, monitoring data, and industrial and consumer uses. EPA's experience with UEIP has shown that the types of data requested by the UEIP are available from industry and can be used to prepare screening level exposure assessments.

The UEIP, however, provided one-time reporting of information by a subset of the manufacturers of a small number of selected HPV chemicals. Given these efforts, the limitations of the data available from past and current information collections that are described in detail in the proposal for these amendments (64 FR 46772, August 26, 1999), and the amount of time it would otherwise take to acquire screening level exposure data for the chemical substances on the TSCA Inventory, it is appropriate to develop a more systematic and broadly applied approach to the prioritization process. The Agency is doing this by requiring that certain basic exposure-related information be reported under this amended rule instead of collecting the information through a one-time voluntary program.

F. What Are the Requirements of IURA?

The regulatory text of this document describes the specific IURA reporting requirements. EPA is also developing a guidance document with specific reporting instructions, and intends to conduct workshops to help potential IURA submitters become familiar with the revised reporting form (Form U) and amended reporting requirements. A draft version of the revised Form U is available in the docket, and EPA intends to develop an electronic version of the revised Form U. EPA will seek additional feedback on the revised form's structure, format, and layout before finalizing it for use in 2006. Submitters should note that the information in § 710.52(c)(1) and (c)(2) of the regulatory text (Part I of the revised Form U) need only be reported once per reporting cycle for each submitter site manufacturing 25,000 lbs. or more of a reportable chemical, while the information in § 710.52(c)(3) and (c)(4) of the regulatory text (Parts II and III of the revised Form U, respectively) will be reported for each reportable chemical at a reporting site, depending upon the chemical's production volume.

1. *What are the changes to the chemical substances covered by IUR*?—a. *Inorganic chemical substances*. EPA is requiring partial reporting for inorganic chemical substances for reporting year 2005 information submitted to EPA during the 2006 submission period, and full reporting for inorganic chemical substances in subsequent submission periods (see § 710.46(b)(3) of the regulatory text). Partial reporting means that the submitter must report the information described in § 710.52(c)(1), (c)(2), and (c)(3), as well as §710.58 of the regulatory text, as applicable (i.e., Parts I and II of revised Form U.). Full reporting means that the submitter must additionally report the processing and use information as described in § 710.52(c)(4) of the regulatory text (i.e., all parts of revised Form U).

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 phasing-in of inorganic chemical reporting provides manufacturers of these chemicals with the opportunity to familiarize themselves with IUR reporting while providing EPA and others with needed basic manufacturing information on inorganic chemicals. Future full reporting of exposure-related information will provide EPA and others with needed additional information for those inorganic chemicals with production volumes of 300,000 lbs. or more at a site. See Unit III.A.1. for a discussion of the importance of this exposure-related information to EPA and others for both organic and inorganic chemicals. Unit III.C.1.a. contains a discussion specific to inorganic chemicals. The basic impetus for collecting information on organic chemicals also holds for inorganic chemicals.

b. *Petroleum process streams*. EPA is exempting certain chemical substances, termed ''petroleum process streams'' for purposes of IURA, from reporting the processing and use data contained in the regulatory text at § 710.52(c)(4). For purposes of this rule, the petroleum process streams included in the exemption are the multi-component complex chemical substances listed by Chemical Abstracts Service (CAS) Registry Number in the regulatory text at § 710.46(b)(1). This list of chemical substances was 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. 4). Chemical substances listed in the API document consisting of a single component chemical, except for water, will not be considered petroleum process streams for IURA reporting purposes. Water (CAS number 7732–18–5) is partially exempt from IURA reporting under the petroleum process stream exemption.

The basis for this exemption is not because these streams are of known low toxicity. EPA believes that the chemicals termed ''petroleum process streams'' for purposes of IURA are often toxicologically active. However, these

chemicals are frequently processed at the site where they are produced in vessels which are designed to minimize losses and, coincidentally, the potential for releases and exposure. In many cases, the flammable nature of these products requires that they also be transported, processed, and stored in well controlled vessels. For these reasons, EPA believes worker exposure to the chemicals termed ''petroleum process streams'' for purposes of IURA is diminished and thus full IURA exposure-related reporting is not warranted at this time. Partial IURA reporting includes site location and production volume information which have important uses by EPA and others apart from gauging exposures and risk screening. EPA may take action to revoke this exemption if circumstances warrant.

In the final rule, EPA is making selected changes to the partial exemption list of petroleum process stream chemicals published in the proposed rule. Certain chemicals are being added to the list because they were inadvertently left off the proposed list covered by the exemption. These multi–component chemicals, all of which are listed in the 1983 API publication (Ref. 4), include the following chemical substances (CAS numbers): 8052–41–3, 64742–21–8, 64742–26–3, 64742–94–5, 68476–32–4, 68515–29–7, 68783–12–0, 68918–98–9, 68919– 15–3, 68953–80–0, and 70693–06–0.

In the final rule, EPA is also removing a number of chemicals from the petroleum process stream partial exemption list published in the proposed rule. These chemicals fall into three groups:

(1) Certain chemicals that are already part of the broader natural gas or polymer exemptions. Those already exempted under the natural gas exemption are: 8006–14–2, 8006–61–9, 64741–48–6, 68410–63–9, 68425–31–0, and 68919–39–1. Additionally, an incorrect CAS number 68425–31–1 was corrected to read 68425–31–0, which, again, has been removed from the partial exemption because it is already fully exempt from IUR reporting under the natural gas exemption. Chemicals removed because they are already fully exempt under the polymer exemption are: 64741–71–5, 64741–72–6, 67891–77–4, 67891–78–5, 68131–77–1, 68131–79–3, 68131–80–6, 68131–81–7, 68131–83–9, 68131–99–7, 68132–00–3, 68410–01–5, 68410–10–6, 68410–13–9, 68410–14–0, 68410–16–2, 68410–59–3, 68425–27–4, 68425–28–5, 68476–87–9, 68477–37–2, 68477–43–0, 68477–45–2, 68477–46–3, 68477–50–9, 68477–51–0, 68477–52–1, 68478–07–9, 68478–09–1, 68527–24–2, 68527–25–3, 68783–10–8, 68783–11–9, and 68955–30–6.

(2) Single component chemicals, except for water, should not have been included in the petroleum process streams partial exemption. As stated in the proposed rule, the exemption was intended to include only certain multi–component chemicals derived from the 1983 API publication (Ref. 4). As a result, the following single–component chemicals have been removed from the petroleum process streams partial exemption list as proposed: 8007–45–2 and 10024–97–2.

(3) Certain chemicals that are not included on the TSCA Inventory and therefore are not currently reportable under IUR have also been removed from the exemption list: 64741–93–1, 64741–94–2, 64742–00– 3, 64742–02–5, 64742–17–2, 64742–66–1, 64742–74–1, 64742–84–3, and 64754–96–7.

In this final rule, EPA is also making some additional corrections to the petroleum process streams partial exemption list published in the proposed rule.

(1) Incorrect CAS numbers for certain chemicals were provided in the proposed rule. These CAS numbers were incorrect because of typographical errors in the proposed rule. The correct CAS numbers (incorrect CAS numbers are in parentheses) are as follows: 8006–20–0 (8006–20–2), 64742–18–3 (64742–18–2), 64742–20–7 (64742–20–3), 68187–60–0 (68187–60–9), 68459–78–9 (68459–79–8), 68513–14–4 (68514–14–4), 68513–19–9 (68512–19–9), and 68514–38–5 (68514–38–4). Two additional incorrect CAS numbers were provided in the proposed rule, i.e., 64742–36–2 and 68741–41–9. The corrected CAS numbers for these chemicals, i.e., 64742–36–5 and 64741–41–9 respectively, were also provided in the proposed rule.

(2) Several duplicate CAS numbers that were included in the proposed rule have been removed.

(3) CAS numbers for certain chemicals have been superceded by new CAS numbers. The new CAS numbers are as follows (superceded CAS numbers are in parenthesis): 68187–58–6 (68334–31–6), 68410–13–9 (68477–56–5), 68308–08–7 (68478–21–7), 68334–30–5 (68512–90–3), 68918–99–0 (68513–26–8), 64742–83–2 (6851–30–7), 68988–79–4 (68515–31–1), 64742–93–4 (68516–21–2), 68606–10–0 (68606–35–9), and 64742–93–4 (68650–78–2).

c. *Natural gas*. EPA is exempting certain forms of natural gas from IUR reporting. These substances are listed in the regulatory text at § 710.46(a)(4). EPA believes that, to date, adequate IUR information has been collected on these chemical substances to fulfill EPA's and other IUR information users' current needs. EPA will take action to revoke this exemption if circumstances warrant in the future.

d. *Specific chemical substances*. EPA is exempting certain specific chemical substances for which EPA has determined that there is a low current interest in the IURA processing and use information from reporting the processing and use information contained in the regulatory text at § 710.52(c)(4). These chemicals are still subject to the other requirements of IURA. The chemical substances included in this partial exemption are listed by CAS Number in the regulatory text at § 710.46(b)(2)(iv). EPA is also establishing a process for revising the list of exempted chemical substances over time.

EPA is establishing this partial exemption in an effort to improve IURA's efficiency and effectiveness. This partial exemption also provides additional benefits in reducing the potential reporting burden of IURA for certain manufacturers of these chemicals, and provides an efficient process for amending the partial exemption list as the need for processing and use information under IURA changes over time. The inclusion of a chemical substance under this partial exemption is not based on the potential risks of a chemical. This partial exemption is solely intended to provide a tool to assist the Agency in better managing the collection of processing and use information under IURA.

In the proposed rule, EPA specifically sought comment on a partial reporting exemption for ''low priority'' chemicals, and requested comment on the criteria the Agency might use to establish such an exemption, as well as the specific chemicals that might qualify for such an exemption. (See Unit IX.3. of the preamble to the proposal, at 64 FR 46794). EPA also offered several approaches for identifying the chemicals that could be considered for such an exemption. A number of commenters supported the creation of a partial exemption, and several provided suggestions for additional chemical substances or classes of substances that they wanted EPA to consider including in this or an expanded partial exemption.

In response to the comments received, EPA has established a partial exemption that applies when EPA has determined that there is a low current interest in the chemical's IURA processing and use information. Because IURA reporting is

chemical-specific, this exemption applies to the specific chemical substances that are listed within the exemption, which are discussed in more detail below. The need for EPA's collection of IURA processing and use information related to a particular chemical substance can change over time; therefore, EPA has also established a process that will allow EPA to revise the list by adding or removing a chemical to reflect the change in interest. The process allows anyone to submit a written request for EPA to consider revising the list of chemical substances covered under this partial exemption. EPA may also revise the list on its own initiative. When a list revision is necessary, EPA's preferred approach will be to issue a direct final rule, which affords an opportunity for public comment, while providing an efficient mechanism for revising the list.

In determining whether there is low current interest in IURA processing and use information related to a specific chemical substance, EPA will look to the specific circumstances surrounding the chemical in question, and may use one or more of the considerations identified below, and/or considerations not identified below, to make an informed decision. EPA will consider the totality of information available for the chemical substance, including but not limited to the following:

(A) Whether the chemical qualifies or has qualified in past IUR collections for the reporting of the information described in § 710.52(c)(4) (i.e., at least one site manufactures 300,000 pounds or more of the chemical).

(B) The chemical substance's chemical and physical properties or potential for persistence, bioaccumulation, health effects, or environmental effects (considered independently or together).

(C) The information needs of EPA, other federal agencies, tribes, states, and local governments, as well as members of the public.

(D) The availability of other complementary risk screening information.

(E) The availability of comparable processing and use information.

(F) Whether the potential risks of the chemical substance are adequately managed by EPA or another agency or authority.

It is important to note that the inclusion of these chemical substances under this partial exemption is not based on the potential risks of the chemicals, but is based on the Agency's current assessment of the need for collecting IURA processing and use information. Additionally, some of these chemicals have issues that may renew interest in them in the future, at which time EPA will reconsider the applicability of this partial exemption for those chemicals.

To create an initial list of specific chemical substances covered by this partial exemption, EPA started with:

(1) The list of chemical substances identified as part of the HPV Challenge Program for which, based upon a preliminary review of known hazard information, it was determined that the SIDS data set would not further our understanding of the chemical's properties.

(2) The list of the chemical substances that the European Union (EU) exempted from its reporting requirements for existing chemical substances.

(3) Certain other chemicals identified during the Executive Order 12866 interagency review, for which EPA was able to quickly determine, based on a review of their chemical structures, properties, existing hazard information, and available exposure information, that IURA processing and use information is of low current interest.

This list was then adjusted based upon the totality of information available to EPA during the Executive Order 12866 interagency review period to ensure that the chemicals included in this partial exemption were those for which EPA determined that IURA processing and use information is of low current interest. EPA chose these chemicals because almost all previously underwent a review to have gotten on these lists and, considering the time available during the Executive Order 12866 interagency review, the Agency was able to utilize these lists, along with the Agency's current knowledge and understanding of the individual chemical's structure, properties, indications of hazards and potential exposures, to inform its determination that there is a low current interest in IURA processing and use information for these specific chemicals (Ref. 5). As indicated previously, EPA has established a process for revising the list of chemicals covered by this partial exemption, and intends to reconsider the chemicals identified in comments for applicability under this partial exemption.

The list currently consists of the following chemicals:

(1) Chemicals for which it had been determined that the SIDS data set would not further our understanding of the chemical's properties, and not otherwise sponsored under the HPV Challenge Program: 50–70–4, 50–99–7, 56–87–1, 57–50–1, 59–02–9, 69–65–8, 124–38–9, 142–47–2, 1592–23–0, 7440–44–0, 8001–21–6, 8001–22–7, 8001–26–1, 8001–29–4, 8001–30–7, 8001–31–8, 8001–78–3, 8001–79–4, 8002–03–7, 8002–75–3, 8006–54–0, 8016–28–2, 8016–70–4, 8021–99–6, 8029–43–4, 9050–36–6, 16291–96–6, 61789–97–7, 61789–99–9, 64147–40–6, 64755–01–7, 65996–63–6, 65996–64–7, 68188–81–8, 68334– 00–9, 68334–28–1, 68409–76–7, 68425–17–2, 68439–86–1, 68476–78–8, 68514–27–2, 68514–74–9, 68525–87–1, 68918–42–3, 68952–94–3, 68989–98–0, and 73138–67–7.

(2) Chemicals from the EU Existing Chemicals Program exempted list that are not currently otherwise a part of another Agency program such as the HPV Challenge Program: 50–81–7, 58–95–7, 59–51–8, 87–79–6, 123–94–4, 137–08–6, 150–30–1, 1317–65–3, 7440–37–1, 7727–37–9, 7782–42–5, 8001–23–8, 8002–13–9, 8002–43–5, 9004–53–9, 9005–25–8, 11103–57–4, 26836–47–5, 61789–44–4, 67701–01–3, 68002–85–7, 68131–37–3, 68308–54–3, 68424–45–3, and 68424–61–3.

(3) Chemicals otherwise identified by EPA based on consideration of the chemical's structure, properties, existing hazard information, and available information concerning the extent of exposure, and which are not currently a part of another Agency program such as the HPV Challenge Program: 1333–74–0, 7782–44–7, 68442–69–3, 68648–86–2, 68648–87–3, 129813–58–7, 129813–59–8 and 129813–60–1.

You may use the process established in § 710.46(b)(2) to submit a request for the Agency to consider other chemical substances for inclusion under this partial exemption. Please ensure that you provide sufficient information in your requests to enable EPA to make the necessary determination after considering the totality of available information. If you have any questions about this process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT** for additional assistance.

Under the list revision process, EPA will provide a written response to requests within 120 days of receipt, and will maintain copies of these responses in a public docket that will be established for each reporting cycle. In order to assist the Agency in completing any necessary revision to the list before the reporting period, any request for revising the list of chemicals under this partial exemption must be received by the Agency no later than January 1 of the year before the reporting period in question (i.e.,12 months prior to the reporting period). For example, any request for inclusion under this partial exemption must be submitted to EPA no later than January 1, 2004, i.e., 12 months prior to the next reporting

period, which begins on January 1, 2005, for the 2006 submission period. If the request is submitted after this date, during an actual reporting period, or during the submission period, EPA is less likely to have sufficient time to complete its evaluation and make a determination, or issue the necessary rulemaking such that the decision can be effective for that submission period. Submitters should check the **Federal Register** for list revisions or may check the electronic CFR to identify what chemicals are on the partial exemption list prior to each reporting period.

EPA intends to develop a standard operating procedure (SOP) for this specific chemical partial exemption process, which will outline the process steps, as well as provide guidance to EPA personnel on making such determinations. EPA would like to seek your input during the development of this SOP, as well as feedback on the implementation of this process, as part of IURA implementation workshops that are planned.

One of the purposes of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, can be achieved through federal agencies working together with the affected industries to design surveys that will achieve multiple purposes with a single survey instrument. EPA plans to identify and initiate dialogue that has the potential for generating additional paperwork burden reductions for the IURA. For example, the current USGS annual survey covers approximately 80 minerals, and accounts for at least 75% of the industrial production and 75% of the facilities included in the USGS survey. If you have identified other federal agency information collections that could satisfy the IURA purposes, or for which IURA information might serve as a viable substitute and have the potential to generate federal paperwork burden reductions, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless the agency has obtained approval for the activity from the Office of Management and Budget (OMB), an approval which must be renewed every 3 years. As part of the PRA approval renewal process, which includes an opportunity for public review and comment prior to OMB review, EPA intends to continue to evaluate this exemption process and will provide information about the chemicals evaluated, requests received, decisions made and related process elements and experiences as part of the information collection request (ICR) submitted to OMB. The Agency will also analyze the information collected from one reporting year to the next, in order to ensure that IURA information collection activities continue to meet the requirements of the PRA, including the demonstration of practical utility.

e. *Polymers.* As a result of recent inquiries regarding the exemption of polymers from IUR reporting, EPA is clarifying this existing exemption. The exemption does not apply to a polymeric substance that has been hydrolyzed, depolymerized, or otherwise chemically modified, except in cases where the intended product of this reaction is totally polymeric in structure. The Agency's intent under the exemption at 40 CFR 710.26(b) has always been (and continues to be under 40 CFR 710.46(a)(1)) that the products of such reactions carried out on polymeric materials are excluded from IUR reporting only if they are intended to have a totally polymeric composition. There is no change in the IUR status of polymeric materials that have not undergone such reactions and are flagged in the TSCA Inventory.

f. *Microorganisms.* EPA is clarifying this existing definition to ensure that the definition used for IURA purposes is consistent with the microorganisms rule at 40 CFR part 725 and to clarify the status of chemicals produced from living microorganisms.

2. *How have the reporting thresholds changed*? EPA is raising the basic IUR reporting threshold from a production volume of 10,000 lbs. per year per site to 25,000 lbs. per year per site. Every person manufacturing a non–excluded chemical substance at or above the threshold will be required to report the information in Parts I and II of the revised Form U (see the regulatory text at §§ 710.52(c)(1), (c)(2), and (c)(3) and 710.58). The increased IUR reporting threshold makes the IUR and Toxics Release Inventory (TRI) reporting thresholds equivalent for manufacturers. These thresholds also approximate the current TSCA section 5 premanufacture notification (PMN) low volume exemption threshold of 10,000 kg (approximately 22,000 lbs.). EPA is raising the basic IUR reporting threshold in order to reduce the number of reports filed, thus reducing the overall industry burden associated with this regulation. The new reporting threshold does not represent a finding of low exposure or low risk.

EPA is also instituting a second, higher production volume threshold of 300,000 lbs. per year per site. Persons who manufacture a reportable chemical substance at or above this level will be required to report the information in Part III of the revised Form U (see § 710.52(c)(4) of the regulatory text) in addition to the information in Parts I and II of the revised Form U. The information reported on Part III of the form relates to the processing and use of chemical substances. EPA is instituting this separate threshold to limit processing and use data reporting to a subset of a few thousand IUR reportable chemicals out of the approximately 76,000 chemicals listed on the TSCA Inventory.

Information concerning lower production volume chemical substances is valuable, especially for identifying trends and additional substitute chemicals. However, wherever possible, the Agency has attempted to limit the reporting burden. In the future, EPA may find it necessary to collect information on chemicals at reporting thresholds below the thresholds introduced in this action. Although both the 25,000 lbs. and 300,000 lbs. thresholds are significantly higher than the current IUR 10,000 lbs. threshold, the enhanced information that will be gathered under the amended rule will enable the Agency and others to more efficiently identify those chemical substances warranting further, more in–depth review, as well as chemicals of lesser concern (see Ref. 6).

3. *Have the reporting year, the submission period, or the reporting frequency changed*? In order to provide clarification, two new definitions are being added at 40 CFR 710.43: ''reporting year'' means the calendar year in which information to be reported to EPA during a submission period is generated and ''submission period'' means the period in which the information generated during the reporting year is submitted to EPA. ''Submission period'' replaces the term ''reporting period,'' as used under the current IUR regulations at 40 CFR part 710.

As proposed, EPA is changing the IUR reporting year to a calendar year basis from a corporate fiscal year basis. This change standardizes reporting time frames across IUR submitters and across various other reporting programs, such as the TRI program.

Under the current IUR regulations at 40 CFR 710.33(b), submitters are required to report on a recurring basis during a 120–day period from August to December (the ''submission period'' under IURA) every 4 years. In a separate action following this final rule, EPA intends to change the submission period to occur earlier in the year, for example from January 1 through May 1. This potential change is related in part to the

reporting year change in this final rule from fiscal year to calendar year. The August to December submission period was originally used because many companies' fiscal years end in July, and starting the IUR submission period in late August allowed these companies to report their most current information. Companies will now report on a calendar year basis, making an earlier submission period more appropriate. Changing the submission period to occur earlier in the year would allow sites to submit their information closer to the period during which it was generated, as well as allow the Agency to obtain the information early in the year, thereby increasing the timeliness of the availability of the data.

In this final rule, EPA has not changed the reporting frequency (every 4 years), although EPA did consider alternative reporting frequencies (see the ''Revised Economic Analysis for the Amended Inventory Update Rule,'' Ref. 7). This means that the first reporting year for IURA information will be 4 years after the reporting year under the existing IUR, i.e., existing IUR reporting year is 2001, so the first reporting year under IURA will be 2005. The submission period will continue to occur in the year following the reporting year, i.e., existing IUR submission period is in 2002, so the first submission period for IURA will be in 2006.

The final rule indicates that subsequent reporting years and submission periods will occur every 4 years. In a separate action following this final rule, however, EPA intends to change the reporting frequency after the first reporting year under IURA (i.e., 2005, with submission to EPA in 2006) from every 4 years to every 5 years. This would mean that, instead of occurring in 2009, the second reporting year under IURA would be 2010 (i.e., 5 years after 2005), and would then occur every 5 years thereafter. The submission period would continue to occur in the year following the reporting year, so it too would occur every 5 years (i.e., 2011, 2016, etc.). In making this change, EPA also intends to change the recordkeeping period from 5 years to 6 years. EPA agreed to make these changes within the next 12 months as part of the interagency review under Executive Order 12866 in an effort to further reduce the potential reporting burden related to IURA. EPA estimates that a 5–year frequency would save regulated entities about $50 million over 20 years at a 3% discount rate (about a 16% reduction), and $37 million over 20 years at a 7% discount rate, and would still meet EPA's most critical data needs (Ref. 8).

For the first reporting year under IURA, EPA intends to issue guidance and conduct workshops to help the regulated community become familiarized with the revised regulations. A draft copy of the guidance for the 2006 submission period can be found in the docket for this rulemaking (Ref. 9).

4. *How have the recordkeeping requirements changed*? EPA is requiring that persons subject to reporting under IURA retain records that document any information reported to EPA under IURA for a period of 5 years beginning with the effective date of that submission period (see § 710.57 of the regulatory text). The effective date of the submission period is the last day of the submission period (currently December 23, although EPA intends to change this date, see Unit II.F.3.) in a year in which data must be submitted to EPA under IURA. Previously, submitters were required to retain records for 4 years (see 40 CFR 710.37). Under IURA, if a person submits a report in the year 2006, that person will retain the records on which the report is based until December 23, 2011. This change ensures that the submitter will have the previous submission available when determining future reporting. The change will also aid in EPA's enforcement of IUR by requiring that submitters maintain records that span successive submission periods. As described in Unit II.F.3., in a separate action EPA intends to change the reporting frequency from every 4 years to every 5 years. In that action, EPA also intends to change the recordkeeping period from 5 years to 6 years in order to continue to span successive submission periods. A 6–year recordkeeping period would require, under IURA, that if a person submits a report in the year 2006, that person will retain the records on which the report is based until December 23, 2012.

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

5. *How have the data elements reported by all submitters changed*? The new and revised data elements to be reported under the amended rule are discussed in this section. Data elements that are currently reported under IUR but that are not revised by these amendments are not generally discussed in this document.

a. *Technical contact identification (§ 710.52(c)(2)(i) of the regulatory text).* In addition to the name of a person who will serve as technical contact for the submitter company, the parent company name, the contact person's full mailing address, and the contact person's telephone number, submitters must report the contact person's e–mail address and the parent company Dun and Bradstreet Number. The technical contact person must be able to answer questions about the information on the revised Form U that is submitted by the company to EPA.

b. *Plant site identification (§ 710.52(c)(2)(ii) of the regulatory text).* Submitters must report the plant site county or parish in addition to the information currently required for each plant site that is subject to reporting.

EPA had additionally proposed to require submitters to report a plant site identification number in order to clearly identify the reporting site in a way that would allow the cross–linking of IUR information with information reported about the same plant site contained in other data bases. EPA specifically proposed requiring the reporting of a newly assigned Facility Registration Identifier (FRI), or, if the Facility Registry System were not yet in place in time for the publication of this final rule, the submitter would report the site's RCRA number, if one has been assigned to the site. In this final rule, EPA has decided not to require the submission of a site identification number in addition to the Dun and Bradstreet number that submitters must continue to report. The Agency may instead make number assignments either directly on the reporting form after it is submitted to EPA, or prior to mailing out the form at the beginning of a submission period. Submitters will not be responsible for obtaining or reporting this number.

c. *Chemical identification (§ 710.52(c)(3)(i) of the regulatory text).* Submitters must indicate which type of chemical identifying number they are reporting, in addition to the number itself. EPA no longer allows the use of certain of the previously used substitute identifying numbers (such as EPA–assigned numbers for Test Market Exemption Applications, original TSCA Inventory form numbers, and numbers associated with Notices of *Bona Fide* Intent to Manufacture) because they are difficult to cross–reference to CAS Registry numbers. Submitters must report a CAS Registry number, or, if a CAS Registry Number is not known to the submitter, the submitter must report

either an EPA–designated accession number for confidential substances or a PMN case number.

d. *Confidentiality of production volume range (§ 710.52(c)(3)(v) of the regulatory text).* Submitters must continue to report the specific production volume of the reportable chemical and may claim CBI protection for that production volume. Additionally, submitters may claim as CBI a pre–determined production volume range corresponding to the reported production volume number. This claim, if needed, would be separate from a CBI claim for the specific production volume.

Submitters of specific CBI production volume data may allow the release of more general range information. EPA expects that roughly 50% of submitters of specific CBI production volume data will allow the public release of volume ranges. This expectation of reduced CBI claims 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'' (Ref. 10)) as well as comments received from industry concerning potential TSCA CBI reforms (Ref. 11). The range option will allow the public greater access to data on chemical production volumes, and the Agency will be better equipped to publicly release more aggregate production volume data relevant to its risk screening and other decisions.

The production volume ranges in the final rule are 25,000 to 300,000 lbs.; 300,000 to 1,000,000 lbs.; 1,000,000 to 10,000,000 lbs.; 10,000,000 to 50,000,000 lbs.; 50,000,000 to 100,000,000 lbs.; 100,000,000 to 500,000,000 lbs.; 500,000,000 to 1,000,000,000 lbs.; and greater than 1,000,000,000 lbs. per year. These ranges are similar to those first used in the development of the original TSCA Inventory, except for one change, i.e., the lowest range starts at the IURA reporting threshold of 25,000 lbs. rather than the 10,000 lb. threshold that was used in the current IUR. EPA additionally made one change to the ranges included in the proposed rule, i.e, the upper end of the first range and the lower end of the second range were raised to 300,000 lbs. from the 100,000 lbs. range limit included in the proposal, resulting in ranges of 25,000 – 300,000 lbs. and 300,000 – 1,000,000 lbs. This change makes the ranges consistent with the second reporting threshold of 300,000 lbs. or more (see § 710.52(c)(4) of the regulatory text), and provides additional protection for submitters' production volume range CBI claims.

Under the proposed rule's 100,000 lbs. range limit for the lowest production volume range, submitters who did not claim the production volume range as CBI might have inadvertently provided the public with more information than they intended. For instance, for a submitter whose production volume was in the 100,000 to 1,000,000 lbs. range, who did not claim their production volume range CBI, and who did not report any information in Part III of reporting Form U (the industrial processing and use and the commercial and consumer use information), public users of the data would be able to infer that the submitter's production was somewhere between 100,000 to 300,000 lbs. per year – information which the submitter might have considered CBI. To protect against such inadvertent disclosures of CBI, EPA changed the production volume ranges to reflect the second reporting threshold of 300,000 lbs. EPA does not believe that the change significantly affects the utility of the data to the public.

e. *Number of potentially exposed workers (§ 710.52(c)(3)(vi) of the regulatory text).* Submitters must report the range code that corresponds to their estimate of the total number of workers reasonably likely to be exposed to each reportable chemical substance at each plant site. EPA defines ''reasonably likely to be exposed'' as an exposure to a chemical substance which, under foreseeable conditions of manufacture, 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, etc.), but exclude accidental or theoretical exposures.

Workers involved in chemical manufacturing, processing, and use are a subpopulation of concern to EPA, the Occupational Safety and Health Administration (OSHA) (Ref. 12), the National Institute of Occupational Safety and Health (NIOSH) (Ref. 13), and other organizations (e.g., labor unions). Workers may often be exposed to chemical substances in higher doses and with greater frequency than the general population, and may therefore be at potentially greater risk of adverse health effects. The number of workers reasonably likely to be exposed to specific chemical substances is important to EPA and other organizations in developing screening level exposure scenarios. These scenarios are then used to develop priorities for testing, more detailed risk assessment, and risk management.

Under IURA, submitters are required to use ranges rather than specific values for reporting certain data, including the number of workers reasonably likely to be exposed and the number of processing or use sites. The ranges for reporting the estimated number of potentially exposed workers are found in § 710.52(c)(3)(vi) of the regulatory text. In general, reporting these ranges reduces the potential burden to submitters of developing a precise point estimate for the data element. The use of ranges should additionally result in fewer CBI claims than if precise point estimates were provided because ranges tend to reveal less sensitive information than specific estimates while still conveying sufficient information useful to effectively screen chemical risks. Submitters are permitted to claim the reported ranges as confidential if revealing even this general information would disclose information of a sensitive nature.

f. *Maximum concentration (§ 710.52(c)(3)(vii) of the regulatory text).* Submitters must report the maximum concentration, measured by weight, of the reportable chemical substance at the time it leaves the submitter's manufacturing site or, if it is a site-limited chemical, at the time it is reacted on-site to produce a different chemical substance. This information is to be reported regardless of the various physical forms in which the chemical may be sent off-site or reacted on–site. Concentration ranges for use in reporting are found in § 710.52(c)(3)(vii) of the regulatory text.

Concentration is an important variable to consider when estimating the magnitude of potential exposures. Information about the maximum concentration of a chemical substance present at processing and use sites is frequently used in chemical risk screening in the review of PMNs for new chemical substances required by section 5 of TSCA and is used to the extent it is available in screening chemicals on the TSCA Inventory. 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. These

standard methods use maximum concentration information to estimate upper limits to exposure estimates. If EPA is aware that a chemical substance is processed or used only as a fraction of a mixture with other chemical substances, exposure estimates may be adjusted downward accordingly. For example, a chemical substance which is a component of a liquid mixture exerts a lower vapor pressure than it would as a pure chemical substance. Because higher vapor pressure is associated with increasing inhalation exposure to a chemical substance, the concentration of a chemical substance in a liquid mixture impacts the exposure assessment.

A chemical may be produced in multiple physical forms and in multiple formulations and products. As described in Unit II.F.5.g., EPA is requiring reporting of each of the physical forms in which a chemical is sent off–site. For the purpose of exposure screening, EPA is requiring only the reporting of the maximum concentration, regardless of the various physical forms in which a chemical may be sent off-site.

EPA had proposed that submitters also report the average concentration of the chemical when leaving the manufacturing site (at 64 FR 46788). EPA is not promulgating this requirement because of the potential difficulty of determining the average concentration. For example, a submitter could produce many formulations containing a particular chemical substance, making a determination of average concentration difficult.

g. *Physical form (§ 710.52(c)(3)(viii) of the regulatory text).* Submitters must report the physical form(s) of the chemical at the time it leaves the site of manufacture or, if the chemical is site-limited, at the time it is reacted on site to produce a different chemical substance. The list of physical forms from which submitters must select is found in § 710.52(c)(3)(viii) of the regulatory text. Further discussion on physical form reporting is found in Unit III.B.1.a.

The physical form of a chemical is an important factor to consider when estimating magnitudes and concentrations of potential exposures. EPA's analyses of TRI and PMN data demonstrated that the physical state of a chemical is a determining factor in predicting the potential for industrial releases of chemicals, and hence, exposures to humans and the environment. The results of the analyses are provided in a technical support document that was developed by EPA in support of this rule (''Inventory Update Rule (IUR) Amendments Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening,'' Ref. 14). The physical state, which provides information on volatility and how the chemical is likely to be handled during manufacturing, processing, and use, is an important data element for the purpose of exposure and risk screening.

h. *Percent production volume (§ 710.52(c)(3)(ix) of the regulatory text).* Submitters are required to report the percentage of total production volume (as reported under regulatory text § 710.52(c)(3)(iv)) of the reportable chemical substance that is associated with each physical form reported. Percent production volume estimates will allow the Agency to aggregate, on a case-by-case basis, the production volume of a particular physical form for a given chemical across multiple sites. These determinations will allow EPA to better characterize the risk associated with chemicals that are manufactured in physical forms that typically result in higher exposures, such as volatile liquids or powders, but that are produced in small quantities. These percent production volume estimates will help put the physical form information into context. Estimates must be rounded off to the nearest 10% of production volume.

6. *What new definitions have been added to explain or reworded to clarify the reporting requirements*? EPA has reorganized the definition section of the regulatory text associated with the original Inventory and IUR. There are now three definition sections. The existing § 710.2 contains definitions relevant primarily to the compilation of the original Inventory, although a few of these definitions are also relevant to both IUR and IURA. EPA has recodified these general definitions in § 710.3. Definitions relevant only to IUR, which were originally in § 710.2, are now in § 710.23. Section 710.43 contains definitions relevant only to IURA. This reorganization clarifies the relationships between the definitions and the various rules, and has no substantive effect.

Two existing definitions are being clarified (§ 710.3 of the regulatory text). EPA defines ''manufacture'' to mean to manufacture, produce, or import for commercial purposes and ''manufacture or import 'for commercial purposes''' to mean to manufacture, produce, or import 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.

Certain new definitions are being added to § 710.43 as a result of this final rule.

a. *Known to or reasonably ascertainable by.* TSCA section 8(a)(2) authorizes EPA to require persons to report information that is known to or reasonably ascertainable by the submitter. For the purposes of reporting under IURA, a submitter will report information described in the regulatory text at § 710.52(c)(1), (c)(2), and (c)(3) that is known to or reasonably ascertainable by the submitter. This 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.

b. *Readily obtainable information.* TSCA section 8(a)(2) authorizes EPA to require persons to report information that is known to or reasonably ascertainable by the submitter. Under IURA, a submitter will report processing and use information (i.e., the information reported for sites at which the 300,000 lbs. threshold has been met or exceeded) 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 of the reportable chemical substance (see regulatory text § 710.43). Extensive file searches are not required. The ''readily obtainable'' standard 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 (see regulatory text § 710.43), while providing sufficiently precise processing and use information for screening level reviews. In addition, the ''readily obtainable'' standard limits the reporting burden associated with processing and use reporting and is identical to the standard currently in effect under EPA's TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) (See 40 CFR 712.7). The ''readily obtainable'' definition is further discussed in Unit III.D.2.

c. *Reasonably likely to be exposed.* For the purposes of reporting under IURA, 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 would 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, etc.), but excludes accidental or theoretical exposures.

d. *Use*. For the purpose of reporting under IURA, EPA is defining ''use'' as any utilization of a chemical substance or mixture that is not otherwise covered by the terms ''manufacture'' or ''process'' (see regulatory text § 710.43). For example, the activity of processing a solvent into a paint formulation is considered ''processing'' rather than ''use'' because the activity incorporates the chemical substance (the solvent) into a formulation. If the paint formulation containing the solvent is then applied to a metal or wood surface (e.g., cars), this application would be considered a use activity. Relabeling or redistributing a container holding a chemical substance or mixture where no repackaging occurs does not constitute use or processing of the chemical substance or mixture.

e. *Repackaging*. For the purpose of reporting under IURA, ''repackaging'' is defined as the physical transfer of a chemical substance or mixture (as is) from one container to another container or containers in preparation for distributing the chemical substance or mixture in commerce. This definition does not apply to sites that only relabel or redistribute the reportable chemical substance without removing the chemical substance from the container in which it is received or purchased.

f. *Industrial use*. EPA defines ''industrial use'' for purposes of reporting under IURA as use at a site at which one or more chemical substances or mixtures are manufactured or processed (see § 710.43 of the regulatory text).

g. *Commercial and consumer use*. For purposes of reporting under IURA, EPA defines ''commercial use'' as 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, a school, or recreational areas (see § 710.43 of the regulatory text). Exposures to commercial and consumer products are similar for risk screening purposes because existing screening level assessment methods are not sophisticated enough to distinguish between these exposures.

h. *Intended for use by children*. For purposes of reporting under IURA, EPA defines ''intended for use by children'' as the use of a chemical substance or mixture in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers ''yes'' to at least one of the following questions for the product into which the submitter's chemical substance or mixture is incorporated: (1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger; (2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger; or (3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

i. *Reportable chemical substance*. For the purposes of reporting under IURA, a reportable chemical substance is a chemical substance described in § 710.45 of the regulatory text.

j. *Reporting year*. For the purposes of reporting under IURA, the reporting year is the calendar year in which information to be reported to EPA during a submission period is generated, i.e., calendar year 2005 and the calendar year at 4–year intervals thereafter. For instance, for information submitted in 2006, the information will be generated during the period from January 1 to December 31, 2005.

k. *Submission period*. For the purposes of reporting under IURA, the submission period is the period in which the information generated during the reporting year is submitted to EPA. For instance information generated during the period from January 1 to December 31, 2005 (i.e., when the chemical substance is manufactured) will be submitted during the 2006 submission period.

l. Site-limited. For purposes of reporting under IURA, EPA defines ''site-limited'' to mean that 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. Although a site-limited chemical substance is not distributed for commercial purposes outside the site at which it is manufactured and processed, the substance is considered to have been manufactured and processed for commercial purposes.

7. *What new data elements are reportable by only larger production volume manufacturers*? As described in Unit II.F.2., EPA is replacing the current IUR reporting threshold of 10,000 lbs. per year per site with two new production volume reporting thresholds of 25,000 lbs. and 300,000 lbs. per year per site. Each person manufacturing a reportable substance at or above the 25,000 lbs. per year per site threshold is required to complete at least a partial report containing the information in Parts I and II of the revised Form U. Persons who manufacture a reportable substance at or above the 300,000 lbs. per year per site threshold are required to complete a full report, providing the information in Part III of the revised Form U in addition to the information in Parts I and II. Part III concerns the processing and use of chemical substances.

a. *Processing and use information (§ 710.52(c)(4) of the regulatory text)*. Submitters with plant sites at which a reportable chemical substance is manufactured in annual quantities of 300,000 lbs. or more must report processing and use information under IURA. EPA requires submitters to report the information described in § 710.52(c)(4) of the regulatory text concerning the processing and use of each reportable chemical substance at sites that receive a reportable chemical substance from the submitter site either directly or indirectly (including through a broker/distributor, from a customer of the submitter, etc.), whether the recipient site(s) are controlled by the submitter site or not. Processing and use information must be reported only to the extent that the data, or an estimate, is ''readily obtainable'' by the submitter (see Unit II.F.6.b.).

i. *Industrial processing or use operations (§ 710.52(c)(4)(i)(A) of the regulatory text)*. Submitters must report the industrial processing or use operation(s) at each site that receives the reportable substance from the submitter site (whether the recipient site(s) are controlled by the submitter site or not). The categories for reporting are listed in § 710.52(c)(4)(i)(A) of the regulatory text.

ii. *North American Industrial Classification System (NAICS) Code (§ 710.52(c)(4)(i)(B) of the regulatory text)*. Submitters must report the five–digit NAICS code(s) that best describe(s) the industrial processing or use activities 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.), whether the recipient site(s) are controlled by the submitter site or not. The NAICS codes, published by the Office of Management and Budget (OMB), have superseded the prior system of Standard Industrial Classification (SIC) codes (Ref. 15). Submitters must report these codes to the extent the information is readily obtainable for processing or use activities at sites that process or use a reportable chemical substance received from the submitter. EPA does not intend for manufacturers to survey their customers or distributors to precisely identify the appropriate NAICS codes at their downstream sites.

The NAICS classification system is being used in IURA to describe the industrial setting in which chemical exposures associated with the industrial processing or use of a chemical substance may occur. Exposure to a chemical substance typically varies among industries. The NAICS code in conjunction with the Industrial Function Category (IFC) code and the processing or use operation will define the industrial, commercial, or consumer setting so that the appropriate scenarios can be applied to estimate worker, community, and environmental exposures to the chemical substance.

The NAICS codes which best describe the industrial activities associated with each reported industrial processing or use operation must be provided. If more than 10 NAICS codes apply to a reportable chemical substance, submitters need only report the 10 NAICS code, IFC and processing or use operation combinations that cumulatively represent the largest percentage of the substance's production volume, measured by weight. Submitters may also report the same NAICS code multiple times if the chemical being reported has several industrial functions or multiple processing or use operations. This limitation on reporting is intended to minimize submitters' reporting burden.

iii. *Industrial function category (IFC) (§ 710.52(c)(4)(i)(C) of the regulatory text).* Submitters must report the IFCs that best represent the specific manner in which a chemical substance is used within each NAICS code reported. Submitters may report the same function category under different NAICS codes. The IFCs to be used are listed in the regulatory text at § 710.52(c)(4)(i)(C).

A NAICS code and IFC combination sufficiently defines a potential exposure scenario for risk screening and priority–setting purposes. EPA conducted studies to determine whether information regarding the industrial sectors in which a chemical substance is processed and used, and information regarding the function a chemical substance performs within industrial processes, are useful for the purpose of screening level exposure assessments. These studies demonstrated that this type of information provides indications of the route, magnitude, and concentration of potential chemical exposures to humans and to the environment. The results of the studies are provided in two of the technical support documents that EPA developed in support of this rule (Refs. 14 and 16).

IFCs are also useful in estimating the frequency and duration of chemical substance exposures by indicating the type of application in which a chemical will be used (e.g., solvents (for cleaning and degreasing) or intermediate). The relationship between industrial function categories and the frequency and duration of exposure to chemical substances is particularly useful in developing exposure assessments in EPA's New Chemicals Program. These data elements are important elements in developing useful exposure scenarios. In the absence of these data, EPA often uses conservative estimates that may indicate a greater risk than is actually the case. Data that will be obtained under IURA will enable EPA to make more realistic characterizations of exposure, instead of ''worst case'' assumptions.

iv. *Percentage of production volume attributable to each combination of NAICS code and industrial function category in each processing or use operation (§ 710.52(c)(4)(i)(D) of the regulatory text).* Submitters must estimate the percentage of total production volume attributable to each reported combination of NAICS code and IFC in each processing or use operation, to the extent that such information is readily obtainable. Estimates must be rounded off to the nearest 10% of production volume. Submitters are not permitted to round off to zero percent if the production volume attributable to a NAICS code/IFC/processing or use operation combination is 300,000 lbs. or more and accounts for 5% or less of the total production volume of a reportable chemical substance. In such cases, submitters must report the percentage of production volume attributable to that combination to the nearest 1% of production volume. This exception to the general rounding rule will ensure that adequate use information is reported for the larger production volume chemical substances.

The total percent production volumes associated with the NAICS code/IFC combinations may add up to more than 100%, given that the submitter is reporting on distribution of a chemical to sites in its control as well as downstream sites, some of which are not immediate purchasers from the original manufacturing site. Additionally, the total percent production volume may add up to less than 100% if the submitter cannot readily obtain information about how all of its production volume is processed or used by industry.

v. *Number of processing or use sites (§ 710.52(c)(4)(i)(E) of the regulatory text).* Submitters must report estimates of the total number of industrial sites, including those beyond the submitter's control, that process or use each reportable chemical substance manufactured by the submitter, with respect to each combination of NAICS code and IFC in each processing or use operation. The ranges that will be used for reporting the number of sites can be found at § 710.52(c)(4)(i)(E) of the regulatory text. For risk screening purposes, the number of sites at which chemical substances are manufactured, processed, or used is a useful indicator of the number of ecosystems and the size of the general population potentially exposed to the chemical substances.

vi. *Number of workers (§ 710.52(c)(4)(i)(F) of the regulatory text).* Submitters must report estimates of the total number of workers, including those at sites not under the submitter's control, that are reasonably likely to be exposed while processing or using the reportable chemical substance, with respect to each combination of NAICS code and IFC in each processing or use operation. The approximate number of workers will be reported using the same definitions and ranges described under Unit II.F.5.e. The 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.

b. *Commercial and consumer use information (§ 710.52(c)(4)(ii) of the regulatory text).* Submitters must report information concerning the commercial and consumer uses of each reportable chemical substance, whether the site(s) at which the chemical substance is used are controlled by the submitter site or not. As for the industrial processing and use information described in Unit II.F.7.a., commercial and consumer use information must be reported only by sites at which a chemical substance is manufactured in annual quantities of 300,000 lbs. or more, and submitters are only required to report the information to the extent that it is readily obtainable.

Consumers comprise a subpopulation of particular concern to EPA, the Consumer Products Safety Commission (CPSC), and other governmental and non–governmental organizations. Information from submitters about whether the chemical substances they manufacture are used in consumer products is useful in estimating the potential risks to consumers that result from chemical exposures. In the absence of more specific data, EPA often assumes for risk screening purposes that large, unprotected populations may potentially be exposed to the chemical substances in consumer products. EPA is also working with industry and other stakeholders to develop hazard, exposure, and risk assessments regarding chemicals to which children are exposed. The commercial and consumer product information that will be reported under IURA will be used by EPA in the identification of chemicals that might be included in these programs, and may contribute to exposure assessments for these chemicals.

i. *Commercial and consumer product categories (§ 710.52(c)(4)(ii)(A) of the regulatory text).* Submitters must report up to 10 categories that best describe the commercial and consumer products in which the reportable chemical substance is used (whether the recipient site(s) are controlled by the submitter site or not). If more than 10 categories apply, submitters need only report the 10 categories for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume, measured by weight. The commercial and consumer product (CCP) categories are listed at § 710.52(c)(4)(ii)(A) of the regulatory text. Information on the use of chemicals in CCPs is useful 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 will be obtained under IURA will enable EPA to make more realistic characterizations of exposure, instead of ''worst case,'' overly conservative assumptions.

ii. *Products intended for use by children (§ 710.52(c)(4)(ii)(B) of the regulatory text).* Submitters must indicate, within each reported CCP category, whether, based on readily obtainable information, any amount of each reportable chemical substance manufactured by the submitter is or is not present in (for example, a plasticizer chemical used to make pacifiers) or on (for example, as a component in the paint on a toy) any products intended for use by children, regardless of the concentration of the substance, or indicate that such information is not readily obtainable.

EPA defines ''intended for use by children'' in § 710.43 of the regulatory text and in Unit II.F.6.h. Using this definition, if a submitter determines, based on readily obtainable information, that its chemical substance or mixture is used in or on a product that is intended to be used by children age 14 or younger, the submitter would indicate this on Form U. For example, EPA believes that certain products, like crayons, coloring books, diapers, and toy cars – to name a few – are typically intended to be used by children age 14 or younger. As such, if a submitter determines, based on readily obtainable information, that its chemical substance or mixture is used in crayons and toy cars, that submitter would report a ''Y'' in the Children's Use column on Form U for categories C01 and C10.

On the other hand, EPA believes that certain products, like household cleaning products, automotive products, and lubricants--to name a few--are typically not intended to be used by children age 14 or younger. As such, if a submitter determines, based on readily obtainable information, that its chemical substance or mixture is used in automotive care products and lubricants, that submitter could report a ''N'' in the Children's Use column on Form U for categories C03 and C09.

For further illustration, some examples of products that are typically intended for use by children 14 or younger are provided for each commercial and consumer use category (this listing is not intended to be exhaustive and should therefore not be considered limiting):

Code	Category	Examples of Children's Products
C01	Artists' supplies	Crayons, children's markers
C02	Adhesives and sealants	Craft glue, model glue
C03	Automotive care products	Typically products in this category are not likely to be intended for use by children 14 or younger
C04	Electrical and electronic products	Electronic games, remote control cars, toys
C05	Glass and ceramic products	Porcelain dolls
C06	Fabrics, textiles and apparel	Pajamas
C07	Lawn and garden products (non-pesticidal)	Lawn and gardening tools designed specifically for children, e.g., children's rake
C08	Leather products	Shoes, jackets, baseball gloves
C09	Lubricants, greases and fuel additives	Typically products in this category are not likely to be intended for use by children 14 or younger
C10	Metal products	Toy trucks, toy cars, wagon
C11	Paper products	Diapers, baby wipes, coloring books
C12	Paints and coatings	Finger paints, water color kits intended for children's use

Code	Category	Examples of Children's Products
C13	Photographic chemicals	Typically products in this category are not likely to be intended for use by children 14 or younger
C14	Polishes and sanitation goods	Typically products in this category are not likely to be intended for use by children 14 or younger
C15	Rubber and plastic products	Pacifiers, action figures, balls
C16	Soaps and detergents	Baby shampoo, children's bubble bath
C17	Transportation products	Child's car seat
C18	Wood and wood furniture	Baby cribs, changing tables, wooden toys
C19	Other	Other items specifically intended for use by children age 14 or younger

EPA chose the phrase ''intended for use by children'' because it appears in the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261 *et seq.*) and has been applied by the Consumer Product Safety Commission (CPSC) for over 20 years. While not specifically defined in FHSA or its implementing regulations, the CPSC regulations list several factors that CPSC considers in determining whether a product is a ''children's product'' intended for use by children (16 CFR 1501.2(b)). After consultation with CPSC, EPA adapted these factors for the purpose of defining ''intended for use by children'' for IURA purposes.

EPA based the ages for the definition, i.e., 14 or younger, on the Standard Consumer Safety Specification on Toy Safety issued by the American Society for Testing and Materials (ASTM), Standard: ASTM F963–96a. This standard covers age groups through 14 years and defines ''toy'' as: ''any object designed, manufactured, or marketed as a plaything for children through the age of 14 years'' (Ref. 17, section 3.1.33).

Obtaining information indicating that a chemical substance or mixture is used in a product that is intended for use by children will enable the Agency and others to identify chemicals affecting this particularly sensitive population. EPA has long had an interest in protecting children from unreasonable adverse affects associated with exposure to chemicals. In 1995, EPA established a policy to ensure that environmental health risks of children are explicitly and consistently evaluated in our risk assessments, risk characterizations, and environmental and public health standards (see http://yosemite.epa.gov/ochp/ochpweb.nsf/homepage). Environmental health threats to children are often difficult to recognize and assess because of limited information to identify where children's exposures occur and limited understanding of when and why children's exposures and responses are different from those of adults.

In 1997, Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), specifically directed each Federal agency to make it a high priority to identify, assess, and address children's environmental health and safety risks. It also created a Task Force on Environmental Health Risks and Safety Risks to Children. On October 9, 2001, President Bush signed Executive Order 13229, entitled *Amendment to Executive Order 13045, Extending the Task Force on Environmental Health Risks and Safety Risks to Children* (66 FR 52013, October 11, 2001), extending the work of the Task Force by another 18 months. These Executive Orders illustrate the interest in and the importance placed on addressing children's environmental health and safety risks.

The inclusion of the children's use category in IURA will provide the Agency and others with valuable information about the relationship between the IUR chemicals and products intended for use by children 14 or younger. This information will allow the Agency to respond to concerns about chemicals used in the manufacture of products intended for use by children, enabling the Agency to identify those chemicals that are reported as not being used in children's products, those chemicals that are used in children's products, and those chemicals where it is not known if they are used in children's products. This initial screen will then allow EPA and others to identify those chemicals used in children's products that might warrant further investigation or assessment, and thereby allow EPA, as well as other interested parties and affected entities, to better prioritize such assessments and maximize available resources.

iii. *Percentage of production volume attributable to each commercial and consumer product category (§ 710.52(c)(4)(ii)(C) of the regulatory text).* Submitters must estimate the percentage of their site production volume for each reportable chemical substance that is attributable to each specific commercial and consumer end–use. This information must be submitted to the extent that it is readily obtainable. Estimates must be rounded off to the nearest 10% of production volume. However, a CCP category which accounts for 5% or less of the total production volume of a reportable chemical substance cannot be rounded off to zero percent 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 rule will ensure that adequate use information is reported for the larger production volume chemical substances.

The total percent production volumes reported may add up to more than 100%, given that the submitter is reporting on distribution of a chemical to sites in its control as well as downstream sites, some of which are not immediate purchasers from the original manufacturing site. Additionally, the total percent production volume may add up to less than 100% if the submitter cannot readily obtain information about how all of its production volume is used in commercial and consumer products.

iv. *Maximum concentration in commercial and consumer products (§ 710.52(c)(4)(ii)(D) of the regulatory text).* Submitters must report the maximum concentration (measured by weight) of each reportable chemical substance in each commercial and consumer product category. In complying with this requirement, submitters will select from the list of concentration ranges provided in § 710.52(c)(3)(vii) in the regulatory text. Concentration is further discussed in Unit III.B.1.b. As with the other processing and use information that submitters must report, such information will be reported only to the extent that it is readily obtainable by the submitter.

8. *What changes have been made to requirements for making CBI claims*? Submitters are able to claim information submitted to EPA under this amended 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 invalid confidentiality claims as much as possible.

Submitters will have an opportunity to make CBI claims for most of the information reported under IURA. To claim information as confidential, a submitter must check the appropriate box and sign the certification statement on the reporting form. If a submitter fails to do so, EPA could release the information to the public without further notice to the submitter. As in the past TSCA Inventory Update collections and the initial TSCA Inventory collection, by signing the certification statement the submitter certifies that its claims of confidentiality are true and correct. Procedures for claiming information submitted electronically (such as a submission on diskette) as CBI will be specified in the instruction manual that will be available each submission period as described in § 710.59 of the regulatory text. CBI should not be submitted by e–mail. A discussion about CBI claims under IURA is provided in this unit.

a. *Upfront substantiation for plant site identity.* Submitters are required to provide upfront substantiation for CBI claims for plant site identity, in a manner similar to the upfront substantiation of chemical identity under the existing IUR (see 40 CFR 710.38). Under IURA (see § 710.58(d) of the regulatory text), a submitter may assert a claim of confidentiality for a plant site identity if the submitter believes that releasing that identity would reveal trade secrets or confidential commercial or financial information, as provided by TSCA section 14. Submitters in past IUR information collections have claimed in excess of 15% of plant site identities 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 necessary. Further discussion on upfront substantiation is found in Unit III.E.2.

In order to assert a claim of confidentiality for a plant site identity under this amended rule, the submitter must check the appropriate box on the reporting form indicating a confidentiality claim for plant site identity and substantiate the claim in writing by answering certain questions provided in § 710.58(d) of the regulatory text. If a submitter fails to substantiate the plant site CBI claim, EPA could make the information available to the public without further notice to the submitter.

b. *CBI claims for chemical production volume information.* EPA did not change the ability of the submitter to 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. However, submitters may now make separate CBI claims for both actual plant site production volume information and a corresponding production volume range. Production volume ranges are similar to those used in the implementation of the original TSCA Inventory collection and can be found at § 710.52(c)(3)(v) of the regulatory text.

In the last four IUR submission periods when EPA sought actual production volume information, approximately 65% of the information was claimed as confidential. In contrast, only 35% of production volume data collected in ranges in the original TSCA inventory collection were claimed as confidential. This difference indicates that submitters may be significantly less likely to make CBI claims for production volume information reported in ranges than for discrete production volume figures. The high proportion of CBI claims in IUR reports has severely limited EPA's ability to convey production volume information to the public, even in the form of a national aggregate production volume for the chemical. EPA needs to be able to convey 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. EPA has added the ability to claim production volume range information CBI in an effort to address this problem. In some cases, submitters may choose to claim their actual production volume as CBI, while allowing the more general production volume range to be made public.

III. Public Comments

EPA carefully considered the comments it received on the proposed IURA. Major comments are discussed below. Additional comment summaries and more detailed responses are contained in the ''Summary of EPA's Responses to Public Comments Submitted in Response to Proposed TSCA Inventory Update Rule Amendments'' (Ref. 18).

A. General Comments

1. *How will EPA and others use the new exposure-related data collected under these amendments*? Several commenters expressed the view that EPA has not provided adequate justification supporting the Agency's need for the new IUR data, nor enough specific examples showing how EPA would use the data for its intended purpose.

EPA has an obligation under TSCA to protect human health and the environment from unreasonable risks associated with chemicals under its jurisdiction. In order to evaluate potential chemical risks, EPA has determined that a portion of the chemicals (both inorganic and organic) on the TSCA Inventory currently warrant the collection of manufacturing information, and that a subset of those chemicals (i.e., those produced in annual quantities of 300,000 lbs. or more at a site) currently warrant the collection of supplementary processing and use information. EPA is amending the IUR to provide an accurate and readily available source of basic exposure-related information for approximately 4,000 of the 76,000 substances listed on the TSCA Inventory. The amendments significantly limit industry's reporting burden while providing EPA with information needed to screen for risks to human health and the environment.

EPA's primary use of these data will be to identify priority TSCA chemicals for more detailed information gathering, risk assessment, and risk management in order to develop targeted programs, allowing the Agency to be proactive in protecting human health and the environment. Screening chemical risks generally requires a combination of both hazard and exposure information. The lack of exposure-related data beyond production volume data in the current IUR has severely limited the usefulness of the current IUR data for risk screening. Moreover, the exposure-related data that will be collected under IURA are not otherwise readily available from publicly available data sources (see Unit III.A.3.). This lack of exposure-related data has made it difficult for EPA and others to identify chemicals with potential exposures of concern, and has resulted in the generation of overly conservative screening level exposure assessments.

The addition of manufacturing, processing and use exposure-related data to IURA, especially when compiled by EPA into a searchable data base format, will enable EPA and others to more readily screen chemicals for exposure and risk. These reviews will allow for better prioritization of chemicals to identify those warranting more detailed assessments and to eliminate chemicals of lesser concern from further review.

Data generated by IURA will be used in a wide variety of programs fundamental to fulfilling the Agency's TSCA statutory mandate. These programs range from the more traditional existing chemicals risk screening efforts, to voluntary programs such as EPA's Design for the Environment program (see http://www.epa.gov/opptintr/dfe), to individual requests for analysis of chemicals not associated with a particular program. The IURA data base will be searched to identify chemicals or use scenarios meeting specific criteria. For instance, the data base could be searched to identify chemicals that, based upon these data, have the greatest potential for consumer exposure, creating a list of chemicals arranged according to the production volumes associated with different consumer uses. Additional examples of uses for IURA data are provided in this section and in EPA's ''IURA Data Use Plan'' (Ref. 19). The Agency anticipates that, as was true even for the basic production data reported under the existing IUR, new uses of IURA data by EPA and by others will continually emerge and cannot be predicted at this time.

Results from EPA tools such as the Use Cluster Scoring System (UCSS) will be greatly improved by IURA data. The UCSS is a computerized tool that combines hazard and exposure information from a variety of data sources, analyzes the data in relation to groupings by commercial use, or ''clusters,'' and identifies clusters of potential concern to EPA. EPA's Science Advisory Board (SAB) commented in its evaluation of the UCSS that the lack of exposure information in the system has impaired its usefulness (Ref. 20). The IURA data base will provide exposure information that the UCSS will be able to download directly and use. (For a description of UCSS, see V.B.6. of the proposed rule at 64 FR 46780 or www.epa.gov/oppt/cahp/actlocal/use.html)

EPA will also use IURA data to perform preliminary exposure and risk screening across a portion of the TSCA Inventory chemicals. Some of the same types of data that will be collected under IURA have been collected under the Agency's TSCA Existing and New Chemicals Programs and have aided EPA in performing exposure and risk screening. These exposure-related data were submitted as part of programs such as: The voluntary UEIP (see http://www.epa.gov/opptintr/exposure/docs/ueip.htm for a description of this project) and the PMN program under TSCA section 5. Although the UEIP and PMN programs involve the submission of certain data that are the same as or similar to data being submitted under IURA, these programs cannot sufficiently serve the needs that IURA will serve (see Units V.A.1. and V.B.5. of the proposed rule at 64 FR 46775 and 46780). However, these programs are examples of the usefulness of certain IURA data elements.

For example, several IURA data elements were used in an Existing Chemicals Program initial review of the chemical methyl ethyl ketoxime (MEKO). This review relied in part upon data submitted by industry under the UEIP. Some of the data are similar to those that will be reported under IURA and include the following: Production volume, manufacturing process, industry sector, industrial processing/use activity, functional use, number of sites, number of workers, physical/chemical properties, and consumer product information. Other UEIP information submitted by industry on MEKO are not of the sort that will be collected under IURA, such as environmental releases (releases to air, water, etc.), worker exposure activities, and monitoring data. The IURA is designed to obtain information that is the most critical for generating screening level exposure profiles.

The UEIP submissions for MEKO indicated that there were one manufacturer and two importers of MEKO in 1993 and five primary end uses (submissions provided percentages of MEKO production and import volumes devoted to each use). The submissions also reported the number of workers at the manufacturing site, the physical forms of products containing MEKO, and the MEKO weight fraction in each use.

The MEKO use information was combined with information from available workplace monitoring studies and modeling approaches to compile a screening level workplace exposure assessment. The UEIP information on use provided crucial information to allow EPA to postulate process operations, worker activities, and possible exposures. For example, MEKO's primary use (92% of production and import volume) is as a paint additive. This fact allows EPA to refer to information on paint manufacturing and use to estimate exposures to workers who either formulate paints or apply the paints using spray guns or other techniques. MEKO use in paint indicates a potential for exposure to several large populations (workers and consumers) because exposure to even small amounts of paint can result in significant exposure levels to chemicals in paints. Such use information can also be used by EPA to generate estimated numbers of workers in very small businesses (< 10 workers) that may be poorly represented by existing National Occupation Exposure Survey (NOES) data. In the MEKO case, such a population would be commercial painters. Without the information about MEKO use in paints and the large percentage of MEKO volume devoted to this use, exposed populations and exposure level estimates may have been severely underestimated or left as a data gap (not estimated). Such underestimations and data gaps can artificially lower the appropriate level of concern for potential risk(s) from a chemical.

The usefulness of IURA data elements is also demonstrated by EPA's use of similar data in its New Chemicals Program. PMNs for new chemical substances submitted to EPA under TSCA section 5 require many of the same exposure-related data elements that will be reported under IURA. Exposure-related data in PMNs include estimates of production volume, categories of use, percent production volume in the categories of use, maximum number of workers exposed,

and concentrations and physical forms of the chemical. EPA uses these exposure-related data to generate screening level risk assessments for regulatory decision-making under TSCA section 5.

The manufacturer of a new chemical provided the following information in a recent PMN submission: An estimated import volume; chemical uses and the percentages of the import volume devoted to each use (non-cosmetic applications as a component of a fragrance formulation used in household products such as detergents, cleaners, soaps, room fresheners, etc.); number of sites and workers; and consumer product information (weight percent in products). EPA used this information in combination with technical references and other data to estimate the number of manufacturers of household products who may use the new substance. Releases of the new substance as a result of the fragrance formulation process and from manufacturers of the household products were estimated, resulting in estimated environmental concentrations of the new substance due to its release and estimated general population exposures to the new substance. EPA also used the information on processing and use in combination with modeling techniques to estimate the number of workers and consumers who may be exposed to the new substance and their estimated exposures to the new substance. These exposure-related estimates, when combined with information on the estimated hazards of the new substance, indicated that the estimated risks to potentially-exposed workers, the general population, consumers, and aquatic species were all below levels of concern. Therefore, the Agency could determine that no further regulation under TSCA section 5 was needed for this new substance. In contrast, without this information, EPA would have had to rely on generic assumptions for approximating potential exposures. These types of assumptions are intended to be conservative in nature and therefore often result in higher than likely exposure estimates.

Information from the IURA may also be used in efforts to identify single chemicals to support potential exposure prevention activities. For example, EPA recently learned that certain imports of zinc sulfate were contaminated with cadmium. Using the IURA processing and use data on inorganic substances, EPA could have quickly identified importers of zinc sulfate and segments of industry or the general population that might use the chemical. EPA then could have targeted warnings of the potential for exposure to cadmium more effectively, thereby preventing exposures to the groups likely to be the most highly exposed.

Other Federal agencies have also long recognized the need for and importance of exposure data. OSHA, NIOSH, and CPSC have written letters supporting EPA's and their own need for exposure data (Refs. 12, 13, 21, 22, and 23). In May 2000, the Government Accounting Office (GAO) stated that ''Various federal agencies have collected such human exposure data for a number of purposes; historically, these collection efforts have been limited to selected chemicals, subpopulations, and time periods'' (Ref. 24).

Other government agencies, industry, public interest groups, and the public in general will be able to access and use the non-CBI portion of IURA information. The IURA exposure-related data will be important to users beyond those who accessed the existing IUR in the past solely for production volume information. The Natural Resources Defense Council (NRDC), for example, has expressed interest in using IURA information (Ref. 25). In another case, persons interested in reviewing the HPV Challenge Program screening level hazard data (see http://www.epa.gov/opptintr/chemrtk/volchall.htm) will be able to use the non-CBI exposure-related IURA data to put the hazard data into context. Risks identified via evaluation of these screening level hazard and exposure data then can be addressed.

Although EPA can envision a wide variety of uses for the new IURA exposure-related information as described in this section, the Agency anticipates that even more opportunities exist for use of this information, as is true for the basic production data reported under the current IUR.

2. *What is the practical utility of the new exposure-related data*? Commenters have questioned whether the data collected as a part of this rulemaking will have ''practical utility.'' Practical utility is defined in the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3502(11)) to mean ''the ability of an Agency to use information, particularly the capability to process such information in a timely and useful fashion.'' The OMB regulatory definition of ''practical utility'' at 5 CFR part 1320.3(l) addresses not only the theoretical or potential usefulness of information to an Agency, but also its actual usefulness, taking into account its accuracy, validity, adequacy, and reliability, the Agency's ability to process the information in a useful and timely fashion, and whether the Agency demonstrates actual timely use of the data by the Agency's own functions. The following discussion addresses commenters' concerns in two parts: First, the accuracy, validity, adequacy, and reliability of the data; and second, the timely use of the data by EPA.

a. *How has the Agency ensured that the data will be accurate, valid, adequate, and reliable*? Commenters asserted that the data EPA proposed to collect through IURA would not be adequate for the purposes stated by EPA, and would not be accurate, valid, or reliable. Commenters stated that the information collected through IURA would be of limited accuracy and would be inferior to data the Agency has collected in other programs. Commenters also stated that the information would be so uncertain that it would not be useful to predict chemical risk, and that there are so many other factors that affect exposure, such as engineering controls, that the data would provide a limited and potentially inaccurate view of potential exposure. Additionally, commenters asserted that they do not know how their chemicals are used downstream of the manufacturing site, therefore if they were required to report such information, the resulting data would be unreliable.

EPA considered the types of information needed for screening level exposure and risk assessments and believes the information that will be collected through IURA will have the necessary level of accuracy, validity, adequacy, and reliability for such assessments. EPA agrees that there are many ways to increase the accuracy, validity, and reliability of the data. However, in developing IURA and considering various alternatives, EPA relied on experience from programs such as TSCA's PMN program and the UEIP data collection, and maintained a balance between data needs for exposure screening and priority setting and the burden associated with providing the information. If the Agency had required very precise, specific reporting, submitter burden would have increased beyond that which is appropriate for a screening level data collection. EPA also agrees that there are many factors that can affect exposure potential; however, the data provided by the submitters will provide baseline information sufficient for an initial screen of exposure potential.

i. *Adequacy of the data.* Before proposing the IURA, EPA analyzed various exposure data collections and assessments to determine the data elements needed for a screening level exposure assessment. This discussion

and analysis are in the document ''Inventory Update Rule (IUR) Amendment Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening'' (Ref. 14). Commenters' suggestions on the proposed rule implied that more extensive information about exposures than was included in the proposed rule would be necessary for even a screening level analysis of potential exposure. One commenter stated that there are many other factors that can significantly affect the potential for exposure. These factors include engineering controls and personal protective equipment practices, the nature of the activities in which workers are engaged, and the physicochemical characteristics of the chemical substances. This commenter also stated that the data collected under IURA will provide a limited and potentially inaccurate view of potential exposure. However, as summarized in Unit III.A.1., risk analyses performed by the Agency in general and OPPT in particular are graduated and data-driven. As the initial levels of concern and the quantity and quality of data increase, the need for methodologies used in risk review become more detailed and exacting, and the reviews become more accurate and reliable. Based on its experience screening chemical risks through such programs as the TSCA New Chemicals Program, the Agency believes IURA data will provide information adequate to perform initial screens of chemicals. The Agency also will be better able to prioritize and make basic risk management decisions about those chemicals of greatest concern as indicated by the available data. These better informed decisions will enhance confidence that the most appropriate chemicals are selected for more detailed assessments.

ii. *Accuracy and reliability of the data*. The Agency considered the data accuracy and reliability needed for screening level exposure analyses, and took several steps to ensure IURA data meet those needs. Screening level data need not be absolutely precise, but should be accurate and reliable enough to make usable and defensible technical assessments. The IURA will supply exposure-related information the Agency currently does not have, recognizing that industry has a greater knowledge than EPA about its own operations and the uses of chemicals it manufactures and sells. Without this information, EPA either would not screen these chemicals, would screen them using outdated or anecdotal exposure information, or would rely on exposure estimates (typically conservative) using modeling data.

Commenters stated that the accuracy and reliability of much of the information reported in Part III of the proposed revised Form U (§ 710.32(c)(4) of the proposed regulatory text, now § 710.52(c)(4)) would be highly questionable because it relates to sites, activities, and products that are not under the direct or indirect control of the reporting company. Industry programs such as the ACC's Responsible Care Program (see http://www.americanchemistry.com for more information) require that, as part of the program, member companies work with customers, carriers, suppliers, distributors, and contractors to foster the safe use, transport and disposal of chemicals. The Responsible Care Program, coupled with basic marketing and sales force activities, suggests that many companies are well informed about downstream uses of their chemicals. EPA recognizes that submitters may not always have detailed information about how the chemical(s) they make are used. As a result, submitters will only be required to report this information to the extent it is ''readily obtainable'' (see Unit II.F.6.b.). In addition, the Agency believes, based on its experience with the New Chemicals Program, the UEIP, stakeholder meetings, discussions with industry about voluntary risk management programs, and industry's various self-regulation initiatives, that most submitters have at least some basic information about downstream uses, such as the information that will be reported under the IURA. These data are believed to be of sufficient reliability for use by the Agency and others for purposes such as screening level risk assessments and prioritization.

EPA also requires much of the IURA information to be submitted in EPA specified ranges. This requirement benefits both the Agency and submitters. First, range reporting is less burdensome for the submitter than calculating specific numeric estimates. Demanding greater data accuracy increases the burdens associated with data collection. Second, information reported in discrete numeric values can indicate a level of accuracy that is not necessarily present. EPA believes that a higher level of confidence in data accuracy can be achieved by specifying ranges.

Commenters suggested that EPA use other methods to obtain processing and use information, such as voluntary data collection programs. However, voluntary industry efforts are not uniformly reliable for collecting data, and the Agency generally cannot ensure that data submitted under voluntary efforts will be complete and accurate. For example, the UEIP was undertaken by EPA in partnership with industry to collect relatively detailed information on 60 high production volume chemicals. EPA received data for 48 of the 60 UEIP chemicals. Many of the forms received for those 48 chemicals were not completely filled out, and only a subset of manufacturers submitted data. Thus, while the information that EPA received was quite useful, it was insufficiently complete for the purposes to which IURA information will be put. EPA's experience with UEIP is an indicator that exposure data collected under a voluntary effort are likely to be uneven and fall short of meeting EPA's needs.

iii. *Validity of the data*. Another commenter had specific concerns about the validity of the worker exposure data and felt that an auditing program would be necessary to generally ensure an acceptable level of quality for data collected under IURA.

EPA agrees that validated exposure data are the most useful for the full range of Agency risk assessment activities. However, EPA's experience with similar data collection efforts such as TSCA's New Chemicals Program demonstrates that the type of data EPA is collecting under IURA are sufficient for the purpose of screening to prioritize follow-on efforts for risk assessment and management. A rigorous validation process for all IURA exposure-related information would impose significant additional burdens on industry and the Agency that would likely outweigh the benefits accruing to the screening process. As discussed in Unit III.A.1., EPA exposure and risk evaluations are often iterative, with screening level assessments succeeded by more intensive and data rich assessments, as indicated by the screening level assessments and as data become available. The IURA data will be useful to the Agency in evaluating potential exposures and risks, serving as indicators as to what levels and types of exposures from which chemicals need further review.

b. *Will the Agency use the data in a timely manner*? Many commenters questioned whether EPA would be able to make effective and timely use of IURA processing and use information, stating that the large amount of data submitted would overwhelm the Agency. EPA acknowledges that IURA will generate a significant quantity of new data that EPA has not handled under past IUR data collections. However, EPA has carefully designed

the data collection to facilitate efficient data management and use. Data collected through IURA will be put into a relational data base format, which can be easily searched, compared, and used. The collection of data organized by codes, rather than narrative information presented in an unstructured manner, lends itself to such a data base format. In addition, providing for electronic IURA submissions allows data to be entered into the data base more accurately and expeditiously, resulting in a quick turnaround between the submission of the data to the Agency and the availability of the data for use. The Agency anticipates that approximately 95% of all reports will be submitted electronically or on disks, as opposed to hard copies. This compares with 70% that were submitted on disks in 1998. The IURA will facilitate EPA's information management and the data will be available quickly for the Agency's and others' use.

3. *Why doesn't EPA use other available sources of data or mechanisms to collect the data sought under IURA*? EPA requested comments on specific mechanisms or data sources it could use to obtain needed exposure-related information with greater ease and less burden to industry. Commenters responded with a variety of sources, ranging from current data collection mechanisms within EPA (such as TSCA 8(a) PAIR, UEIP, and cooperative approaches) to public data sources such as the Hazardous Substances Data Bank (HSDB) (HSDB is a toxicology data file on the National Library of Medicine's (NLM) Toxicology Data Network (TOXNET)). In addition, many commenters stated that EPA has not made effective use of the exposure-related data it has collected already under current or prior programs. For example, they stated that data collected under two other TSCA rules - the PAIR and the Comprehensive Assessment Information Rule (CAIR) rules - have not been used effectively to support Agency risk assessment or risk management decisions. Commenters went on further to say that under the voluntary UEIP, EPA was furnished exposure-related data on 60 HPV chemicals (actually only 48), but only two reached the initial risk assessment stage.

The alternate data sources commenters described were generally sources that EPA had already evaluated in its analysis for the proposed rule or with which EPA was otherwise familiar. EPA explored a wide variety of public data sources, as demonstrated in the following: ''Inventory Update Rule (IUR) Amendments Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening'' (Ref. 14), ''Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule'' (Ref. 26), and ''A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA'' (Ref. 27) (see also Unit V.B.5. of the proposed rule at 64 FR 46780)). For the most part, commenters did not identify new sources or provide additional information to support the assertion that these alternate data sources provide the information that EPA proposed to collect under IURA. After considering the information provided, EPA believes the decision not to use an alternate data source as a replacement for IURA is still sound. The Agency may, however, evaluate an alternate source for individual chemicals as part of its consideration of a particular chemical under the new exemption process established in the final rule.

EPA has spent considerable effort and resources evaluating other data sources that could potentially provide the accurate and up-to-date information that the Agency needs. A primary consideration, as mandated by TSCA, was not to subject industry to unnecessary or duplicative reporting. The exposure information sought under IURA is not currently accessible to EPA. Although some useful exposure-related data exist in some sources, the data are insufficient for the purposes to which IURA data will be put, typically because they are neither timely or detailed enough. Without IURA, EPA has difficulty efficiently screening potential risks posed by approximately 4,000 higher production chemicals on the TSCA Inventory.

Commenters stated that, if EPA were to have specific concerns about information collection for substances or categories of substances, the selective use of TSCA section 8(a) PAIR (40 CFR part 712) reporting would be more cost effective than requiring all manufacturers exceeding a production trigger to report manufacturing, processing, and use information. EPA disagrees with the suggestion that PAIR rules would be an efficient or cost effective way to compile a data base to allow the relatively large-scale risk screening of chemicals on the TSCA Inventory. PAIR is a very useful data collection tool when one or a small group of chemicals is targeted for risk assessment; however, PAIR is limited when collecting information on a large number of chemicals. Additionally, the PAIR rule has fewer, less definitive data elements than IURA, is a one-time collection versus the recurring collection of IURA, and will not provide data sufficient to meet the goals of IURA. Use of PAIR rather than IURA would force EPA to set risk screening priorities based on hazard and production volume alone, or in response to requests from others. As discussed in the document entitled ''A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response To CMA'' (Ref. 27), this approach greatly hinders EPA's ability to make effective and efficient risk management decisions.

EPA plans to continue using existing data sources and information sets. For example, EPA has used data previously collected under PAIR, CAIR, and the UEIP in a variety of ways, such as to support TSCA section 4 test rule analyses, to provide analyses for the Agency's efforts under the OECD SIDS program, and in support of international efforts (Refs. 18 and 27). However, the existing sources are generally best used when conducting a more detailed risk assessment of a specific chemical of concern, rather than preliminary risk screening of a relatively large set of chemicals. The IURA submissions will provide a consistent set of screening level exposure data that will allow EPA to better identify on a relative basis the chemicals of highest priority for further risk evaluation. EPA will use IURA data to identify those specific chemicals which are of potential concern and need follow up assessment. For instance, IURA exposure data integrated with HPV Challenge Program hazard data will provide the input needed to effectively develop risk-based priorities for more detailed assessment of chemicals. Once EPA has determined that a specific chemical (or group of chemicals) has sufficient potential for exposure or risk to warrant further assessment, the Agency will use the other information sources and data gathering tools as appropriate.

4. *Can TSCA information be used for right-to-know purposes*? Some of the commenters stated that TSCA does not authorize EPA to promulgate IURA based in part on EPA's goal of providing ''right-to-know'' information to the public, non-governmental entities and private organizations. In addition, some commenters noted that OSHA and other agencies have their own authorities to collect information on chemicals.

TSCA contains many of the principles embodied in the right-to-know concept. For instance, TSCA section 14(b) specifically authorizes EPA to disclose health and safety data collected under the statute. TSCA section 14 reflects the legislative determination that certain TSCA data should be available to the

public and interested parties. In addition, sections 4, 5, 6, as well as section 21, for example, provide opportunities for public participation in chemical management decisions. Participation must be meaningful, and to be meaningful the public must have access to TSCA non-confidential information.

TSCA was designed in part to address the lack of health, safety, and exposure information government agencies and the public faced in dealing with chemicals. See, H.R. Rep. 94-1341 at 6 (1976), reprinted in Legislative History of the Toxic Substances Control Act, at 414 (1976) (''Present authorities for protecting against and regulating hazardous chemicals are fragmented and inadequate . . . Most significant among the deficiencies are . . . (3) No authority exists for collection of data to determine the totality of human and environmental exposure to chemicals.''). TSCA was seen as a way of providing federal agencies and the public with access to health, safety, and exposure data so that the risks of chemical substances could be more fully evaluated and understood. See, Statement of Sen. Hartke, Cong. Rec., March 26, 1976 [S4397- 4432], reprinted in Legislative History of the Toxic Substances Control Act, at 218 (1976) (''[T]he essential element of this legislation is that it has attempted to provide for the individual- not only who works, but for the rest of American society- the right to know what is in store as far as the toxicity of the chemicals is concerned.''). Congress envisioned TSCA as a tool for providing the public and others with health, safety, and exposure information about chemical substances.

Finally, TSCA does not limit the use or disclosure of data (except if data are considered confidential) collected under the statute. Congress drafted TSCA in part to provide basic health, safety, and exposure information to other federal agencies, as well as state, local and international governments. TSCA provides several mechanisms--TSCA sections 9, 10, and 12 for example--for sharing health and safety data among various levels of government. These sections again demonstrate TSCA's role as a tool for gathering and disseminating information about chemicals.

B. Comments on Specific Data Elements

1. *Manufacturing information*—a. *Physical form.* EPA requested comment on its proposed requirement that submitters report the physical form of a chemical as it leaves the site of manufacture. Several commenters suggested variations on the specifics of physical form reporting, but generally agreed with reporting the physical form as the chemical leaves the site of manufacture. For instance, one commenter suggested expanding the types of physical forms that can be reported. EPA has determined that the six categories as proposed (see § 710.52(c)(3)(viii) of the regulatory text) will be adequate for risk screening purposes, and is not adding additional physical form categories at this time. Experience with the same six physical form categories as part of EPA's exposure screening assessment of over 20,000 chemicals in its New Chemicals Program indicates that the categories of physical forms that EPA is using under IURA will be adequate.

Other commenters recommended that EPA allow submitters to report more than one physical form for each reportable substance, because a substance may leave a site in more than one physical form. EPA agrees with this comment and is requiring in this final rule that submitters report all physical forms of a substance when the substance is sent off-site. Reporting on all physical forms in IURA will lead to a better assessment of exposure to a chemical substance. For example, processing a fine, nonagglomerating powder could result in occupational exposure by inhalation of chemical dust. Processing the same chemical as a liquid solution would eliminate, or at least reduce, the inhalation risk (the liquid could become an aerosol and be inhaled, depending on the processing activity). By combining data elements on the physical form of a chemical substance, its production volume, and the fraction directed to each industrial processing or use activity, a screening estimate of the potential exposure associated with manufacturing or processing of a chemical substance can be derived. The resulting exposure assessment will be more representative and less conservative than if the physical form(s) were unknown. For these reasons, EPA is requiring the reporting of all physical forms in which a chemical substance leaves the manufacturing site.

b. *Concentration.* EPA originally proposed to require the reporting of both maximum and average concentrations of each reportable chemical substance at the time the substance is sent off-site. A number of commenters felt that this information would be difficult to report for the following reasons: Chemicals may be used in many product formulations at a given plant site and there may often be no consistent average or maximum concentration of an individual chemical across these formulations; such information does not reside in any currently available data bases and would need to be generated for IURA reporting (which would be particularly difficult with respect to average concentration information); and average and maximum concentrations may vary in product formulations during different IURA reporting cycles. Commenters suggested that maximum concentration information will be misleading if only a small amount of the reportable chemical substance is made available commercially at that concentration, while the bulk of the total quantity leaving the site has a lower concentration. They also indicated that determining average concentration requires a complicated calculation which falls outside the scope of ''reasonably ascertainable'' information. Commenters suggested that average concentration can be calculated by product or by the weighted average of each product, and each of the calculations can result in tremendously different answers.

The Agency has determined that average concentration information is not critical for purposes of screening level exposure assessment and has not included this element in this final rule. Screening level review is typically meant, in part, to serve as a method of identifying chemicals that even at their maximum concentration are less likely to present a risk to human health or the environment. Average concentration information cannot be used to make such a determination.

EPA recognizes that the concentration of an IUR reportable chemical may vary from shipment to shipment leaving a submitter's site, or when reacted on-site to produce a different chemical substance. However, maximum concentration is to be reported in wide ranges and not specific numbers, thereby alleviating the need to determine specific concentrations. Additionally, EPA does not intend for submitters to go to great lengths to determine what maximum concentration ranges to select for IUR reporting. Instead, EPA is simply requiring that submitters select a range of concentrations from a list of given ranges. The ranges from which submitters must select are: Less than 1% by weight; 1–30% by weight; 31–60% by weight; 61–90% by weight, and greater than 90% by weight.

One commenter was concerned that EPA did not specify whether it would require submitters to conduct specific chemical testing or statistical analysis in order to report concentration data, or whether submitters should merely estimate concentrations. In addition, the

commenter was unsure whether a submitter should report the maximum concentration level for each product it manufactures/imports, or simply estimate the overall maximum concentration of the chemical substance. EPA recognizes that concentration data may vary from product to product and from shipment to shipment, and may be difficult to report in some instances, particularly in product formulations. EPA is not requiring the reporting of concentrations in all products and formulations but rather only one maximum concentration, regardless of the chemical substance's physical form(s) or product formulation(s). Because concentration information will be reported in ranges and not as individual values, this information or at least an estimate should be known to or reasonably ascertainable by most submitters. Submitters are not expected to conduct chemical testing or statistical analysis beyond any testing or analyses already done by the submitter as part of normal operations in order to report maximum concentration information. EPA anticipates that chemical importers will frequently receive maximum concentration information from their suppliers, and manufacturers will obtain this information from samples analyzed for quality control. This information is often found in the physical property or hazardous constituents sections of the MSDS.

2. *Industrial processing and use*. The Agency received three comments regarding the IFCs to be reported by submitters that have plant sites at which 300,000 lbs. or more of a reportable chemical substance are manufactured. The first comment questioned how the IFCs would apply to chemicals with multiple industrial uses. The second comment suggested that the Agency provide submitters with a ''free response'' option if their industrial function is not represented among the IFCs. The third comment stated that the IFCs proposed by EPA were adequate.

Submitters are required to report up to 10 unique combinations of processing or use categories, IFCs, and NAICS codes (see § 710.52(c)(4)(i)(A), (c)(4)(i)(B), and (c)(4)(i)(C) of the regulatory text). In making their selection from among the IFC codes, submitters must determine which IFC best represents the specific industrial use of the reportable chemical within a given NAICS code/processing and use category. The Agency will provide examples of how to select which code ''best represents'' an industrial use in the instruction manual that will be available to all submitters (see § 710.59 of the regulatory text). Submitters may report multiple IFCs for the same NAICS code, and multiple NAICS codes may be paired with the same IFC. Unit II.F.7. provides further information on reporting industrial processing and use information.

The set of IFCs adopted by EPA at § 710.52(c)(4)(i)(C) encompasses the vast majority of uses for chemicals subject to IUR reporting. Rather than include all possible industrial functions, EPA selected categories based upon information developed due to other Agency programs such as the TSCA New Chemicals Program and believes that the categories included in this final rule are sufficient for initial risk screening purposes. One commenter suggested that the submitter be allowed to supply a ''free response'' for an industrial function that is not on the EPA list. However, a ''free response option'' could result in a wide array of answers, which EPA would then have to group. The Agency believes the chemical manufacturer is best equipped to determine with which industrial function scenario the industrial processing and use data should be matched. If none of the categories fit, however, the submitter could report the ''other'' category. By aggregating similar uses under a single NAICS and a single IFC code, EPA will be able to more effectively characterize the risk associated with the totality of the production of each chemical substance. By requiring the submitter to identify the appropriate IFC code(s) from the provided list, EPA seeks to minimize the errors that could occur if the Agency, rather than the submitter, attempted to aggregate uses other than those identified in the prescribed list of IFCs.

3. *Commercial and consumer use*—a. *Commercial and consumer product categories*. In the proposed rule, the Agency requested comment on the appropriateness of the commercial and consumer product categories. Commenters had a range of opinions about the proposed categories. One commenter felt that EPA should adopt the use categories used by the European Commission (EC) (Ref. 28). Another commenter stated that the categories appeared to be adequate. A third commenter suggested that the ''C-19 Other'' category be deleted and that the Agency consider requiring the submitter to identify the specific use.

EPA is not changing the commercial and consumer product categories at this time, although the Agency may revisit these categories in the future should a need arise for more specific commercial and consumer use information. EPA has evaluated the EC's set of use categories and has determined that these categories blend functional use information with end use information. They therefore constitute a more complex identification system than the one that will be used under IURA. For the screening level purposes of IURA data, EPA currently believes that focusing on end use information alone for commercial and consumer uses provides the necessary level of detail for its screening level reviews. EPA is concerned that the use of EC's scheme for the commercial and consumer reporting would be overly burdensome for the current needs identified by EPA, due to the greater number of categories (55 EC categories versus 19 IURA categories). Further guidance on the relationship between EC and IURA categories can be found in the instruction manual for IURA (see § 710.59 of the regulatory text) (Ref. 9).

In addition, the EC system does not appear to describe the commercial or consumer end uses in a way that meets the needs identified by EPA and targeted by IURA. For example, a chemical that is used as a propellant would be listed under the category ''aerosol propellants'' using the EC system. Such a listing would not provide the Agency with the information it needs about the type of commercial/consumer product in which the submitter uses the propellant (e.g., paint, a lubricant). For more information on EPA's commercial and consumer category analysis, see the document ''Inventory Update Rule (IUR) Technical Support Document Selection of Consumer and Commercial End-Use Categories'' (Ref. 29). EPA will provide examples of the types of products that fit into its commercial and consumer product categories in the instruction manual that will be made available to all submitters (see § 710.59 of the regulatory text).

EPA considered requiring submitters to identify the specific use of the product, rather than the use a miscellaneous ''Other'' category. However, the Agency prefers to require submitters to choose from among the commercial and consumer product categories provided at § 710.52(c)(4)(ii)(A) of the regulatory text in order to encourage manufacturers to more carefully consider the listed categories, as opposed to being allowed to provide their own specific description. In this manner, EPA can more effectively assign chemicals to the correct categories, and avoid guessing the appropriate categories because the Agency believes the chemical manufacturer is best equipped to determine with which commercial or

consumer category their product use best fits. By aggregating similar product categories, EPA will more effectively characterize the risk associated with the totality of the use of each chemical substance. Requiring the submitter to identify the appropriate product categories from the provided list will minimize the errors that could occur if the Agency, rather than the submitter, attempted to aggregate uses other than those identified in the prescribed list of product categories.

b. *Non-TSCA end uses.* Three commenters requested that EPA not only continue to exempt chemicals that are manufactured only for non-TSCA purposes (such as pesticides, drugs, cosmetics, etc.) from all IURA reporting, but also exempt manufacturers of IURA-reportable TSCA chemicals from the requirement that non-TSCA downstream uses be reported (such as use of a TSCA chemical by a downstream processor in making a pesticide, etc.). These commenters assert that EPA does not have authority under TSCA to implement requirements of this sort.

EPA agrees that substances that are manufactured only for non-TSCA purposes, as described in TSCA section 3(2)(B), are exempt from all TSCA requirements and are not subject to reporting under IURA. Therefore, substances that are intended at the time of manufacture to be used for non-TSCA purposes (e.g., as a pesticide, as a drug) do not have to be reported.

The Agency also agrees that submitters under IURA will not be required to report on the non-TSCA downstream uses of the TSCA chemicals that they manufacture. It is important to note that EPA was able to reach this conclusion without reaching the issue of whether it has the authority to require such reporting. Descriptions of IFCs (see § 710.52(c)(4)(i)(C) of the regulatory text) have been clarified to reflect the fact that they only include TSCA uses. For example, one of the IFCs is called ''Agricultural chemicals (non-pesticidal).'' The consumer and commercial product categories (see § 710.52(c)(4)(ii)(A) of the regulatory text) are also restricted to TSCA uses. An example of one of these categories is ''Lawn and garden products (non-pesticidal).'' This category includes chemicals such as compressed gasses in delivery systems for many pesticides used indoors and outdoors, and other intermediates, but does not include pesticides. Additionally, many lawn amendments such as fertilizers contain chemicals that may be regulated under TSCA, (e.g., surfactants).

c. *Exempt reporting of use information for chemicals in articles.* Two commenters believed that to the extent a submitter's reportable chemical is used in an article, the submitter should be exempt from the reporting of consumer and commercial end-use information (i.e., § 710.32(c)(5) of the proposed regulatory text). The commenters stated that there is no reason to believe that consumer exposure will result from chemicals in articles.

EPA does not agree that manufacturers of chemicals that are later incorporated into articles should be exempt from the reporting of consumer and commercial end-use information. Certain exposures do result from chemicals incorporated in articles. For example, potential dermal and inhalation exposures occur from chemicals incorporated into products in the category ''fabrics, textiles and apparel.'' Specific cases, such as formaldehyde from pressed wood products used in mobile homes or chlorinated flame retardants used on children's sleep wear, also demonstrate that potentially harmful exposures can occur from chemicals incorporated into articles.

d. *Usefulness of percent production data and maximum concentration data.* A commenter felt that in the case of consumer products in particular, it is unclear whether the percent production data and maximum concentration data required under § 710.32(c)(5)(i)(B) and (c)(5)(i)(C) of the proposed regulatory text would add any material information to the production volume information already required under the existing IUR. The commenter stated that the volumes of chemicals they will report as having been manufactured, and for which they will report maximum concentration information, are in the products the commenter sells. Therefore, the Agency will already have the needed production volume and concentration information and does not need to collect these particular data elements for consumer products.

Production volume and concentration information reported at the manufacturing site is typically different information than percent production volume and concentration in consumer and commercial categories. Often manufacturers will sell a chemical for multiple uses, in a variety of products, or the chemical will be used multiple times before reaching the consumer/commercial product. For instance, a manufacturer may report that a chemical is used in three different commercial and consumer product categories—20% of the manufactured production volume is used in category A, 35% in category B, and 45% in category C. Additionally, while the manufacturer sells the product at a certain concentration (say 90%), a final product may have a different concentration. For instance, the final product may contain only 5% of the chemical. The resulting potential exposure scenario associated with such a product would be very different from a scenario where the concentration in the final product is 90%. The Agency, therefore, is retaining the commercial and consumer percent production volume and maximum concentration data elements.

4. *General data elements comments—*
a. *Workers who are ''reasonably likely to be exposed'' to a reportable chemical.* EPA requested comment on alternative definitions of ''potentially exposed worker'' and ''reasonably likely to be exposed.'' Specifically, EPA requested comment on whether OSHA definition of ''employee'' in its hazard communication standard (29 CFR 1910.1200(c)) is more appropriate for use in IURA. 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. OSHA's hazard communication standard also defines ''exposure'' or ''exposed'' as the exposure 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.

One commenter stated that OSHA's definition of an employee is appropriate to identify persons reasonably likely to be exposed to chemical substances. This commenter stated that the Agency should broaden the definition of exposure in IURA to include potential (accidental or possible) exposures to chemical substances which workers may experience in the course of their employment. This commenter also stated that this is what worker exposure entails in the real world and to exclude some portion of those worker exposures, as EPA proposed, is inappropriate. A second commenter felt that persons who could be exposed to a chemical substance in foreseeable emergencies should be included in EPA's new definition for persons who are reasonably likely to be exposed to a reportable substance.

EPA has determined that the OSHA definition of ''employee'' does not provide a more appropriate standard than the one proposed and finalized in IURA. Whereas OSHA wanted to provide all persons who could foreseeably be exposed to a chemical substance with knowledge of the potential hazards of that chemical, EPA is seeking to specifically identify those persons routinely exposed to chemical substances and for whom engineering controls and personal protective equipment are likely to provide the greatest benefit. The definition adopted by EPA for a person ''reasonably likely to be exposed'' in this rule will target those individuals who routinely have the potential to be exposed to chemical substances, and for whom chronic risks are greatest. This definition provides more useful and realistic information for the risk screening purposes for which EPA envisions IURA data will be used.

b. *Personal protective equipment*. EPA requested comment on whether the Agency should collect information on the use of PPE during the manufacture of chemicals reported under IURA. Several commenters stated that EPA should not collect PPE information for the purposes of risk screening. After reviewing these comments, EPA agrees that collecting information on the availability of PPE would not enhance the initial risk screening process, and has determined that this data element should not be added to the IUR as part of this rulemaking. Because EPA cannot ensure that protective equipment will be available to all employees and, if available, will be used properly in a well managed hygiene program, the potential risk encountered in the manufacture, processing, or use of a chemical substance is initially assessed by EPA in the absence of PPE information. The IURA is designed primarily to collect only screening level information. Inclusion of PPE in risk assessment would require collection and integration of location-specific information on physical conditions and the PPE used, and would greatly complicate the risk assessment. This type of information is more likely to be included in assessments more detailed than the initial risk screening assessment for which IURA information will be used.

A commenter suggested that EPA use PPE information as a way to submit lower estimates for various IUR data elements, such as the number of workers. For the reasons provided in the previous paragraph, EPA will not use PPE information to lower the estimates of workers reasonably likely to be exposed. Because the reporting of PPE information would not contribute to the initial risk screening process and would impose an additional burden on persons reporting under IUR, EPA is not including information on PPE in the reporting requirements for this rule.

c. *Metric system reporting*. Under IUR, data are currently reported using the U.S. customary system of measurement units (e.g., pounds and yards). EPA requested comment on changing reporting requirements to require metric system reporting instead (e.g., kilograms and meters). Two commenters suggested that EPA convert to metric system units or at least give submitters the option of using either metric or U.S. customary units. One commenter requested that EPA continue to require the use of U.S. customary units or give submitters the option of reporting in either metric or U.S. customary units. EPA has decided to continue to require the use of the U.S. customary system because at least in the short term, this allows the IUR data base to remain compatible with other Agency data bases, especially TRI, which also typically use the U.S. customary system. EPA believes allowing for reporting using either the U.S. customary or metric systems of units would create confusion and increase reporting and administrative error. EPA may revisit this issue in future IUR amendments.

C. Reporting Universe Comments

EPA received a variety of comments concerning which chemicals and sites should be subject to reporting and recordkeeping requirements.

1. *Chemical categories undergoing changes in reporting status*. In the IURA proposal, EPA created exemptions from reporting for several groups of chemicals that would otherwise be IUR-reportable. The IUR currently contains full reporting exemptions for inorganic chemicals, polymers, microorganisms, and naturally occurring chemicals. EPA proposed to modify these exemptions by: (1) Requiring partial reporting for inorganic chemicals in lieu of the existing full exemption; (2) creating a partial reporting exemption for chemical substances termed ''petroleum process streams'' for purposes of reporting under IURA; and, (3) creating a full exemption for certain forms of natural gas. EPA also requested comment on the creation of additional exemptions, but asked that commenters provide a clear supporting rationale for creating such exemptions.

a. *Inorganic chemicals* - Many commenters submitted comments about the removal of the full exemption for inorganic chemicals.

EPA originally created the inorganic chemical exemption because it believed that the hazard potential of many inorganics was ''relatively well-established'' (50 FR 9944, 9947, March 12, 1985) and that hazard information alone was sufficient for prioritization within inorganic chemical substance risk assessments. 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. The Agency no longer believes that chemical hazard information alone provides a sufficient basis for prioritization for these purposes. As a result, the former basis for this exemption is no longer applicable.

i. *Why does the Agency need basic IUR information on inorganic chemical substances*? During interagency review prior to proposal it was suggested that EPA first collect the IUR information in §§ 710.52(c)(1), (c)(2), (c)(3), and 710.58 of the regulatory text (Parts I and II of the revised Form U) on inorganic substances before collecting the processing and use information in § 710.52(c)(4) of the regulatory text (Part III of the revised Form U). It was thought that partial reporting would allow EPA to become generally familiar with the production volumes of inorganic chemicals, and would permit manufacturers of these substances to familiarize themselves with the most basic IUR requirements before being required to comply with the processing and use data requirements. Many commenters stated that EPA had not demonstrated the practical utility of collecting basic information on inorganic substances. Other commenters felt the Agency should collect these data and that inorganic chemicals should not have had an exemption under IUR.

EPA uses basic IUR information in a wide variety of ways (as described in Units II.C. and E.) and expects the basic IUR information on inorganic chemicals to be used in similar ways. For example, EPA used IUR information in the HPV Challenge Program (see http://www.epa.gov/opptintr/chemrtk/volchall.htm) to identify chemicals produced in aggregate national volumes of one million pounds or more. The HPV Challenge Program has not been able to include inorganic chemicals as EPA did not have the necessary production volume information on the inorganic chemicals produced in or imported into this country. Additionally, the TSCA Interagency Testing Committee (ITC) has encountered difficulties in its attempts to identify inorganic chemicals for recommendations to EPA for testing or other further evaluations due to the lack

of even the most basic IUR data for these chemicals (Ref. 30).

ii. *Why is EPA phasing in reporting for inorganic chemical substances*? EPA requested comment on completely removing the inorganic chemicals exemption, requiring reporting of all of IURA information, including the information described in § 710.52(c)(4) of the regulatory text on inorganic chemicals manufactured in volumes of 300,000 lbs. or more at a site. Some commenters supported phased-in reporting of this information, where EPA would maintain a partial exemption (i.e., requiring the reporting of all of IURA information except the information in § 710.52(c)(4)) for the first submission period only and would require full reporting in subsequent submission periods. EPA agrees with this approach because it provides new submitters with an opportunity to become familiar with basic IUR reporting, allows EPA to become familiar with the current inorganic chemical industry, and provides basic production information in the first submission period. Requiring full reporting for inorganic chemicals in subsequent submission periods provides EPA with the processing and use exposure-related information needed to continue efforts begun with the first reporting year information.

EPA's primary use of both the basic data collected during the first submission period and the additional exposure-related data collected during subsequent submission periods will be to identify priority TSCA chemicals for more detailed information gathering, risk assessment, and risk management in order to develop targeted programs to protect human health and the environment. Screening chemical risks generally requires a combination of both hazard and exposure information. The absence of exposure-related data for inorganic chemicals, beyond even the basic production data collected during the first submission period under IURA, would severely limit the usefulness of IURA data for risk screening. See Unit III.A.1. for further discussion of additional uses of IURA exposure-related data.

While some commenters supported the phasing-in approach, other commenters suggested that EPA review the information collected on inorganic chemicals under the partial exemption and collect additional information on these chemicals through a future rulemaking. Commenters suggested a variety of ways to collect this additional information, including specifically listing chemicals that would be subject to future IUR collections or using PAIR. However, EPA's experience with using information from other sources or collecting information using PAIR has demonstrated that this approach is insufficient, as discussed in Unit III.A.3.

iii. *Why doesn't EPA use already available information on inorganic chemical substances*? Commenters stated that the inorganic chemicals data that EPA needs to conduct screening level risk assessments are already available from a variety of sources, including the USGS's annual reports on mineral production, health assessment documents prepared by the Agency for Toxic Substances and Disease Registry, studies by OSHA, the TRI compiled by EPA, and literature published by trade associations. EPA closely examined these data sources, and concluded that, while useful, these sources are inadequate to meet the Agency's data needs for inorganic chemicals.

Some of the suggested data sources pertain to naturally occurring substances which are exempted from reporting by a provision in IUR that EPA has not proposed to change, i.e., 40 CFR 710.26(a)(3), which is codified as § 710.46(a)(3) for IURA. Many of the remaining data sources identified by commenters pertain to metallic alloys or studies of a single metal species and do not include information on the multiplicity of pigments, flocculating agents, oxidants, photochromic salts, flame retardants, catalysts, and other inorganic compounds for which data are sought through IURA. In some cases, the data sources are one-time collections of information and therefore would not provide current information on the inorganic chemical industries. Others, although revised from time to time, do not identify the chemicals with sufficient specificity, do not identify the manufacturing site or a technical contact, and/or do not provide information on the use of the inorganic chemical. In sum, the data sources identified by commenters and by EPA are not sufficient to provide the information sought through IURA. EPA has consulted with USGS to investigate whether the USGS annual survey of approximately 80 minerals could be amended to better serve as a source for use and exposure data that could be used in place of IURA for those minerals (Ref. 31). EPA plans to identify and initiate dialogues with other federal agencies about collection activities that have the potential for generating additional federal paperwork burden reductions, particularly related to the IURA. The new exemption process established in the final rule provides an opportunity for EPA to consider alternate sources of information for individual chemicals. EPA is extremely sensitive to the PRA's directive for federal agencies to reduce unnecessary burden, and will continue to consistently strive to find areas in which burden can be decreased to the maximum extent practical, as well as carefully evaluate new or revised information collections to ensure that the Agency's informational needs are met with the minimal burden possible. Although none of the identified alternate sources appear to be sufficient to replace IURA, EPA believes that an alternate information source could provide sufficient information for a particular chemical. EPA is also willing to work with other agencies to perhaps resolve differences in the various information collection activities in an effort to reduce overall reporting burden on industry.

Additional discussion of the applicability of available data sources is found in ''Summary of EPA's Responses to Public Comments Submitted in Response to Proposed TSCA Inventory Update Rule Amendments'' (64 FR 46772) (Ref. 18) and in ''Inorganic Chemicals: Sources of Information Suggested by Commenters to the Proposed Inventory Update Rule Amendments'' (Ref. 32).

b. *Partial exemption for petroleum process streams*. EPA proposed a partial exemption from IURA reporting for certain chemical substances that the Agency is calling ''petroleum process streams'' for purposes of IURA and requested comment on duplication of reporting under the information collections conducted by DOE's Energy Information Administration (EIA) through EIA forms EIA 810, EIA 816, and EIA 64A. 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. Operators of domestic natural gas processing plants must complete form EIA 64A to provide an annual report of the geographical location and geological formation of natural gas liquids production to DOE. In the IURA proposal, EPA stated its intention to work with DOE to identify potential duplication and to further investigate the potential usefulness of DOE's information collections in fulfilling EPA's statutory obligations under TSCA.

One commenter stated that EPA could use the DOE data along with other supplemental information sources to generate the type of petroleum process stream information that IURA proposed to collect. Several commenters also stated that the proposed IURA reporting would be duplicative of DOE reporting for certain chemicals, particularly fuel oil #2 and kerosene, and that EPA should therefore fully exempt those chemicals from reporting under IURA.

EPA has investigated the information collection conducted by DOE through EIA forms EIA 64A, EIA 810, and EIA 816, and has determined that chemical substances are not sufficiently identified for EPA's purposes in the DOE reports. For example, many of the chemical substances in the DOE reports are identified by nomenclature other than the CAS nomenclature used by EPA for TSCA purposes, are identified in broad categories, or are not identified by CAS number. Many of the chemical names used by DOE are either generic or represent groups of chemicals. For example, distillate fuel oil, reported on EIA Form 810, may refer to several chemicals on the TSCA Inventory, such as fuel oil #2, fuel oil #4, or fuel oil #6. This lack of specific identifier information means that EPA and others cannot distinguish which information collected by DOE is attributable to which chemical. More specific identification is needed to attribute the appropriate hazard and physical and chemical properties to the petroleum stream.

The DOE information also lacks important exposure components and identifiers that are necessary for exposure and risk screening activities. For example, the DOE information does not contain the number of workers reasonably likely to be exposed to a chemical or the maximum concentration of the chemical. In addition, it may be difficult to discern from the DOE data if a petroleum process stream is used as a solvent in a consumer product or as a combustible fuel. This is an important distinction because the likelihood of exposure to a petroleum process stream depends on its use. These data are needed elements that will fill a vital data gap in chemical risk screening.

Several persons commented that there is no need to collect exposure-related data for petroleum process stream manufacturing operations because physical hazards existing at many sites currently necessitate extensive safety precautions that limit worker exposure. Discussed in more detail in Unit II.F.1.b.

c. *Exemption for certain forms of natural gas.* EPA proposed that six natural gas substances be fully exempt from reporting under IURA. In addition, EPA requested comment on whether reporting for the six substances should be required in upcoming submission periods and whether they were the appropriate natural gas substances for inclusion in the proposed exemption.

Commenters expressed support for the full exemption of the six natural gas streams listed in the proposed IURA. These commenters also recommended adding fuel oil #2, kerosene, methane, ethane, propane, butane, pentane, and hexane, and liquefied natural gas to the full exemption list. The commenters stated that an exemption is warranted for these chemicals because: (1) DOE already requires annual and monthly reports for the chemicals which contain the same information requested by EPA; (2) the chemicals are similar in chemical composition to the six chemicals EPA proposed to exempt; (3) their chemical structure and identity remain the same throughout processing; (4) a similar amount of data is available for these chemicals as for the six chemicals EPA proposed to exempt; and, (5) a similar number of TSCA reports are filed for these chemicals as for the six chemicals EPA proposed to exempt.

EPA has retained the exemption for certain forms of natural gas as proposed. Adequate IUR information has been collected on the six chemical substances to fulfill EPA's and other IUR information users' current needs. EPA will take action to revoke this exemption if circumstances warrant in the future.

Liquefied natural gas, which is a form of natural gas (CAS No. 8006–61–9), is covered under the natural gas exemption. EPA did not include ethane, methane, propane, butane, other paraffinic hydrocarbons, fuel oil #2, or kerosene in the list of substances included in the natural gas exemption because they are not just isolated components of natural gas but are also chemical substances which can be produced from other source materials, chemical process streams, feedstocks, or reactants. These alkanes have significant uses in chemical manufacturing, including the production of ammonia and methanol from synthesis gas derived from methane, thermal cracking of ethane/propane mixtures to produce ethylene, and vapor-phase oxidation of n-butane to produce maleic anhydride. At present, there is not a sufficient basis to conclude that data on all significant uses of these alkanes are adequate.

EPA did not rely on the data contained in the DOE reports discussed in Unit III.C.1.b. in its creation of the new exemption for certain forms of natural gas. While some useful information for these chemicals is included in the DOE reports, it is insufficient for exposure or risk screening (see Unit III.C.1.b.). Downstream processing and use exposure information collected through IURA for these chemicals will not duplicate information collected by DOE.

2. *Exemption of additional groups of chemicals from IURA reporting or from the reporting of specific data elements.* EPA requested comment in the proposed rule on the selection of chemicals that might be exempted from reporting under IURA and on specific criteria to distinguish these chemicals from those that remain subject to reporting. EPA received many industry comments in favor of creating a new exemption for chemicals that may be considered to be ''low priority,'' but commenters did not indicate standard criteria for establishing such exemptions. However, in response to these comments and comments received during interagency review, EPA created a partial exemption (i.e., an exemption from the reporting of information required under regulatory text § 710.52(c)(4)) for certain chemicals for which the collection of processing and use information is currently of ''low interest.'' This new partial exemption is intended to improve IURA's efficiency and effectiveness. EPA has established a process by which future changes to the chemicals included in the partial exemption can be made after careful examination of the totality of information available for the chemical substance, including but not limited to the considerations provided in § 710.46(b)(2) and discussed in Unit II.F.1.d. This partial exemption also provides additional benefits in reducing the potential reporting burden of IURA for certain manufacturers of these chemicals. The inclusion of a chemical substance under this partial exemption does not address the potential risks of a chemical. This partial exemption is solely intended to provide a tool to assist the Agency in better managing the collection of processing and use information under IURA. See Unit II.F.1.d for a discussion of the exemption and the process to add or remove chemical substances from the exemption.

In addition, commenters suggested classes of chemicals for exemption. EPA has determined that none of these suggested exemptions can be implemented at this time, as described in the remainder of this section.

a. *HPV chemicals.* A number of commenters stated that industry is already providing EPA with sufficient hazard data via the HPV Challenge

Program (see http://www.epa.gov/opptintr/chemrtk/volchall.htm), as well as exposure data through other voluntary programs (e.g., International Council of Chemical Associations (ICCA) data collections and UEIP). Therefore, providing exposure-related information on HPV chemicals via IURA would be duplicative and unnecessary.

The Agency recognizes that a variety of voluntary and regulatory efforts to collect hazard data are underway, such as the voluntary HPV Challenge Program. However, the scope and expected output from the HPV Challenge Program differ markedly from those anticipated under IURA. The HPV Challenge Program centers on providing basic hazard data for HPV chemicals, most of which will also be IURA-reportable chemicals. The IURA focus is on gathering exposure-related information for moderate and high volume chemicals in a wide range of industrial operations, involving multiple sites and covering manufacturing, processing, and use of the chemical substances.

The Agency is unable to limit its IURA information collection efforts to HPV chemicals alone, for several reasons. The Agency could not know definitively which chemicals are HPV substances in any particular IURA reporting cycle as of that reporting year. A chemical substance meets the criteria for an HPV chemical by meeting a one million pound national production volume threshold, based upon the aggregate production volume in the nation (as reported to IUR). Production volumes can vary significantly over a 4–year reporting cycle, and it is not uncommon for chemicals to rise above or fall below the HPV threshold each reporting cycle. For instance, EPA used 1990 IUR reporting to identify approximately 2,800 HPV substances. An additional 500 substances which were not HPV chemicals in 1990 were identified as being HPV via the 1994 IUR production volume data. The IURA collection could be limited to the HPV Challenge Program chemicals (i.e., the baseline set of chemicals for the program, consisting of chemicals that were HPV according to 1990 IUR information). However, that restricts IURA's ability to supply screening level exposure information to only those HPV chemicals. This would severely limit the usefulness of IURA over time, as the universe of chemicals that were HPV in 1990 will not be the same universe of chemicals that are HPV in future years, and would compromise the Agency's broader responsibility for risk screening.

b. *Existing Chemicals Program ''low concern'' chemicals*. Commenters recommended that the chemicals previously determined by EPA to be of low concern via the Existing Chemicals Program be exempt from reporting under IURA. However, commenters did not provide sufficient criteria that would clearly distinguish exempted chemicals from others subject to IUR reporting. EPA cannot create exemptions without a clear basis or justification. During the development of these amendments, EPA considered exempting chemicals previously reviewed by the Existing Chemicals Program, but was unable to develop standard criteria for such an exemption (See Ref. 33 and Unit IX.3. of the proposal preamble, at 64 FR 46794). Under the Existing Chemicals Program, no standard criteria were used for determining which chemicals were lower priority, because in the course of the program many different chemicals involve unique risk assessment or risk management issues. For example, many chemicals were analyzed within a specific use, and other uses were not examined. As an alternative to this approach, EPA developed a partial exemption for chemicals which are determined to be of low current interest for purposes of IURA processing and use information reporting, based on considerations described in Unit II.F.1.d., and identified an initial list of chemicals currently covered by the partial exemption (Ref. 5).

c. *Organization for Economic Cooperation and Development (OECD) chemicals*. Commenters recommended that the chemicals for which EPA has a minimum set of hazard and exposure data, such as OECD's SIDS chemicals that have completed the SIDS process, be exempt from reporting under IURA. Commenters also suggested that chemicals in the International Council of Chemical Association (ICCA) screening level data collection programs be included in this exemption.

EPA disagrees that data collection efforts through the OECD and ICCA programs provide sufficient exposure information to replace IURA information. Data collection efforts under the auspices of OECD and ICCA concentrate on the development of hazard assessments and generally provide only a small fraction of the exposure-related data called for under IURA. A goal of the ICCA Program is to process chemical cases through OECD's HPV SIDS Program, which develops hazard information for the program chemicals. As hazard data do not change from year to year, the data collection supports a one-time report. The IURA will provide current exposure-related information for risk screenings and preliminary assessments. Exposure information, as collected under IURA, will vary from reporting year to reporting year and therefore needs to be collected on a continuing basis. While the OECD HPV SIDS Program does not specifically disallow the collection of exposure information, the program does leave such collection to the discretion of the sponsor country (Ref. 34). Exposure information available via SIDS is therefore generally not specific to U.S. uses and concerns.

d. *Metals*. Various commenters stated that either metals as a group, or specific metals such as zinc and copper, should be granted special consideration for IURA reporting. Several commenters asserted that providing information on maximum concentrations is unnecessary for the metals, because they will generally have close to 100% concentrations when they leave the manufacturing site or whenever they are present in consumer or commercial products. Further, commenters indicate that the only exposure potential for these substances in commercial or consumer products will be dermal (not via other routes such as inhalation or ingestion). Additionally, a commenter stated that workers ''in proximity'' to or handling solid metal articles should not be considered to be exposed for reporting purposes, because the metal is in a form in which neither inhalation nor dermal exposure will occur. Other commenters believed that any IUR reporting on metals is unnecessary because ample information on metals production and exposure potentials is already available from other sources, such as the USGS, or because specific metals, such as copper and zinc, are beneficial to human health and therefore should be of no exposure concern.

Metals present some unique issues regarding exposure potential, and the information that will be collected under IURA on metals will do much to improve EPA's and others' knowledge about the uses and exposures associated with these chemicals. Not all metal-containing products are pure metal. For example, metal powders used in fine arts, metal pastes used in repairs, and commercial metallic paints contain varying percentages of metals. In addition, although some metals in trace quantities, such as chromium, are essential nutrients to plants and/or animals, in greater exposure concentrations these same metals can be harmful.

Because metals are ubiquitous and can be present in a variety of physical forms, different routes of exposure are possible. Chronic exposure to solutions

containing metals such as nickel may result in contact dermatitis. Milling metal parts containing antimony and beryllium creates dusts which, if inhaled, can result in acute chemical pneumonitis. Inhalation of fumes containing chromium resulted in an elevated incidence of bronchial carcinoma among workers in the U.S. chromate industry before the source of the exposure was recognized and corrected. Exposure by ingestion is of concern for metals that may enter water sources following improper disposal of used materials, for example. The use of cadmium in batteries for portable electronic devices, including computers, is increasing; long-term exposure to cadmium has a potential to cause kidney, liver, bone, and blood damage.

EPA has exempted submitters that would otherwise be subject to IUR reporting from reporting with respect to chemicals that are imported in the form of an article (see 40 CFR 710.30(b) and § 710.50(b) of the regulatory text). However, submitters that manufacture a reportable chemical and incorporate it into an article will continue to be subject to reporting under the IURA.

The Agency reviewed a number of sources that provide information about metals production and characteristics, including USGS data specifically noted by commenters (Ref. 32). The information, although useful for depicting global mining and production of the major commercial metals, is not comparable to the national scale and domestic exposures data that will be provided under IURA. Further, because metals are subject chemicals in many EPA programs, including the Great Lakes Binational Toxics Strategy; the revised drinking water standards; the revised emission standards for secondary metal refinishers; and the Waste Minimization National Plan, current information about domestic metals production and use will benefit many EPA offices and programs.

As indicated previously, EPA will be reconsidering individual chemicals for applicability under the new partial exemption, and plans to identify and initiate dialogues with other federal agencies about collection activities that have the potential for generating additional federal paperwork burden reductions, particularly related to the IURA.

e. *Other chemical groups*. Commenters suggested EPA exempt a variety of additional groups of chemicals from either full or partial IURA reporting. These groups included fossil fuel combustion byproducts such as coal combustion products; fertilizers; substances encapsulated in a polymer matrix; pesticides; and certain chemicals outside the scope of TSCA jurisdiction (such as drugs). Commenters stated that exposures associated with fossil fuel combustion byproducts are already well known, and, with information currently being submitted to EPA and other federal organizations such as DOE, well beyond the amount needed for ''basic screening.'' Commenters argued that reporting on these byproducts under IURA would be duplicative (therefore unnecessary) and overly burdensome, especially because these chemicals are considered ''beneficially used in an environmentally sound manner'' by EPA's Office of Solid Waste (OSW). A parallel argument was made for fertilizers, in that certain commenters consider them to be well-characterized and generally ''safe.'' Similarly, a commenter believed encapsulated substances are of little concern, due to low exposure potentials for the encapsulated chemicals, as implied by the Agency's treatment of such substances under Significant New Use Rules (SNURs); the commenter believed that, when chemicals are secured within a polymer matrix, the SNUR requirements no longer apply. Commenters also stated that pesticides and other chemicals not subject to TSCA should be fully exempt from reporting.

Comments specific to these different groups of chemicals are addressed below.

i. *Fossil fuel combustion byproducts*. Commenters stated that fossil fuel combustion byproducts have been sufficiently studied for beneficial reuse to justify their full exemption from IURA reporting. They asserted that EPA's OSW had adequately reviewed data on these substances to allow their use as solid waste in situations where exposures were possible, such as in the case of soil amendments. The commenters believe that EPA offices such as OPPT and OSW must coordinate their efforts related to fossil fuel combustion byproducts prior to undertaking any actions under TSCA, and suggested that continued reporting on these chemicals would be particularly burdensome.

EPA disagrees with these comments. Review of the recent OSW Report to Congress on the subject of fossil fuel combustion byproducts (Ref. 35) indicates that these products can be hazardous to human health and the environment when mismanaged. These products not only typically contain heavy metals such as cadmium, chromium, lead, and mercury, but leachates from fuel combustion byproducts can contain significant concentrations of arsenic. Despite these concerns, OSW has decided to exempt these substances from regulation as hazardous waste when they are beneficially reused. While OSW was not able to identify damage cases or significant risks to human health or the environment associated with these types of beneficial uses based on available data, OSW plans to assess new information on risks as that information becomes available. The IURA will be instrumental in providing manufacturing, processing, and use data for fossil fuel combustion byproducts to enable OSW to monitor the potential risk associated with these chemical substances. Additionally, as with any chemical byproduct with a use, EPA in general needs information to be able to screen these chemicals for potential concerns outside of the OSW purview. Review of such contemporary data, as shared between OPPT and OSW, will allow EPA to make well-informed risk management decisions by constructing realistic screening level exposure profiles for these substances. These profiles could be adjusted as the production dynamics change between IURA reporting cycles. EPA believes the importance of accurate exposure-related data in formulating sound risk management decisions for fossil fuel combustion byproducts justifies the associated reporting burden.

ii. *Fertilizers*. Fertilizers that qualify for the inorganic exemption have not been subject to IUR reporting in the past. A number of commenters emphasized that, in general, fertilizers are chemicals whose risks have already have been well-characterized. According to the commenters, ample recent hazard and exposure data from studies conducted by EPA's OSW indicate that fertilizers generally are of low toxicity, and some constituents of major fertilizer types are ''safe'' because the exposure potentials are low. Further, as the commenter pointed out, recent SIDS program studies on urea, a common fertilizer, described the chemical to be ''of low priority'' for further investigation, thereby implying that the chemical poses little hazard to human health and the environment, and that adequate risk information is available. Commenters stated that because they believe the constituents are not harmful to human health or the environment, fertilizers should be exempt from downstream use and exposure reporting under IURA (i.e., a partial exemption from IURA reporting). Other commenters stated that fertilizers should be granted a full exemption from

IURA reporting, or that EPA should exempt certain fertilizers by CAS number. One commenter suggested that 20 substances be included in the fertilizer list (see list provided in Comment C4b-6 of the comment summary document, Ref. 18).

EPA does not believe the suggested IURA exemptions for fertilizers and fertilizer constituents are warranted at this time. The Agency does not agree with industry comments citing a 1999 EPA OSW risk evaluation on ''non-nutritive'' components in fertilizers as adequate justification for classifying fertilizers as ''safe,'' and therefore eligible for exemption. The OSW report addresses trace quantities of metal contaminants in those fertilizers (i.e., the non-nutritive elements), not the fertilizers themselves. A review of basic hazard identification guides, such as the Merck Index, the Condensed Chemical Dictionary, and Dangerous Properties of Industrial Materials, shows that exposure to many fertilizers and fertilizer materials, including those cited in industry comments such as anhydrous ammonia, potassium sulfate, and urea, can cause both reversible and irreversible adverse health effects ranging from acute to chronic. The availability of IURA exposure-related data will allow for the risk screening of chemicals used as fertilizers and fertilizer constituents to extend beyond environmental effects and aid the screening of risks to workers, consumers, and the general population. The Agency therefore believes it is appropriate to require reporting for fertilizers under IURA.

iii. *Encapsulated substances.* A commenter stated that the import volumes of IUR reportable components contained within compounded imported polymers should be exempt from IURA reporting. The commenter indicated that volumes of these encapsulated components are difficult to determine. Such components include antioxidants, colorants, lubricants, and stabilizers that are commonly used additives in polymer products. The polymers are sometimes manufactured by a foreign company and imported into the United States. The commenter stated that these additives, which are encapsulated in a polymer matrix, are typically present in the matrix at a few weight percent. The commenter's understanding was that when chemicals are secured within a polymer matrix, the SNUR requirements no longer apply, thus their suggestion was for EPA to treat such substances similarly under IURA.

The SNUR requirements in 40 CFR part 721 do not exempt substances encapsulated in a polymer matrix. Although chemicals incorporated into a polymer matrix are not subject to SNURs in certain limited circumstances, for example, when an individual SNUR specifically states that the SNUR requirements do not apply to such substances (see, e.g., 40 CFR 721.8160(a)), such chemicals are not otherwise generally exempt from SNUR requirements.

Although EPA appreciates the difficulty in ascertaining quantitative production information from manufacturers outside direct U.S. jurisdiction, exempting IUR reportable components encapsulated in a polymer matrix from IURA is not warranted. Not all polymers are inviolable. Additives such as colorants and lubricants, which can be hazardous to human health or the environment, can leach from the polymer matrix, resulting in subsequent exposures. Also, additives which are inherently insoluble in the polymer may migrate to the surface of the polymeric material and be released over time from the polymer. Under IURA, each non-exempted mixture component is reportable if imported above the stated thresholds. Reasonably ascertainable information can be used to estimate these import quantities.

iv. *Pesticides.* Some commenters stated that the Agency should exempt pesticide chemicals from reporting under the IURA, and also should exempt those substances outside the scope of TSCA, including drugs and cosmetics.

The original IUR did not require reporting for chemicals manufactured for non-TSCA purposes. Similarly, in IURA, amounts of an otherwise IUR-reportable substance that are intended at the time of manufacture to be used for non-TSCA purposes (e.g., as a pesticide, as a drug) do not have to be reported. For example, if a company were to manufacture 300,000 lbs. of an IUR-reportable substance, 170,000 lbs. of which were intended at the time of manufacture to be sold as a drug precursor, and 130,000 lbs. of which were intended at the time of manufacture to be used for a TSCA purpose, only 130,000 lbs. of the substance would have to be reported under IUR. The company would not have to report the processing and use information described in § 710.52(c)(4) of the regulatory text for that chemical at that plant site, since the company did not manufacture a total of at least 300,000 lbs. of the chemical at the site for TSCA purposes. Many substances, such as the pesticide active ingredient pentachlorophenol, are also used in industrial and commercial applications regulated under TSCA. In those cases, the chemicals will continue to be reportable under IURA.

v. *Food additives.* Commenters stated that low hazard chemicals, such as food additives, should be categorically excluded from the new reporting requirements. The commenter stated that food use substances, for example, are regulated by the Food and Drug Administration (FDA) and must either be generally recognized as safe (GRAS), the subject of a prior sanction, or the subject of a food additive regulation promulgated by FDA.

According to FDA's Office of Premarket Approval (OPA), food use substances for FDA's purposes are those that are added directly to food, and could inadvertently contact and be incorporated into food because of use in packaging material or in food processing. FDA does not evaluate chemicals for environmental effects--only for human health effects. The chemicals subject to FDA rules are not inherently low hazard in many cases. For example, substances such as plasticizers, lubricants, release agents, acids (e.g., hydrochloric acid), boiler water additives, and solvents (e.g., acetone and hexane) are included as food use substances. Furthermore, even direct (i.e., listed) GRAS chemicals can be of concern when used at industrial concentrations, such as sulfuric acid. Thus, as is true with other chemical substances, food additives can present a risk to human health or the environment depending on use and the resulting exposure pathways. EPA does not believe a categorical exemption for chemicals that may be used as food additives is warranted at this time. Again, such chemicals are only reportable under IURA to the extent that they are intended at the time of manufacture to be used for TSCA purposes.

3. *Thresholds.* EPA requested comment on the 300,000 lbs. threshold for reporting industrial processing and use, and consumer and commercial use information (required under § 710.52(c)(4) of the regulatory text). Commenters generally were supportive of having a second, higher reporting threshold for this exposure-related information. However, one commenter stated that the 300,000 lbs. threshold is too low, and that it should be set at one million pounds to coincide with the HPV Challenge Program threshold.

EPA considered chemicals with aggregate, nationwide U.S. production and importation volumes of one million pounds or more (based on 1990 IUR data) for the HPV Challenge Program. That is, if one million pounds of a

certain chemical were reported for the 1990 IUR as being produced or imported collectively, by manufacturers throughout the United States, then that chemical was identified as an HPV chemical for purposes of the HPV Challenge Program. The 300,000 lbs. IURA threshold captures at least one report for more than 95% of the HPV chemicals reported to the 1990 IUR.

The production volume that defines chemicals as HPV should not be confused with the 300,000 lbs. per year reporting threshold for processing and use data reporting in IURA. The 300,000 lbs. threshold applies to the amount manufactured at a single site and is not an aggregate, industry-wide production number. EPA is implementing the 300,000 lbs. per year reporting threshold for individual IUR submitters because it limits the increase in burden associated with the new IURA processing and use reporting requirements and it limits the number of chemicals for which exposure-related data will be reported to approximately 4,000. This number is consistent with the ''several thousand chemicals'' suggested by GAO in its 1995 report ''EPA Should Focus Its Chemical Use Inventory on Suspected Harmful Substances'' (Ref. 36), and ensures that exposure-related data will be reported for almost all HPV chemicals (defined by national aggregate production). Increasing the 300,000 lbs. threshold to one million lbs. would drastically undermine the Agency's collection of processing and use exposure-related data. The higher threshold would reduce the number of chemicals for which this information is submitted and eliminate processing and use data reporting on many of the HPV chemicals. The Agency would be left with very little information with which to conduct the needed screening- level assessments and the resulting prioritization would be less meaningful.

In the proposed IURA, EPA also solicited comments on the possibility of replacing the chemicals identified using the 300,000 lbs. annual production volume threshold (by site) with any of five other groups of chemicals. Those groups include: (1) A set of HPV chemicals that submitters identify as being produced nationwide in amounts of one million lbs. or more; (2) chemicals that are currently subject to testing under TSCA section 4 (i.e., test rules and enforceable consent agreements (ECAs)); (3) chemicals identified for voluntary testing; (4) chemicals designated for testing by the ITC; and (5) chemicals listed in the Agency's Master Testing List (the current edition is available at http://www.epa.gov/opptintr/chemtest/mtl.htm).

With respect to the possibility of limiting the collection of processing and use information to HPV chemicals identified by submitters, the Agency asked for comment on: (1) Whether submitters would be able to determine which chemicals have exceeded the nationally aggregated HPV threshold in a given submission period, especially given how frequently chemical production rises above and falls below this threshold from IUR submission period to submission period; (2) what additional burdens such a determination would place on submitters; and (3) whether IURA data would be less useful if processing and use data reporting were limited to HPV chemicals.

Many commenters favored use of the set of HPV chemicals in lieu of the proposed IURA reporting with the 300,000 lbs. threshold, yet none directly responded to the specific Agency questions. Commenters failed to take into account the added burden of aggregating chemical production to determine which substances are HPV chemicals. They also offered no justification for substituting the 300,000 lbs. plant site-specific threshold with a one million lbs. national aggregate threshold, beyond stating that relevant information is being provided already through other programs. Nor did they offer possible solutions to the problem of reliably aggregating production volumes.

EPA does not believe that submitters will be able to effectively aggregate nationwide production volumes. Aggregation is especially difficult in light of continual, market-driven changes in production and many submitters' interest in protecting individual plant site production volume information as CBI. Additionally, for a nationally aggregated one million lbs. threshold 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 one 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.

D. Definitions and Clarification Requests

1. *Is mining considered manufacturing*? Commenters asked whether mining is considered ''manufacturing'' under TSCA. Under TSCA, the term ''manufacture'' includes production or importation of a chemical substance as well as its manufacture (TSCA section 3(7)). Mining, which includes extracting metal ores or minerals from their natural deposits by any means, including secondary recovery of metal ore from reuse or other storage piles, wastes, or rock dumps, or from mill tailings derived from the mining, cleaning, or concentration of metal ores, is production and is considered to be a manufacturing activity under TSCA.

However, chemical substances which are naturally occurring and which, among other things, are unprocessed or processed only by manual, mechanical, or gravitational means (see 40 CFR 710.4(b)(1)) are currently excluded from IUR reporting and will continue to be excluded under IURA (see 40 CFR 710.46(a)(3)). For example, rocks, ores, and minerals are not IURA-reportable to the extent they are manufactured only via the means described in 40 CFR 710.4(b). The § 710.46(a)(3) exclusion is a process-specific exclusion rather than a chemical- or industry-specific one. Therefore, persons who manufacture a substance in a manner other than as specified in § 710.4(b) are required to report under IURA unless they or the substance they manufacture are otherwise excluded. As a result, many mined materials are listed on the TSCA Inventory because at least some of the time they are produced by other than manual, mechanical, or gravitational means.

Section 710.46(a)(3) intentionally exempts from IURA reporting any chemical substance which is isolated or removed from nature, for a commercial purpose, by any means listed in § 710.4(b). It also exempts any other chemical substance derived or separated from the substance originally removed from nature, provided such derivation involved only the means specified in § 710.4(b). For example, when using manual, mechanical, or gravitational processes to separate one or more substances from a naturally-occurring mixture, these isolated component substances are also considered naturally-occurring and excluded from reporting. However, any substance manufactured from a naturally occurring precursor substance via a chemical reaction is not considered naturally occurring and, therefore, not excluded from reporting under § 710.46(a)(3).

2. *What is the difference between ''reasonably ascertainable'' information and ''readily obtainable'' information*? A number of commenters raised concerns about the meaning of ''readily obtainable'' and ''reasonably

ascertainable,'' what level of effort is required for each, and the difference in the level of effort required. Commenters also stated that the expectation that submitters will provide data on users outside their control seems to be an unworkable and unrealistic mandate. The reporting standard of TSCA section 8(a)(2) is ''reasonably ascertainable,'' and commenters stated that this should not be construed to include data that are not in the possession of the person reporting.

''Known to or reasonably ascertainable by'' is the current standard for data collection under which IUR operates and is the standard authorized by TSCA section 8(a). ''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. The ''known to or reasonably ascertainable by'' standard is applicable to the information required under § 710.52(c)(1), (c)(2), and (c)(3) of the regulatory text.

''Readily obtainable'' is a lesser standard EPA is applying to the reporting of information concerning the processing and use of chemicals subject to IURA (§ 710.52(c)(4) of the regulatory text). The readily obtainable standard is limited to information known by management and supervisory employees of the submitter, and does not require additional effort to collect information on processing or use of chemicals by others not under the control of the submitter. Although the Agency is requiring submitters to provide only information that it knows, EPA believes that in many cases submitters will possess some knowledge concerning use of chemicals sold by the submitter to their customers, even though the submitter does not control its customers' sites. For example, when a company markets the substances for certain end uses. EPA's experience with over 30,000 TSCA section 5 PMNs demonstrates that companies generally do know the intended ultimate use, as well as intervening processing steps, of their products. In choosing the readily obtainable standard, the Agency is lessening the burden on submitters compared to the ''known to or reasonably ascertainable by'' standard, while recognizing that the submitter is supplying data on uses of chemicals that are beyond his or her control. The standard for reporting information on processing and use of chemical substances under IURA is the same as the standard adopted in the PAIR, which was also promulgated under the authority of TSCA section 8(a). (See 40 CFR 712.7)

E. Confidential Business Information

The Agency's intent under these regulations is to achieve balance and ensure that the submitter only claims as confidential that information which is legally entitled to confidential treatment. EPA believes that these amendments will discourage the assertion of invalid CBI claims by focusing submitter's attention more closely on their decision to make certain claims.

1. *General CBI.*—a. *Reducing the amount of CBI claims.* EPA solicited suggestions from commenters on what could be done to the IUR reporting process and data elements to reduce CBI claims, thereby allowing better public access to the data. Some commenters suggested that EPA is trying to discourage legitimate CBI claims by making assertion of such claims overly burdensome. Some commenters stated that the new data elements that are being added by these amendments raise significant CBI concerns and that IURA can be expected to result in a significant increase in the number of legitimate CBI claims.

EPA agrees that submitters will make CBI claims for the new data elements that are being added by these amendments, most likely resulting in a greater number of CBI claims overall. However, EPA is requiring reporting for most of the new data elements in ranges, a reporting method EPA believes will result in fewer CBI claims compared to reporting discrete numbers. Additionally, EPA is amending the IUR to encourage the assertion of only legally valid CBI claims, and to ensure that CBI claims are well thought out by the submitter. The IURA includes a new requirement to provide upfront substantiation of CBI claims for site identity. This requirement will minimize claims by prompting submitters to perform an initial evaluation of the need for and validity of a CBI claim for plant site identity, an essential data element. These efforts will greatly assist in limiting CBI claims to those that are legitimate.

EPA wishes to clarify that it is not attempting to discourage legitimate confidentiality claims; rather, the Agency intends only to discourage inappropriate claims. This allows the Agency to protect legitimate CBI while also increasing the amount of information available for public use.

EPA has information indicating the existence of inappropriate or no longer valid CBI claims. For instance, when EPA has selectively challenged CBI claims in the past, many of these claims have been amended by the companies to make the information available to the public. Additionally, OPPT's administrative record 00125, which contains state CBI data reviews, published articles, industry letters, and other papers discussing CBI issues, provides further indication that inappropriate or no longer valid CBI claims exist. For instance, the Georgia Department of Natural Resources reported in a 1996 CBI Data Review that IUR data identified as confidential was available in other non-confidential data bases (Ref. 37). The administrative record is in the same location as the Docket and is available by following the procedures identified in Unit I.B.1.

Some commenters suggested reducing the number of data elements that will be collected under IURA, perhaps using instead a format such as the one used by OECD for SIDS chemicals, which aggregates information for all manufacturers and thus protects company-specific information. EPA considered alternate reporting formats with different data elements, and has determined that the reporting of site-specific information by the individual sites is the best way to collect the information needed. EPA will continue to perform the aggregating function when providing the public with information that is subject to a site-specific CBI claim. Collecting only national aggregate values would drastically reduce the usefulness of the information to the Agency, even though it may reduce the number of CBI claims. The IUR is used to address both national needs and local issues. For example, IUR production volume information was used to identify the national list of High Production Volume (HPV) chemicals for the Agency's HPV Challenge Program (see http://www.epa.gov/opptintr/chemrtk/volchall.htm). Moreover, site-specific IUR information is used to secure a better overall understanding of activities at individual sites. This information is used for site-specific risk assessments for the use of federal, state and local entities.

b. *Protection of CBI.* Some commenters expressed concern about the Agency's ability to protect against the inappropriate release of CBI and stated that, under section 14 of TSCA, EPA has a statutory obligation to protect information properly claimed as CBI. These commenters are concerned about past releases of information claimed as confidential, and would like to see the Agency take steps to guarantee greater protection of CBI data.

EPA agrees that it has a statutory obligation to protect information

properly claimed CBI and is continually involved in exploring ways to better protect such information. In this light, these amendments reflect the Agency's efforts to assure that information it protects qualifies for that protection under the established legal standards. The new IURA requirements will help assure that EPA's system of information protection is limited to valid claims.

c. *Production volume ranges*. EPA requested comment on the use of production volume ranges as a mechanism to reduce the number of confidentiality claims by allowing characterizations of site-specific chemical and specific production volume information without releasing CBI. In general, commenters felt that the use of the ranges would not necessarily result in reduced CBI claims. Commenters cited a few examples where production volume would still be claimed CBI, including information reported in ranges. Other commenters suggested using broader ranges.

Despite these comments, the Agency has determined that it is worthwhile to require submitters to consider whether their production volumes, within ranges similar to those used for the original TSCA Inventory, warrant protection as CBI (EPA made adjustments to the original TSCA Inventory ranges by making the ranges consistent with the second reporting threshold of 300,000 lbs., as described in Unit II.F.5.d.). EPA recognizes that some submitters will make CBI claims for both the specific and the ranged production volume information. However, EPA believes that in many cases submitters will allow the release of ranged production volume information. This belief is supported by some industry organizations. For example, in a 1993 letter, a company suggested the use of the original Inventory production volume ranges for non-confidential reporting. While the company did state that ''conceivably, a submitter could be able to justify a CBI claim for a range,'' the conclusion was that many companies would be satisfied with non-confidential reporting (Ref. 11). These conclusions are further supported by EPA's experience with the original TSCA Inventory, where only 35% of production volume values reported were claimed CBI, compared to the typical claim level of 65% for production volumes under IUR.

d. *Disclosing customer confidential information*. A commenter expressed concern that, as a producer of chemical feedstocks, they might inadvertently report customer data and not claim the data as CBI, while their customer reports the same data and does claim the data as CBI.

EPA does not believe that this will be a significant issue. The downstream processing and use information that some submitters will be required to provide under IURA is not tied to customer identities. Submitters will not report where or who their customers are or how much their individual customers produce. In addition, CBI claims can be made as necessary for any information provided on Form U.

2. *Upfront substantiation*.—a. *Authority for substantiation*. A commenter stated that the plant site identity substantiation requirement is not authorized under TSCA. Another commenter felt that requiring upfront substantiation is overly burdensome and an arbitrary exercise of authority. The commenter stated that substantiation should only be required if and when a request for public disclosure is made, and substantial and reasonable need are demonstrated.

Under TSCA section 14(c), ''a [confidential] designation under this paragraph shall be made in writing and in such manner as the Administrator may prescribe.'' EPA is continuing to require that those reporting under IURA substantiate their chemical identity CBI claims, and is requiring under these amendments that submitters also substantiate any plant site identity CBI claims. Section 710.58 of the regulatory text requires submitters to substantiate these claims submitted under IUR by providing answers to specified questions. EPA has long required upfront substantiation for specified CBI claims under the authority specified in TSCA (see, e.g., 40 CFR 710.38(c) of the current regulatory text) and will continue to require upfront substantiation where appropriate.

The Agency is adding upfront substantiation requirements for plant site identity information because EPA has observed that, on occasion, plant site information has been claimed as confidential even though, for example, it was revealed in filings required under sections 311, 312, and 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. sections 11021 to 11023. EPA believes that many of these CBI claims are inappropriate and that the new substantiation requirement will 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.

Upfront substantiation of CBI claims imposes some additional burden, although this burden is not substantial. EPA's economic analysis for this rule estimates 0.2 to 0.3 hour per plant site reporting under IURA for the incremental costs of reporting all elements of plant site identity information. The burden of upfront substantiation for plant site identity CBI claims is included in this estimate.

b. *Alternate substantiation questions*. One commenter suggested a simplified set of substantiation questions, consisting of two questions: (1) Are the specified data confidential? and, (2) In as much detail as possible, explain why this information should be given CBI protection.

EPA believes that requiring responses to the list of substantiation questions in § 710.58 of the regulatory text is necessary to ensure that information submitted for confidential protection qualifies for that protection. The commenter's proposed questions, while providing the opportunity for a submitter to express its business reasons and preferences regarding the information, do not provide all of the necessary information to definitively evaluate the eligibility of the information for confidential treatment.

3. *Reassertion*. EPA received a number of comments regarding the proposed new CBI reassertion provisions. All of these comments were opposed to the proposed new requirement. Some comments expressed the position that reassertion is overly burdensome and even punitive, requiring submitters to retrace old steps by answering all the original substantiation questions anew. Commenters were concerned that reassertion could possibly require the retention of voluminous old records. Others felt the proposed standards would violate the Agency's obligation under TSCA to protect confidential information and that EPA would exceed its authority if it required the reassertion of CBI claims.

EPA has considered these industry comments, and weighed the concerns expressed against the public's need for access to information on chemicals in commerce in the United States. While the Agency believes the requirement to reassert old claims of CBI is justified as a practical measure to ensure that information withheld meets the legal criteria and that the expressions of concern relating to burden associated with reassertion, appear to be the result of a misunderstanding of the practical aspects of the proposed reassertion requirement, the Agency is not finalizing the proposed reassertion

requirement. EPA has made this decision in an effort to reduce the overall burden of these amendments.

F. Administrative Comments

1. *Frequency of reporting.* Several commenters stated that one-time reporting of IURA information would be more appropriate in most cases for the intended purposes expressed by EPA. In general, commenters stated that EPA could use tools such as PAIR to identify changes in a particular chemical's exposure or use profile at the time the Agency decides to do a risk analysis for that chemical (see Unit III.A.3.). A few commenters stated that there is insufficient change in the chemical industry to warrant recurring reporting of IURA information, especially for higher volume chemicals.

EPA's experience with past IUR reporting demonstrates that the chemical industry is dynamic, with a 30% change in the number of chemicals reported from one submission period to the next. The specific chemicals that are reported or not reported in any single submission period change at a variety of production volumes; this change is by no means limited to lower production volume chemicals.

Although a chemical's hazards may be fully characterized, EPA needs up-to-date exposure information to stay current with developments and adequately screen chemicals for possible risks to human health and the environment. While the toxicity of a chemical does not change (although new information can modify the assessment or identify new concerns), a chemical's exposure profile can vary greatly over time. Human and/or environmental exposures to the substance can at one time be minor, but as uses change from industrial applications to consumer uses, or as production volumes increase, exposures also tend to increase. Because exposures and uses can and do change over time as technologies develop or innovations arise, updated exposure information is needed to maintain an adequate understanding of current exposures. EPA did consider one-time reporting for IURA processing and use data, but the information would quickly become out of date.

A primary goal of IURA is to provide a data base of exposure-related information which can be used for screening level purposes to identify chemicals for further assessment, as well as chemicals of lesser concern (see Unit III.A.1.). EPA intends to use other data sources and collection tools, as appropriate, once a chemical has been identified as a candidate for further assessment.

2. *Calendar year reporting.* One commenter stated that the requirement to report data on a calendar year basis instead of a company fiscal year basis would increase systems development needs for companies who report their manufacturing volume on a fiscal year versus a calendar year (by creating the need for a second tracking system), while adding no additional value or accuracy in the reporting of manufacturing data. This commenter pointed out that because the most that companies' fiscal years can differ from a calendar year is 6 months and IUR reporting occurs every 4 years (instead of every year), there can be little difference in the data with a maximum 6–month time frame shift. Other commenters supported the change to a calendar year basis, supporting the idea of having a consistent time frame to better enable linkages with other data bases.

EPA has retained the calendar year reporting cycle as proposed. By moving the collection to a calendar year basis, the IURA data collection becomes more compatible with other data bases such as the TRI. This compatibility increases the usefulness of the IURA collection by allowing IURA data to be combined with data from other collections. Generally, companies should be sufficiently familiar with their production that this provision should not present special challenges that are unaccounted for in the burden estimates provided by survey respondents, as described in the economic analysis.

G. Economic Impact Estimates

Commenters raised a number of concerns about the economic analysis. In response, EPA has made a number of changes to make the analysis a more readable document and to incorporate changes made to the final IURA requirements.

1. *General burden comments.* Commenters raised a variety of concerns about the size of the burden associated with the amendments, and EPA's estimates of that burden. In general, commenters felt that the Agency's burden estimates were too low. However, few commenters provided evidence as to why they felt EPA underestimated the burden, and none provided any specific analytical basis for amending the estimates. Some commenters claimed that the revised form represents a 5-, 10-, or 30–fold increase in burden, at least partly based upon the fact that the original Form U was only 1 page and the sample revised Form U provided in the proposed rule was 3 pages.

In response to these comments, EPA reviewed the burden analysis and, although the estimated burden was adjusted, determined that the comments do not warrant modifications to the Agency's general approach to the analysis. EPA based much of the burden analysis on a survey of 78 industry respondents (Ref. 7). In addition, EPA considered the burden associated with such programs as the UEIP (described in Unit III.A.1.), a voluntary project in which EPA collected information similar in some ways to IURA information. UEIP respondents provided estimates of the amount of time they used to complete the survey forms (Ref. 7). However, EPA did reassess the results of the burden survey and did make some changes to the analysis. The burden from the analysis associated with the proposed rule was $36 to $51 million in the first year, and $27 million to $41 million in future reporting years. Changes in the rule and methodology raised estimated costs of the final rule to between $72 and $87 million in the first reporting cycle, and $64 to $77 million in future reporting cycles. These changes are primarily due to revising the analysis from the survey data, revising the analysis to remove the reassertion burden, updating costs to year 2000 dollars, and updating the number of report submissions to incorporate the 1998 IUR data collection. These changes are discussed further in ''Revised Economic Analysis for the Amended Inventory Update Rule'' (Ref. 7).

a. *Burden over time.* Commenters raised concerns about specific burden issues. Several commenters felt that burden associated with IURA will not decrease over time because of the 4–year time lapse between submission periods. Those commenters believe that the 4–year period between submission periods will result in changes to product lines and personnel such that a complete reintroduction to IUR reporting will be necessary in each reporting cycle. EPA disagrees, and expects rule familiarization to require the most effort in the first year of reporting. EPA believes that there will be some similarity in the information reported from one submission period to the next, especially for Parts I and II of the revised Form U. Subsequent reporting will be facilitated by the site's maintenance of its previous submission period's records.

b. *Characterization of burden reduction.* Commenters asserted that the economic analysis for the proposed rule was misleading in its characterization of

the actions that constitute burden reduction and cost savings. Specifically, commenters referred to EPA's claim of a burden reduction and cost savings associated with the 300,000 lbs. threshold for reporting of Form U, Part III information on industrial processing and use, and consumer and commercial use. EPA simply meant that providing a partial exemption for chemicals below the 300,000 lbs. threshold is a concession to the burden that the rule imposes on reporting sites, and that the Agency has no other basis for this exemption other than to mitigate the increase in burden. EPA presented a similar discussion comparing options considered under the rule for other partial reporting exemptions such as the petroleum streams exemption. These discussions are put into the appropriate context in the economic analysis. A commenter also took issue with the fact that EPA asserts that reporting processing and use information on the top 10 NAICS codes will reduce costs (versus reporting on an unlimited number of NAICS codes), given that identifying these top 10 could take considerable effort. EPA continues to believe that reporting only the top 10 NAICS codes will be less burdensome than reporting all NAICS codes associated with industrial processing or use operations.

2. *Cost comments*. Two commenters asserted that compliance costs for chemicals manufactured in amounts below the 25,000 lbs. threshold are not zero and that, as production volume for a chemical approaches the threshold, tracking costs will accrue to determine if production will cross the threshold.

Compliance determination (the act of determining the need to comply with a regulation) occurs on a per-site basis. This means that all sites that report under IURA are assumed to incur the same average cost for determining compliance, regardless of the number of chemicals reported. Some small number of firms that are not required to report may incur some negligible costs in this regard, but EPA believes the costs to be relatively small given that it is standard business practice for a company to be aware of the volumes it produces. The existence of voluntary submitters does not imply that below-threshold compliance costs are non-zero; it simply indicates that some firms choose to respond to IUR when reporting is not required.

Another commenter determined that member companies in its organization would experience no savings from raising the threshold from 10,000 lbs. to 25,000 lbs. as no reports are eliminated. In 1994, EPA received approximately 3,800 reports for chemicals produced in quantities between 10,000 and 25,000 lbs. As a result, the Agency anticipates that a significant number of reports will be eliminated by raising the reporting threshold.

3. *Benefits comments*. Commenters stated that EPA has overestimated the benefits of this rule and should quantify the benefits. However, given that IURA is an information rule and its benefits are therefore indirect, it is currently not possible to quantify the benefits of the rule. Only by collecting the information required under the IURA can EPA begin to assess thoroughly the risks from a portion of the more than 76,000 chemicals in commerce. The actions that result from EPA review of the IURA data will have direct health and environmental benefits, benefits that typically can be quantified. Commenters offered no alternate assessment, quantitative or otherwise, of the benefits from IURA. In the absence of quantified benefit figures, it is impossible to make simple comparisons to estimates of reporting costs. Thus, EPA must balance the needs of the Agency for data with which to address important environmental and health risks, with the burdens of obtaining such data. In doing so, the uses of and need for the data are carefully addressed both within the Agency, and during interagency review. EPA has made every attempt to collect only the information necessary to meet Agency goals for obtaining screening level exposure-related information.

4. *Small business impact comments*. Several commenters argued that EPA's analysis of the impacts of IURA on small businesses is insufficient to meet the requirements of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996. EPA's analysis of small business impacts fully complies with the RFA, as amended. For rules subject to the RFA, the Agency is required to undertake specific actions (such as preparing an initial regulatory flexibility analysis and convening a small business advocacy review panel) unless it certifies that the rule will not have a significant impact on a substantial number of small entities. EPA prepared a thorough small entity analysis that meets the requirements of the RFA. The analysis for the final rule can be found in the ''Revised Economic Analysis for the Amended Inventory Update Rule'' (Ref. 7). For both the proposed and final rules, EPA certified that there will not be a significant impact on a substantial number of small entities. A summary of the analysis and the certification can be found in Unit V.B.

5. *Non-regulatory alternatives*. Commenters also stated that EPA did not identify any non-regulatory alternatives and failed to assess the relative costs and benefits of an alternative approach. In the economic analysis for the proposed rule, the Agency did not specifically identify non-regulatory alternatives to the reporting requirements. However, the Agency did consider non-regulatory alternatives and has added a discussion to the economic analysis.

The Agency primarily considered two non-regulatory alternatives. First, the Agency considered using publicly available information, as discussed in Unit III.A.3. The Agency found that the information to be collected through IURA was not publicly available and therefore this was not a viable option. Second, the Agency considered a voluntary approach to collecting this information, similar to the UEIP collection discussed in Unit III.A.1. However, information collected through a voluntary program may lack consistency, may not be sufficiently comprehensive, or may not occur on a recurring basis, and therefore would not fully serve the purposes of IURA information. Therefore, a voluntary approach was not a viable option.

IV. Materials in the Rulemaking Record

The public version of the official record for this rulemaking has been established as described in Unit I.B.1. under docket ID number OPPT–2002–0054. This record includes the documents located in the docket as well as the documents that are referenced in those documents. The following is a listing of the documents that are specifically referenced in this final rule. These documents, and the documents referenced therein, are also included in the public version of the official record. Please note that some referenced documents are already publicly available and this list includes the relevant location information.

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

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

3. 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.

4. 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.

5. USEPA, ''Methodology Used for the Initial Selection of Chemicals for the Inventory Update Rule Amendments (IURA) 'Low Current Interest' Partial Reporting Exemption,'' OPPT, July 24, 2002.

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

7. USEPA, ''Economic Analysis for the Amended Inventory Update Final Rule,'' OPPT, August 2002.

8. USEPA, ''Incremental Cost Estimates for IURA: Interagency Review Comparison and Five Year Reporting Cycle,'' OPPT/EETD/EPAB, July 17, 2002.

9. USEPA, ''Draft Instructions Manual for the 2006 Inventory Update Rule Reporting,'' OPPT, August 2002.

10. USEPA, ''Inventory Update Rule (IUR) Technical Support Document: Evaluation of Likelihood of Confidential Business Information Claims for Production Volume Information,'' OPPT, August 26, 1996.

11. 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.

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

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

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

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

16. USEPA, ''Preliminary Assessment Information Rule (PAIR) Database, Manufacturing Process Type/Release Analysis and Number of Workers/Production Quantity Analysis,'' OPPT, September 26, 1996.

17. Standard Consumer Safety Inspection ASTM F963-96A (sec. 3.1–3.3).

18. USEPA, ''Summary of EPA's Responses to Public Comments Submitted in Response to Proposed TSCA Inventory Update Rule Amendments (64 FR 46772),'' OPPT/EETD, September 6, 2002.

19. USEPA, ''IURA Data Use Plan,'' OPPT/EETD, August 23, 2002.

20. USEPA, ''A 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. Also available at www.epa.gov/sab/pdf/eec95017.pdf.

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

22. Letter from Robert Franklin, U.S. Consumer Product Safety Commission, to EPA, December 23, 1999.

23. Letter from Paul A. Schulte, Ph.D., National Institute for Occupational Safety & Health, to EPA, December 21, 1999.

24. General Accounting Office, ''Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans,'' GAO/HEHS-00-80, May 2, 2000.

25. Letter from Linda Greer, Ph.D., Natural Resources Defense Council, to Carol Browner, EPA, February 12, 1999.

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

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

28. European Commission, ''Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances; Part III.''

29. USEPA, '''Inventory Update Rule (IUR) Technical Support Document: Selection of Consumer and Commercial End-Use Categories,'' OPPT, 1996.

30. Letter from the TSCA Interagency Testing Committee providing a response to an Interagency proposed rule review question, undated.

31. Letter from John DeYoung, Chief Scientist, U.S. Geological Survey, to Mary Ellen Weber, EPA, July 25, 2002.

32. USEPA, ''Inorganic Chemicals: Sources of Information Suggested by Commenters to the Proposed Inventory Update Rule Amendments,'' OPPT, June 2000.

33. Memorandum from Sandy Zavolta, U.S. EPA, to Heidi King, Office of Management and Budget, May 21, 1999.

34. OECD, ''Guidance for Collection and Transmission of Exposure Information for SIDS Initial Assessment,'' OECD SIDS Manual (Third Revision), Section 2.5, July 1997, available at http://www.epa.gov/opptintr/sids/sidsman.htm.

35. USEPA, ''Report to Congress: Wastes from the Combustion of Fossil Fuels (EPA Docket #F–2000–FF2F–FFFFF) Public Comment Summary and Response Document,'' OSW, April 25, 2000, available at http://www.epa.gov/epaoswer/other/fossil/ffc-resp.pdf.

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

37. Confidential Business Information Data Review, Georgia Department of Natural Resources, Docket entry 00125 B2a-010 filed June 19, 1996, page 4.

V. Statute and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this is a ''significant regulatory action'' under section 3(f) of the Executive Order, because it raises ''novel legal or policy issues arising out of legal mandates'' relating to information collection. This action was therefore submitted to OMB for review under this Executive Order, and any comments or changes made during that review have been documented in the public record.

In addition, EPA has prepared an economic analysis of the potential impacts of this action, which is contained in a document entitled *Economic Analysis for the Amended Inventory Update Rule* (Ref. 7). The Agency, in promulgating this rule, is required under TSCA to consider the potential costs and benefits associated with IURA. The analysis was therefore used by the decision-makers to help in the selection of the final rule requirements presented in this document. This document is available as a part of the public version of the official record for this action and is briefly summarized here.

EPA estimates that these amendments will cost between $72 and $87 million in the first reporting cycle, and $64 to

$77 million in future reporting cycles, resulting in an annualized cost of $17 to $21 million over the next 20 years at a 3% discount rate, and $19 to $22 million at a 7% discount rate.

Under these amendments, approximately 8,900 chemicals will be subject to reporting, and the Agency expects that it will receive approximately 26,800 submissions during the first submission period. In the first submission period, approximately 9,800 of those submissions (providing information on about 4,000 chemicals) will be full reports which include information found in Part III of revised reporting Form U. The remainder will report only company, site and chemical identification and manufacturing information (Parts I and II of revised Form U). In future submission periods with the addition of full reporting for inorganic chemicals, EPA expects to receive over 12,300 full forms, covering 4,600 chemicals. In order to keep the reporting burden as low as possible, EPA is requiring 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 of revised Form U be reported.

EPA analyzed the effects of a number of different alternatives for the rule, including variations in exemptions, different thresholds for both partial- (i.e., Parts I and II of revised Form U) and full-form (i.e., all parts of revised Form U) reporting, and various frequencies of collection. These options are explored further in the Economic Analysis (Ref. 6).

EPA considered continuing the existing full exemption from IUR reporting for inorganic chemicals and adding a full exemption for site-limited petroleum streams. EPA examined the effects of keeping the partial-form threshold at 10,000 lbs. and considered full-form thresholds of 100,000, 300,000, 500,000, and one million lbs., 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, and a 2–year cycle.

EPA believes that this final rule represents an appropriate balance between the burden placed on industry to provide information and the Agency's need for that information to fill its statutory obligations and fulfill its mission under TSCA and, as part of that mission, to provide information needed by other agencies (OSHA, NIOSH, CPSC, etc.).

The costs of these amendments will 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 that would potentially be filed by industry. EPA has provided a second threshold for reporting use information required in Part III of revised Form U, reducing the per report burden for submitters. Recognizing that this information will be used for screening level purposes, EPA has reduced the specificity of the information that will be required in three ways: (1) By requiring the reporting of only readily obtainable information for the processing and use exposure-related data; (2) by requiring that submitters report much of the information in ranges, reducing the need to generate specific estimates; and, (3) by requiring processing and use exposure-related information on only the top 10 uses/NAICS codes/IFCs, 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.

EPA assumes that the burden associated with reporting under IURA will decrease over time as industry's familiarity with the reporting rule increases and to the extent that the information being reported remains somewhat constant from one submission period to the next. Projected costs to EPA are relatively small and are estimated to be $576,000 in the first reporting year, and $270,000 in subsequent reporting years.

Substantial changes in the economic analysis have occurred since the economic analysis produced for the proposed rule, which is summarized in Unit XI. of the proposed rule (at 64 FR 46799). The economic analysis was revised primarily due to changes in the final rule and changes to the cost methodology that more fully reflect potential industry burden. The revised economic analysis in support of this final rule can be found in the public version of the official record for this rulemaking (Ref. 6).

Changes made since the proposal due to public comments or interagency review include deleting the average concentration data element, phasing-in full reporting for inorganic chemicals, adding a partial exemption for specific chemical substances for which the Agency has determined that the IURA processing and use information is of low current interest, and deleting the proposed CBI reassertion requirement. Changes made to the cost methodology include increasing burden estimates for reporting processing and use data. The increase in burden estimate was initiated in response to industry comment, and stemmed from differences in the survey instrument used to estimate costs of IURA in 1996, and the sample Form U in 1999.

Estimates for reporting processing and use data were revised upward after reviewing public comments and the survey data. Differences between the survey instrument and the proposed Form U required EPA to aggregate certain responses. After reading the comments, EPA is using more conservative assumptions in this process. Therefore, it is more likely that EPA cost estimates overestimate, rather than underestimate, actual costs.

B. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070–0162. In accordance with the procedures at 5 CFR 1320.11, EPA submitted an Information Collection Request (ICR) document to OMB in 1999 (identified as EPA ICR No. 1884.02), which is also included in the public docket that is described in Unit I.B.1.

The information that will be reported under IURA will better enable EPA to screen thousands of chemical substances for potential risk. Risk screening is necessary in order to conserve limited Agency and industry resources by focusing risk assessment work on chemical substances for which some level of potential risk has been indicated. The new information that will be reported under this rule is critical to the risk screening process and is unavailable through other sources. Responses to this collection of information will be mandatory, pursuant to TSCA section 8(a), 15 U.S.C. 2607(a). The regulations codifying the reporting requirements appear at 40 CFR part 710. CBI claims may be made for all or part of the information that will be reported under IURA. This action includes new substantiation procedures for CBI claims regarding plant site identity (See § 710.58(d) in the regulatory text).

As a result of IURA, reporting sites will submit either a full report for a

chemical (which includes site identification, manufacturing information and processing and use data) or a partial report (which does not include processing and use data). For the first reporting cycle, inorganic chemical manufacturers will only submit partial reports while organic chemical manufacturers will submit a mix of partial and full reports. The IURA increases the average reporting burden for both partial and full reports compared to previous IUR reporting.

Companies will continue to report under IURA once every 4 years, so the average annual IURA reporting burden and cost is calculated in the ICR as one quarter of the burden and cost in a reporting cycle. Thus, the results in the ICR differ slightly from those in the economic analysis prepared under Executive Order 12866, which calculates the annualized cost of multiple reporting cycles over a 20–year period. In addition, the economic analysis calculates the incremental increase in burden due to IURA, while the ICR calculates the total reporting and recordkeeping burden for IURA (i.e., the sum of the incremental IURA burden and the baseline IUR burden). Companies may continue to report for multiple chemicals on a single Form U (as revised). Companies generally submit one Form U per site, so the burden per Form U is approximately equivalent to the burden per site.

For the first reporting cycle, the annual average burden for organic chemical manufacturers is estimated to be 121.5 to 152.4 hours per site at a cost of $8,313 to $10,448 (reflecting an average of 5.1 partial reports and 3.8 full reports per site). For inorganic chemical manufacturers, the annual average burden is estimated at 43.3 to 66.1 hours per site at a cost of $2,936 to $4,547 (reflecting an average of 8.3 reports per site). These estimates include the time needed to review instructions; search data sources; gather and maintain the data needed; complete and review the collection of information; and transmit or otherwise disclose the information. The actual burden on any specific site may be different from this estimate depending on the complexity of the site, the number of IURA reportable chemicals at the site, and the profile of the site's operations. There will be approximately 2,500 submitters for organic chemicals (including petroleum process streams), and 500 submitters for inorganic chemicals. For the first reporting cycle, the total annual burden is estimated to be approximately 325,000 to 414,000 hours at a total estimated industry cost of $22.2 to $28.4 million per year.

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.

As part of the PRA approval renewal process, which occurs every 3 years and includes an opportunity for public review and comment prior to OMB review, EPA intends to evaluate this collection activity, particularly the new exemption process, in order to demonstrate the practical utility of IURA information collection activities. The Agency will provide information in the ICR renewal document that details the chemicals evaluated under the exemption process, the exemption requests received, and the Agency's decisions made, as well as provide information about the process elements and experiences.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The currently approved ICR control numbers issued by OMB for various EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. This ICR was previously subject to public notice and comment prior to OMB approval. Due to the technical nature of the table, EPA finds that further notice and comment is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), to amend this table without further notice and comment.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the economic analysis for this rule (Ref. 6), and is briefly summarized here.

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 rule, ''small entity'' for purposes of this final 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 Small Business Administration (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 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 in § 710.49 and was not reopened for comment. In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and the Agency.

Despite the fact that small manufacturers that fully meet the 40 CFR 704.3 definition are generally exempt from reporting under IUR, and thus are not significantly impacted by IURA, 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 manufacturers of organic chemicals subject to reporting, the Agency estimates the impact to be 0.15% to 0.18% of sales. For small manufacturers of inorganic chemicals subject to reporting, the Agency estimates the impact to be 0.07% to 0.20% of sales.

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 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 action are described in Unit V.A. In addition, EPA has determined that this rule does not significantly or uniquely affect small governments. Accordingly, this rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Executive Order 13132

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications, because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Orders 13084 and 13175

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 communities, 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 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.''

This rule does not significantly or uniquely affect the communities of Indian tribal governments, nor does it impose substantial direct compliance costs on such communities. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

On November 6, 2000, the President issued Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249). Executive Order 13175 took effect on January 6, 2001, and revokes Executive Order 13084 as of that date. EPA developed this rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084.

G. Executive Order 13211

This rule is not a ''significant energy action'' as defined in Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This final rule modifies the existing IUR reporting and recordkeeping requirements that apply to chemical manufacturers and importers. As such, we have concluded that this rule is not likely to have adverse energy effects.

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 rule will provide the Agency with information needed to screen and prioritize chemical substances, including information on potential exposures to children. 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 Amendment Act

This 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, 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, and business practices) 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.

J. Executive Order 12898

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

K. Executive Order 12630

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with*

Constitutionally Protected Property Rights (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive Order.

L. Executive Order 12988

In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, titled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

VI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 710

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

List of Subjects in 40 CFR Part 723

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

Dated: December 18, 2002.

Stephen L. Johnson,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR chapter I is amended as follows:

1. Part 9 is amended as follows:

PART 9—[AMENDED]

a. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

b. In § 9.1, the table is amended by revising the heading ''Inventory Reporting Regulations'' to read ''TSCA Chemical Inventory Regulations''; removing the existing entry under the heading; and adding the following entries to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB Control No.
* *	* * *
TSCA Chemical Inventory Regulations	
Part 710, Subpart B.	2070–0070
Part 710, Subpart C.	2070–0162
* *	* * *

* * * * *

2. Part 710 is amended as follows:

PART 710—[AMENDED]

a. The authority citation for part 710 continues to read as follows:

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

b. Revise the part heading and table of contents for part 710 to read as follows:

PART 710—TSCA CHEMICAL INVENTORY REGULATIONS

Subpart A—General Provisions

Sec.
710.1 Scope and compliance.
710.3 Definitions.
710.4 Scope of the inventory.

Subpart B—2002 Inventory Update Reporting

710.23 Definitions.
710.25 Chemical substances for which information must be reported.
710.26 Chemical substances for which information is not required.
710.28 Persons who must report.
710.29 Persons not subject to this subpart.
710.30 Activities for which reporting is not required.
710.32 Reporting information to EPA.
710.33 When to report.
710.35 Duplicative reporting.
710.37 Recordkeeping requirements.
710.38 Confidentiality.
710.39 How do I submit the required information?

Subpart C—Inventory Update Reporting for 2006 and Beyond

710.43 Definitions.
710.45 Chemical substances for which information must be reported.
710.46 Chemical substances for which information is not required.
710.48 Persons who must report.
710.49 Persons not subject to this subpart.
710.50 Activities for which reporting is not required.
710.52 Reporting information to EPA.
710.53 When to report.
710.55 Duplicative reporting.
710.57 Recordkeeping requirements.
710.58 Confidentiality.
710.59 Availability of reporting form and instructions.

c. Sections 710.1 through 710.4 are designated as subpart A and the subpart heading is added to read as follows:

Subpart A—General Provisions

d. Revise § 710.1 to read as follows:

§ 710.1 Scope and compliance.

(a) This part establishes regulations governing reporting and recordkeeping by certain persons who manufacture, import, or process chemical substances for commercial purposes under section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)) (TSCA). Section 8(a) authorizes the Administrator to require reporting of information necessary for administration of the Act and requires EPA to issue regulations for the purpose of compiling and keeping current an inventory of chemical substances manufactured or processed for a commercial purpose, as required by section 8(b) of the Act. Following an initial reporting period, EPA published an initial inventory of chemical substances manufactured, processed, or imported for commercial purposes. In accordance with section 8(b), EPA periodically amends the inventory to include new chemical substances which are manufactured or imported for a commercial purpose and reported under section 5(a)(1) of the Act. EPA also revises the categories of chemical substances and makes other amendments as appropriate.

(b) The regulations in this part apply to the activities associated with the compilation of the TSCA Chemical Inventory and the update of information on a subset of the chemical substances included on the Inventory. The Inventory Update regulations were

amended in 2002; however, these amendments apply to updates after 2002, not to the 2002 update. In order to prevent confusion as to which regulations apply to which update, EPA has preserved the provisions that apply to the 2002 update in subpart B. The new and revised requirements that apply to updates after 2002 appear in subpart C. Prior to January 1, 2003, the regulations in subpart B of this part are effective for purposes of Inventory update activities. As of January 1, 2003, subpart C is effective for purposes of Inventory update activities. The Agency intends to remove subpart B from the CFR once the 2002 update is complete.

(c) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under these reporting regulations. In addition, section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by these regulations. Section 16 provides that any person who violates a provision of section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to section 17, the Government may seek judicial relief to compel submission of section 8(a) information and to otherwise restrain any violation of section 15. (EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.)

(d) Each person who reports under these regulations must maintain records that document information reported under these regulations and, in accordance with the Act, permit access to, and the copying of, such records by EPA officials.

§ 710.2 [Removed]

e. Remove § 710.2.

f. Add § 710.3 to subpart A to read as follows:

§ 710.3 Definitions.

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

(a) The following terms will 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* will 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 will 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/her authority to carry out his/her functions, or any other person who will 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.

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/her behalf (as defined in 19 CFR 1.11).

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

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.

Manufacture means to manufacture, produce, or import for commercial purposes.

Manufacture or import ''for commercial purposes'' means to manufacture, produce, or import 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.

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 section 8(b) of the Act.

Person means any natural or juridical 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.

Site means a contiguous property unit. Property divided only by a public right-of-way will 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 will be the business address of the importer.

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 lbs. (454 kg) annually will 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/her supervision,

(2) Who is responsible for enforcing appropriate 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 paragraph 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.

§ 710.4 [Amended]

g. Section 710.4 is amended as follows:

i. In paragraphs (a), (c)(1), (c)(2), (c)(3), and the Note at the end of paragraph (d)(8), change the references to ''§ 710.2'', ''§ 710.2(h)'', ''§ 710.2(q)'', ''§ 710.2(y)'', and ''§ 710.2(n)'', respectively to ''§ 710.3(d)''.

ii. In paragraph (b)(2), change ''shall'' to ''will''.

iii. In the Note to paragraph (d)(2), change ''premanufacturing'' to ''premanufacture''.

iv. In paragraph (d)(5), change ''photographic, films'' to ''photographic films''.

h. Sections 710.25 through 710.39 are designated as subpart B and the subpart heading is added to read as follows:

Subpart B—2002 Inventory Update Reporting

i. Add § 710.23 to subpart B to read as follows:

§ 710.23 Definitions.

In addition to the definitions in § 704.3 of this chapter and § 710.3, the following definitions also apply to subpart B of this part.

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.

Non-isolated 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.

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.

§ 710.39 [Amended]

j. Section 710.39 is amended as follows:

i. Revise the section heading to read ''How do I submit the required information?''

ii. In paragraph (a), the second sentence is revised to read: ''Copies of the Form U are available from EPA at the address set forth in paragraph (c) of this section and from the EPA Internet Home Page at http://www.epa.gov/oppt/iur/iur02/index.htm.''

iii. In the introductory text of paragraph (c), change ''1994'' to ''1998''.

iv. In paragraph (c)(1), insert a period after ''554–1404'' and remove the remainder of the sentence.

v. In paragraph (c)(3), change ''7408,'' to ''7408M,''.

vi. In paragraph (d), change ''Document Control Officer'' to ''OPPT Document Control Officer'' and change ''7407,'' to ''7407M,''.

k. Add a new subpart C to read as follows:

Subpart C—Inventory Update Reporting for 2006 and Beyond

§ 710.43 Definitions.

In addition to the definitions in § 704.3 of this chapter and § 710.3, the following definitions also apply to subpart C of this part:

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.

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

Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers ''yes'' to at least one of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:

(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?

(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?

(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

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.

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.

Non-isolated 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.

Readily obtainable information means information which is known by management and supervisory employees of the submitter company who are responsible for manufacturing, processing, distributing, technical services, and 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 would 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 § 710.45.

Reporting year means the calendar year in which information to be reported to EPA during an IUR submission period is generated, i.e., calendar year 2005 and the calendar year at 4–year intervals thereafter.

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. Although a site-limited chemical substance is not distributed for commercial purposes outside the site at which it is manufactured and processed, the substance is considered to have been manufactured and processed for commercial purposes.

Submission period means the period in which the information generated during the reporting year is submitted to EPA.

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.

§ 710.45 Chemical substances for which information must be reported.

Any chemical substance which is in the Master Inventory File at the beginning of a submission period described in § 710.53, unless the chemical substance is specifically excluded by § 710.46.

§ 710.46 Chemical substances for which information is not required.

The following groups or categories of chemical substances are exempted from some or all of the reporting requirements of this subpart, with the following exception: A chemical substance described in paragraph (a)(1), (a)(2), or (a)(4), or (b) of this section is not exempted from any of the reporting requirements of this subpart 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) *Full exemptions.* The following categories of chemical substances are exempted from the reporting requirements of this subpart.

(1) *Polymers.* (i) Any chemical substance described with the word fragments ''*polym*'', ''*alkyd'', or ''*oxylated'' in the Chemical Abstracts Service Index or Preferred Nomenclature in the Chemical Substance Identities section of the 1985 edition of the Inventory or in the Master Inventory File, where the asterisk (*) indicates that any sets of characters may precede, or follow, the character string defined.

(ii) Any chemical substance which is identified in the 1985 edition of the Inventory or the Master Inventory File as siloxane and silicone, silsesquioxane, a protein (albumin, casein, gelatin, gluten, hemoglobin), an enzyme, a polysaccharide (starch, cellulose, gum), rubber, or lignin.

(iii) This exclusion does not apply to a polymeric substance that has been hydrolyzed, depolymerized, or otherwise chemically modified, except in cases where the intended product of this reaction is totally polymeric in structure.

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

(3) *Naturally occurring chemical substances.* Any naturally occurring chemical substance, as described in § 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the substance in question. Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person described in § 710.48 manufactures a chemical substance by means other than those described in § 710.4(b), the person must report regardless of whether the substance also could have been produced as described in § 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in § 710.4(b) is reportable unless otherwise excluded.

(4) *Certain forms of natural gas.* Chemical substances with the following Chemical Abstract Service (CAS) Registry 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.

(b) *Partial exemptions.* The following groups of chemical substances are partially exempted from the reporting requirements of this subpart (i.e., the information described in § 710.52(c)(4) need not be reported for these substances). Such chemical substances are not excluded from the other reporting requirements under this subpart. A chemical substance described in paragraph (b)(3) of this section qualifies for a partial reporting exemption during the 2006 submission period; in subsequent submission periods, the chemical substances described in paragraph (b)(3) of this section will be subject to full reporting under this subpart (i.e., all of the information described in this subpart must be reported), unless otherwise exempted.

(1) *Petroleum process streams.* EPA has designated the following chemical substances, listed by CAS Number, as partially exempt from reporting under the IUR.

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING

CAS No.	Product
7732–18–5	Water
8002–05–9	Petroleum
8002–74–2	Paraffin waxes and hydrocarbon waxes
8006–20–0	Fuel gases, low and medium B.T.U.
8008–20–6	Kerosine (petroleum)
8009–03–8	Petrolatum
8012–95–1	Paraffin oils
8030–30–6	Naphtha
8032–32–4	Ligroine
8042–47–5	White mineral oil (petroleum)
8052–41–3	Stoddard solvent
8052–42–4	Asphalt
63231–60–7	Paraffin waxes and hydrocarbon waxes, microcryst.
64741–41–9	Naphtha (petroleum), heavy straight-run
64741–42–0	Naphtha (petroleum), full-range straight-run
64741–43–1	Gas oils (petroleum), straight-run
64741–44–2	Distillates (petroleum), straight-run middle
64741–45–3	Residues (petroleum), atm. tower
64741–46–4	Naphtha (petroleum), light straight-run
64741–47–5	Natural gas condensates (petroleum)
64741–49–7	Condensates (petroleum), vacuum tower
64741–50–0	Distillates (petroleum), light paraffinic
64741–51–1	Distillates (petroleum), heavy paraffinic
64741–52–2	Distillates (petroleum), light naphthenic
64741–53–3	Distillates (petroleum), heavy naphthenic
64741–54–4	Naphtha (petroleum), heavy catalytic cracked
64741–55–5	Naphtha (petroleum), light catalytic cracked
64741–56–6	Residues (petroleum), vacuum
64741–57–7	Gas oils (petroleum), heavy vacuum
64741–58–8	Gas oils (petroleum), light vacuum
64741–59–9	Distillates (petroleum), light catalytic cracked

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
64741–60–2	Distillates (petroleum), intermediate catalytic cracked
64741–61–3	Distillates (petroleum), heavy catalytic cracked
64741–62–4	Clarified oils (petroleum), catalytic cracked
64741–63–5	Naphtha (petroleum), light catalytic reformed
64741–64–6	Naphtha (petroleum), full-range alkylate
64741–65–7	Naphtha (petroleum), heavy alkylate
64741–66–8	Naphtha (petroleum), light alkylate
64741–67–9	Residues (petroleum), catalytic reformer fractionator
64741–68–0	Naphtha (petroleum), heavy catalytic reformed
64741–69–1	Naphtha (petroleum), light hydrocracked
64741–70–4	Naphtha (petroleum), isomerization
64741–73–7	Distillates (petroleum), alkylate
64741–74–8	Naphtha (petroleum), light thermal cracked
64741–75–9	Residues (petroleum), hydrocracked
64741–76–0	Distillates (petroleum), heavy hydrocracked
64741–77–1	Distillates (petroleum), light hydrocracked
64741–78–2	Naphtha (petroleum), heavy hydrocracked
64741–79–3	Coke (petroleum)
64741–80–6	Residues (petroleum), thermal cracked
64741–81–7	Distillates (petroleum), heavy thermal cracked
64741–82–8	Distillates (petroleum), light thermal cracked
64741–83–9	Naphtha (petroleum), heavy thermal cracked
64741–84–0	Naphtha (petroleum), solvent-refined light
64741–85–1	Raffinates (petroleum), sorption process
64741–86–2	Distillates (petroleum), sweetened middle
64741–87–3	Naphtha (petroleum), sweetened
64741–88–4	Distillates (petroleum), solvent-refined heavy paraffinic
64741–89–5	Distillates (petroleum), solvent-refined light paraffinic
64741–90–8	Gas oils (petroleum), solvent-refined
64741–91–9	Distillates (petroleum), solvent-refined middle
64741–92–0	Naphtha (petroleum), solvent-refined heavy
64741–95–3	Residual oils (petroleum), solvent deasphalted
64741–96–4	Distillates (petroleum), solvent-refined heavy naphthenic
64741–97–5	Distillates (petroleum), solvent-refined light naphthenic
64741–98–6	Extracts (petroleum), heavy naphtha solvent
64741–99–7	Extracts (petroleum), light naphtha solvent
64742–01–4	Residual oils (petroleum), solvent-refined
64742–03–6	Extracts (petroleum), light naphthenic distillate solvent
64742–04–7	Extracts (petroleum), heavy paraffinic distillate solvent
64742–05–8	Extracts (petroleum), light paraffinic distillate solvent
64742–06–9	Extracts (petroleum), middle distillate solvent
64742–07–0	Raffinates (petroleum), residual oil decarbonization
64742–08–1	Raffinates (petroleum), heavy naphthenic distillate decarbonization
64742–09–2	Raffinates (petroleum), heavy paraffinic distillate decarbonization
64742–10–5	Extracts (petroleum), residual oil solvent
64742–11–6	Extracts (petroleum), heavy naphthenic distillate solvent
64742–12–7	Gas oils (petroleum), acid-treated
64742–13–8	Distillates (petroleum), acid-treated middle
64742–14–9	Distillates (petroleum), acid-treated light
64742–15–0	Naphtha (petroleum), acid-treated
64742–16–1	Petroleum resins
64742–18–3	Distillates (petroleum), acid-treated heavy naphthenic
64742–19–4	Distillates (petroleum), acid-treated light naphthenic
64742–20–7	Distillates (petroleum), acid-treated heavy paraffinic
64742–21–8	Distillates (petroleum), acid-treated light paraffinic
64742–22–9	Naphtha (petroleum), chemically neutralized heavy
64742–23–0	Naphtha (petroleum), chemically neutralized light
64742–24–1	Sludges (petroleum), acid
64742–25–2	Lubricating oils (petroleum), acid-treated spent
64742–26–3	Hydrocarbon waxes (petroleum), acid-treated
64742–27–4	Distillates (petroleum), chemically neutralized heavy paraffinic
64742–28–5	Distillates (petroleum), chemically neutralized light paraffinic
64742–29–6	Gas oils (petroleum), chemically neutralized
64742–30–9	Distillates (petroleum), chemically neutralized middle
64742–31–0	Distillates (petroleum), chemically neutralized light
64742–32–1	Lubricating oils (petroleum), chemically neutralized spent
64742–33–2	Hydrocarbon waxes (petroleum), chemically neutralized
64742–34–3	Distillates (petroleum), chemically neutralized heavy naphthenic
64742–35–4	Distillates (petroleum), chemically neutralized light naphthenic
64742–36–5	Distillates (petroleum), clay-treated heavy paraffinic
64742–37–6	Distillates (petroleum), clay-treated light paraffinic

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
64742–38–7	Distillates (petroleum), clay-treated middle
64742–39–8	Neutralizing agents (petroleum), spent sodium carbonate
64742–40–1	Neutralizing agents (petroleum), spent sodium hydroxide
64742–41–2	Residual oils (petroleum), clay-treated
64742–42–3	Hydrocarbon waxes (petroleum), clay-treated microcryst.
64742–43–4	Paraffin waxes (petroleum), clay-treated
64742–44–5	Distillates (petroleum), clay-treated heavy naphthenic
64742–45–6	Distillates (petroleum), clay-treated light naphthenic
64742–46–7	Distillates (petroleum), hydrotreated middle
64742–47–8	Distillates (petroleum), hydrotreated light
64742–48–9	Naphtha (petroleum), hydrotreated heavy
64742–49–0	Naphtha (petroleum), hydrotreated light
64742–50–3	Lubricating oils (petroleum), clay-treated spent
64742–51–4	Paraffin waxes (petroleum), hydrotreated
64742–52–5	Distillates (petroleum), hydrotreated heavy naphthenic
64742–53–6	Distillates (petroleum), hydrotreated light naphthenic
64742–54–7	Distillates (petroleum), hydrotreated heavy paraffinic
64742–55–8	Distillates (petroleum), hydrotreated light paraffinic
64742–56–9	Distillates (petroleum), solvent-dewaxed light paraffinic
64742–57–0	Residual oils (petroleum), hydrotreated
64742–58–1	Lubricating oils (petroleum), hydrotreated spent
64742–59–2	Gas oils (petroleum), hydrotreated vacuum
64742–60–5	Hydrocarbon waxes (petroleum), hydrotreated microcryst.
64742–61–6	Slack wax (petroleum)
64742–62–7	Residual oils (petroleum), solvent-dewaxed
64742–63–8	Distillates (petroleum), solvent-dewaxed heavy naphthenic
64742–64–9	Distillates (petroleum), solvent-dewaxed light naphthenic
64742–65–0	Distillates (petroleum), solvent-dewaxed heavy paraffinic
64742–67–2	Foots oil (petroleum)
64742–68–3	Naphthenic oils (petroleum), catalytic dewaxed heavy
64742–69–4	Naphthenic oils (petroleum), catalytic dewaxed light
64742–70–7	Paraffin oils (petroleum), catalytic dewaxed heavy
64742–71–8	Paraffin oils (petroleum), catalytic dewaxed light
64742–72–9	Distillates (petroleum), catalytic dewaxed middle
64742–73–0	Naphtha (petroleum), hydrodesulfurized light
64742–75–2	Naphthenic oils (petroleum), complex dewaxed heavy
64742–76–3	Naphthenic oils (petroleum), complex dewaxed light
64742–78–5	Residues (petroleum), hydrodesulfurized atmospheric tower
64742–79–6	Gas oils (petroleum), hydrodesulfurized
64742–80–9	Distillates (petroleum), hydrodesulfurized middle
64742–81–0	Kerosine (petroleum), hydrodesulfurized
64742–82–1	Naphtha (petroleum), hydrodesulfurized heavy
64742–83–2	Naphtha (petroleum), light steam-cracked
64742–85–4	Residues (petroleum), hydrodesulfurized vacuum
64742–86–5	Gas oils (petroleum), hydrodesulfurized heavy vacuum
64742–87–6	Gas oils (petroleum), hydrodesulfurized light vacuum
64742–88–7	Solvent naphtha (petroleum), medium aliph.
64742–89–8	Solvent naphtha (petroleum), light aliph.
64742–90–1	Residues (petroleum), steam-cracked
64742–91–2	Distillates (petroleum), steam-cracked
64742–92–3	Petroleum resins, oxidized
64742–93–4	Asphalt, oxidized
64742–94–5	Solvent naphtha (petroleum), heavy arom.
64742–95–6	Solvent naphtha (petroleum), light arom.
64742–96–7	Solvent naphtha (petroleum), heavy aliph.
64742–97–8	Distillates (petroleum), oxidized heavy
64742–98–9	Distillates (petroleum), oxidized light
64742–99–0	Residual oils (petroleum), oxidized
64743–00–6	Hydrocarbon waxes (petroleum), oxidized
64743–01–7	Petrolatum (petroleum), oxidized
64743–02–8	Alkenes, C>10 .alpha.-
64743–03–9	Phenols (petroleum)
64743–04–0	Coke (petroleum), recovery
64743–05–1	Coke (petroleum), calcined
64743–06–2	Extracts (petroleum), gas oil solvent
64743–07–3	Sludges (petroleum), chemically neutralized
64754–89–8	Naphthenic acids (petroleum), crude
64771–71–7	Paraffins (petroleum), normal C>10
64771–72–8	Paraffins (petroleum), normal C5-20
67674–12–8	Residual oils (petroleum), oxidized, compounds with triethanolamine
67674–13–9	Petrolatum (petroleum), oxidized, partially deacidified

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
67674–15–1	Petrolatum (petroleum), oxidized, Me ester
67674–16–2	Hydrocarbon waxes (petroleum), oxidized, partially deacidified
67674–17–3	Distillates (petroleum), oxidized light, compounds with triethanolamine
67674–18–4	Distillates (petroleum), oxidized light, Bu esters
67891–79–6	Distillates (petroleum), heavy arom.
67891–80–9	Distillates (petroleum), light arom.
67891–82–1	Hydrocarbon waxes (petroleum), oxidized, compounds with ethanolamine
67891–83–2	Hydrocarbon waxes (petroleum), oxidized, compounds with isopropanolamine
67891–85–4	Hydrocarbon waxes (petroleum), oxidized, compounds with triisopropanolamine
68131–05–5	Hydrocarbon oils, process blends
68131–49–7	Aromatic hydrocarbons, C6-10, acid-treated, neutralized
68131–75–9	Gases (petroleum), C3-4
68153–22–0	Paraffin waxes and Hydrocarbon waxes, oxidized
68187–57–5	Pitch, coal tar-petroleum
68187–58–6	Pitch, petroleum, arom.
68187–60–0	Hydrocarbons, C4, ethane-propane-cracked
68307–98–2	Tail gas (petroleum), catalytic cracked distillate and catalytic cracked naphtha fractionation absorber
68307–99–3	Tail gas (petroleum), catalytic polymn. naphtha fractionation stabilizer
68308–00–9	Tail gas (petroleum), catalytic reformed naphtha fractionation stabilizer, hydrogen sulfide-free
68308–01–0	Tail gas (petroleum), cracked distillate hydrotreater stripper
68308–02–1	Tail gas (petroleum), distn., hydrogen sulfide-free
68308–03–2	Tail gas (petroleum), gas oil catalytic cracking absorber
68308–04–3	Tail gas (petroleum), gas recovery plant
68308–05–4	Tail gas (petroleum), gas recovery plant deethanizer
68308–06–5	Tail gas (petroleum), hydrodesulfurized distillate and hydrodesulfurized naphtha fractionator, acid-free
68308–07–6	Tail gas (petroleum), hydrodesulfurized vacuum gas oil stripper, hydrogen sulfide-free
68308–08–7	Tail gas (petroleum), isomerized naphtha fractionation stabilizer
68308–09–8	Tail gas (petroleum), light straight-run naphtha stabilizer, hydrogen sulfide-free
68308–10–1	Tail gas (petroleum), straight-run distillate hydrodesulfurizer, hydrogen sulfide-free
68308–11–2	Tail gas (petroleum), propane-propylene alkylation feed prep deethanizer
68308–12–3	Tail gas (petroleum), vacuum gas oil hydrodesulfurizer, hydrogen sulfide-free
68308–27–0	Fuel gases, refinery
68333–22–2	Residues (petroleum), atmospheric
68333–23–3	Naphtha (petroleum), heavy coker
68333–24–4	Hydrocarbon waxes (petroleum), oxidized, compds. with triethanolamine
68333–25–5	Distillates (petroleum), hydrodesulfurized light catalytic cracked
68333–26–6	Clarified oils (petroleum), hydrodesulfurized catalytic cracked
68333–27–7	Distillates (petroleum), hydrodesulfurized intermediate catalytic cracked
68333–28–8	Distillates (petroleum), hydrodesulfurized heavy catalytic cracked
68333–29–9	Residues (petroleum), light naphtha solvent extracts
68333–30–2	Distillates (petroleum), oxidized heavy thermal cracked
68333–81–3	Alkanes, C4-12
68333–88–0	Aromatic hydrocarbons, C9-17
68334–30–5	Fuels, diesel
68409–99–4	Gases (petroleum), catalytic cracked overheads
68410–00–4	Distillates (petroleum), crude oil
68410–05–9	Distillates (petroleum), straight-run light
68410–12–8	Distillates (petroleum), steam-cracked, C5-10 fraction, high-temp. stripping products with light steam-cracked petroleum naphtha C5 fraction polymers
68410–71–9	Raffinates (petroleum), catalytic reformer ethylene glycol-water countercurrent exts.
68410–96–8	Distillates (petroleum), hydrotreated middle, intermediate boiling
68410–97–9	Distillates (petroleum), light distillate hydrotreating process, low-boiling
68410–98–0	Distillates (petroleum), hydrotreated heavy naphtha, deisohexanizer overheads
68411–00–7	Alkenes, C>8
68425–29–6	Distillates (petroleum), naphtha-raffinate pyrolyzate-derived, gasoline-blending
68425–33–2	Petrolatum (petroleum), oxidized, barium salt
68425–34–3	Petrolatum (petroleum), oxidized, calcium salt
68425–35–4	Raffinates (petroleum), reformer, Lurgi unit-sepd.
68425–39–8	Alkenes, C>10 .alpha.-, oxidized
68441–09–8	Hydrocarbon waxes (petroleum), clay-treated microcryst., contg. polyethylene, oxidized
68459–78–9	Alkenes, C18-24 .alpha.-, dimers
68475–57–0	Alkanes, C1-2
68475–58–1	Alkanes, C2-3
68475–59–2	Alkanes, C3-4
68475–60–5	Alkanes, C4-5
68475–61–6	Alkenes, C5, naphtha-raffinate pyrolyzate-derived
68475–70–7	Aromatic hydrocarbons, C6-8, naphtha-raffinate pyrolyzate-derived
68475–79–6	Distillates (petroleum), catalytic reformed depentanizer
68475–80–9	Distillates (petroleum), light steam-cracked naphtha
68476–26–6	Fuel gases
68476–28–8	Fuel gases, C6-8 catalytic reformer

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
68476–29–9	Fuel gases, crude oil distillates
68476–30–2	Fuel oil, no. 2
68476–31–3	Fuel oil, no. 4
68476–32–4	Fuel oil, residues-straight-run gas oils, high-sulfur
68476–33–5	Fuel oil, residual
68476–34–6	Fuels, diesel, no. 2
68476–39–1	Hydrocarbons, aliph.-arom.-C4-5-olefinic
68476–40–4	Hydrocarbons, C3-4
68476–42–6	Hydrocarbons, C4-5
68476–43–7	Hydrocarbons, C4-6, C5-rich
68476–44–8	Hydrocarbons, C>3
68476–45–9	Hydrocarbons, C5-10 arom. conc., ethylene-manuf.-by-product
68476–46–0	Hydrocarbons, C3-11, catalytic cracker distillates
68476–47–1	Hydrocarbons, C2-6, C6-8 catalytic reformer
68476–49–3	Hydrocarbons, C2-4, C3-rich
68476–50–6	Hydrocarbons, C≥5, C5-6-rich
68476–52–8	Hydrocarbons, C4, ethylene-manuf.-by-product
68476–53–9	Hydrocarbons, C≥20, petroleum wastes
68476–54–0	Hydrocarbons, C3-5, polymn. unit feed
68476–55–1	Hydrocarbons, C5-rich
68476–56–2	Hydrocarbons, cyclic C5 and C6
68476–77–7	Lubricating oils, refined used
68476–81–3	Paraffin waxes and Hydrocarbon waxes, oxidized, calcium salts
68476–84–6	Petroleum products, gases, inorg.
68476–85–7	Petroleum gases, liquefied
68476–86–8	Petroleum gases, liquefied, sweetened
68477–25–8	Waste gases, vent gas, C1-6
68477–26–9	Wastes, petroleum
68477–29–2	Distillates (petroleum), catalytic reformer fractionator residue, high-boiling
68477–30–5	Distillates (petroleum), catalytic reformer fractionator residue, intermediate-boiling
68477–31–6	Distillates (petroleum), catalytic reformer fractionator residue, low-boiling
68477–33–8	Gases (petroleum), C3-4, isobutane-rich
68477–34–9	Distillates (petroleum), C3-5, 2-methyl-2-butene-rich
68477–35–0	Distillates (petroleum), C3-6, piperylene-rich
68477–36–1	Distillates (petroleum), cracked steam-cracked, C5-18 fraction
68477–38–3	Distillates (petroleum), cracked steam-cracked petroleum distillates
68477–39–4	Distillates (petroleum), cracked stripped steam-cracked petroleum distillates, C8-10 fraction
68477–40–7	Distillates (petroleum), cracked stripped steam-cracked petroleum distillates, C10-12 fraction
68477–41–8	Gases (petroleum), extractive, C3-5, butadiene-butene-rich
68477–42–9	Gases (petroleum), extractive, C3-5, butene-isobutylene-rich
68477–44–1	Distillates (petroleum), heavy naphthenic, mixed with steam-cracked petroleum distillates C5-12 fraction
68477–47–4	Distillates (petroleum), mixed heavy olefin vacuum, heart-cut
68477–48–5	Distillates (petroleum), mixed heavy olefin vacuum, low-boiling
68477–53–2	Distillates (petroleum), steam-cracked, C5-12 fraction
68477–54–3	Distillates (petroleum), steam-cracked, C8-12 fraction
68477–55–4	Distillates (petroleum), steam-cracked, C5-10 fraction, mixed with light steam-cracked petroleum naphtha C5 fraction
68477–58–7	Distillates (petroleum), steam-cracked petroleum distillates, C5-18 fraction
68477–59–8	Distillates (petroleum), steam-cracked petroleum distillates cyclopentadiene conc.
68477–60–1	Extracts (petroleum), cold-acid
68477–61–2	Extracts (petroleum), cold-acid, C4-6
68477–62–3	Extracts (petroleum), cold-acid, C3-5, butene-rich
68477–63–4	Extracts (petroleum), reformer recycle
68477–64–5	Gases (petroleum), acetylene manuf. off
68477–65–6	Gases (petroleum), amine system feed
68477–66–7	Gases (petroleum), benzene unit hydrodesulfurizer off
68477–67–8	Gases (petroleum), benzene unit recycle, hydrogen-rich
68477–68–9	Gases (petroleum), blend oil, hydrogen-nitrogen-rich
68477–69–0	Gases (petroleum), butane splitter overheads
68477–70–3	Gases (petroleum), C2-3
68477–71–4	Gases (petroleum), catalytic-cracked gas oil depropanizer bottoms, C4-rich acid-free
68477–72–5	Gases (petroleum), catalytic-cracked naphtha debutanizer bottoms, C3-5-rich
68477–73–6	Gases (petroleum), catalytic cracked naphtha depropanizer overhead, C3-rich acid-free
68477–74–7	Gases (petroleum), catalytic cracker
68477–75–8	Gases (petroleum), catalytic cracker, C1-5-rich
68477–76–9	Gases (petroleum), catalytic polymd. naphtha stabilizer overhead, C2-4-rich
68477–77–0	Gases (petroleum), catalytic reformed naphtha stripper overheads
68477–79–2	Gases (petroleum), catalytic reformer, C1-4-rich
68477–80–5	Gases (petroleum), C6-8 catalytic reformer recycle
68477–81–6	Gases (petroleum), C6-8 catalytic reformer
68477–82–7	Gases (petroleum), C6-8 catalytic reformer recycle, hydrogen-rich

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
68477–83–8	Gases (petroleum), C3-5 olefinic-paraffinic alkylation feed
68477–84–9	Gases (petroleum), C2-return stream
68477–85–0	Gases (petroleum), C4-rich
68477–86–1	Gases (petroleum), deethanizer overheads
68477–87–2	Gases (petroleum), deisobutanizer tower overheads
68477–88–3	Gases (petroleum), deethanizer overheads, C3-rich
68477–89–4	Distillates (petroleum), depentanizer overheads
68477–90–7	Gases (petroleum), depropanizer dry, propene-rich
68477–91–8	Gases (petroleum), depropanizer overheads
68477–92–9	Gases (petroleum), dry sour, gas-concn.-unit-off
68477–93–0	Gases (petroleum), gas concn. reabsorber distn.
68477–94–1	Gases (petroleum), gas recovery plant depropanizer overheads
68477–95–2	Gases (petroleum), Girbatol unit feed
68477–96–3	Gases (petroleum), hydrogen absorber off
68477–97–4	Gases (petroleum), hydrogen-rich
68478–00–2	Gases (petroleum), recycle, hydrogen-rich
68478–01–3	Gases (petroleum), reformer make-up, hydrogen-rich
68478–02–4	Gases (petroleum), reforming hydrotreater
68478–03–5	Gases (petroleum), reforming hydrotreater, hydrogen-methane-rich
68478–04–6	Gases (petroleum), reforming hydrotreater make-up, hydrogen-rich
68478–05–7	Gases (petroleum), thermal cracking distn.
68478–08–0	Naphtha (petroleum), light steam-cracked, C5-fraction, oligomer conc.
68478–10–4	Naphtha (petroleum), light steam-cracked, debenzenized, C8-16-cycloalkadiene conc.
68478–12–6	Residues (petroleum), butane splitter bottoms
68478–13–7	Residues (petroleum), catalytic reformer fractionator residue distn.
68478–15–9	Residues (petroleum), C6-8 catalytic reformer
68478–16–0	Residual oils (petroleum), deisobutanizer tower
68478–17–1	Residues (petroleum), heavy coker gas oil and vacuum gas oil
68478–18–2	Residues (petroleum), heavy olefin vacuum
68478–19–3	Residual oils (petroleum), propene purifn. splitter
68478–20–6	Residues (petroleum), steam-cracked petroleum distillates cyclopentadiene conc., C4-cyclopentadiene-free
68478–22–8	Tail gas (petroleum), catalytic cracked naphtha stabilization absorber
68478–24–0	Tail gas (petroleum), catalytic cracker, catalytic reformer and hydrodesulfurizer combined fractionater
68478–25–1	Tail gas (petroleum), catalytic cracker refractionation absorber
68478–26–2	Tail gas (petroleum), catalytic reformed naphtha fractionation stabilizer
68478–27–3	Tail gas (petroleum), catalytic reformed naphtha separator
68478–28–4	Tail gas (petroleum), catalytic reformed naphtha stabilizer
68478–29–5	Tail gas (petroleum), cracked distillate hydrotreater separator
68478–30–8	Tail gas (petroleum), hydrodesulfurized straight-run naphtha separator
68478–32–0	Tail gas (petroleum), saturate gas plant mixed stream, C4-rich
68478–33–1	Tail gas (petroleum), saturate gas recovery plant, C1-2-rich
68478–34–2	Tail gas (petroleum), vacuum residues thermal cracker
68512–61–8	Residues (petroleum), heavy coker and light vacuum
68512–62–9	Residues (petroleum), light vacuum
68512–78–7	Solvent naphtha (petroleum), light arom., hydrotreated
68512–91–4	Hydrocarbons, C3-4-rich, petroleum distillates
68513–02–0	Naphtha (petroleum), full-range coker
68513–11–1	Fuel gases, hydrotreater fractionation, scrubbed
68513–12–2	Fuel gases, saturate gas unit fractionater-absorber overheads
68513–13–3	Fuel gases, thermal cracked catalytic cracking residue
68513–14–4	Gases (petroleum), catalytic reformed straight-run naphtha stabilizer overheads
68513–15–5	Gases (petroleum), full-range straight-run naphtha dehexanizer off
68513–16–6	Gases (petroleum), hydrocracking depropanizer off, hydrocarbon-rich
68513–17–7	Gases (petroleum), light straight-run naphtha stabilizer off
68513–18–8	Gases (petroleum), reformer effluent high-pressure flash drum off
68513–19–9	Gases (petroleum), reformer effluent low-pressure flash drum off
68513–62–2	Disulfides, C5-12-alkyl
68513–63–3	Distillates (petroleum), catalytic reformed straight-run naphtha overheads
68513–65–5	Butane, branched and linear
68513–66–6	Residues (petroleum), alkylation splitter, C4-rich
68513–67–7	Residues (petroleum), cyclooctadiene bottoms
68513–68–8	Residues (petroleum), deethanizer tower
68513–69–9	Residues (petroleum), steam-cracked light
68513–74–6	Waste gases, ethylene oxide absorber-reactor
68514–15–8	Gasoline, vapor-recovery
68514–29–4	Hydrocarbons, amylene feed debutanizer overheads nonextractable raffinates
68514–31–8	Hydrocarbons, C1-4
68514–32–9	Hydrocarbons, C10 and C12, olefin-rich
68514–33–0	Hydrocarbons, C12 and C14, olefin-rich
68514–34–1	Hydrocarbons, C9-14, ethylene-manuf.-by-product

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
68514–35–2	Hydrocarbons, C14-30, olefin-rich
68514–38–5	Hydrocarbons, C4-10-unsatd.
68514–36–3	Hydrocarbons, C1-4, sweetened
68514–37–4	Hydrocarbons, C4-5-unsatd.
68514–79–4	Petroleum products, hydrofiner-powerformer reformates
68515–25–3	Benzene, C1-9-alkyl derivs.
68515–26–4	Benzene, di-C12-14-alkyl derivs.
68515–27–5	Benzene, di-C10-14-alkyl derivs., fractionation overheads, heavy ends
68515–28–6	Benzene, di-C10-14-alkyl derivs., fractionation overheads, light ends
68515–29–7	Benzene, di-C10-14-alkyl derivs., fractionation overheads, middle cut
68515–30–0	Benzene, mono-C20-48-alkyl derivs.
68515–32–2	Benzene, mono-C12-14-alkyl derivs., fractionation bottoms
68515–33–3	Benzene, mono-C10-12-alkyl derivs., fractionation bottoms, heavy ends
68515–34–4	Benzene, mono-C12-14-alkyl derivs., fractionation bottoms, heavy ends
68515–35–5	Benzene, mono-C10-12-alkyl derivs., fractionation bottoms, light ends
68515–36–6	Benzene, mono-C12-14-alkyl derivs., fractionation bottoms, light ends
68516–20–1	Naphtha (petroleum), steam-cracked middle arom.
68526–52–3	Alkenes, C6
68526–53–4	Alkenes, C6-8, C7-rich
68526–54–5	Alkenes, C7-9, C8-rich
68526–55–6	Alkenes, C8-10, C9-rich
68526–56–7	Alkenes, C9-11, C10-rich
68526–57–8	Alkenes, C10-12, C11-rich
68526–58–9	Alkenes, C11-13, C12-rich
68526–77–2	Aromatic hydrocarbons, ethane cracking scrubber effluent and flare drum
68526–99–8	Alkenes, C6-9 .alpha.-
68527–00–4	Alkenes, C8-9 .alpha.-
68527–11–7	Alkenes, C5
68527–13–9	Gases (petroleum), acid, ethanolamine scrubber
68527–14–0	Gases (petroleum), methane-rich off
68527–15–1	Gases (petroleum), oil refinery gas distn. off
68527–16–2	Hydrocarbons, C1-3
68527–18–4	Gas oils (petroleum), steam-cracked
68527–19–5	Hydrocarbons, C1-4, debutanizer fraction
68527–21–9	Naphtha (petroleum), clay-treated full-range straight-run
68527–22–0	Naphtha (petroleum), clay-treated light straight-run
68527–23–1	Naphtha (petroleum), light steam-cracked arom.
68527–26–4	Naphtha (petroleum), light steam-cracked, debenzenized
68527–27–5	Naphtha (petroleum), full-range alkylate, butane-contg.
68553–00–4	Fuel oil, no. 6
68553–14–0	Hydrocarbons, C8-11
68602–79–9	Distillates (petroleum), benzene unit hydrotreater dipentanizer overheads
68602–81–3	Distillates, hydrocarbon resin prodn. higher boiling
68602–82–4	Gases (petroleum), benzene unit hydrotreater depentenizer overheads
68602–83–5	Gases (petroleum), C1-5, wet
68602–84–6	Gases (petroleum), secondary absorber off, fluidized catalytic cracker overheads fractionater
68602–96–0	Distillates (petroleum), oxidized light, strong acid components, compds. with diethanolamine
68602–97–1	Distillates (petroleum), oxidized light, strong acid components, sodium salts
68602–98–2	Distillates (petroleum), oxidized light, strong acid components
68602–99–3	Distillates (petroleum), oxidized light, strong acid-free
68603–00–9	Distillates (petroleum), thermal cracked naphtha and gas oil
68603–01–0	Distillates (petroleum), thermal cracked naphtha and gas oil, C5-dimer-contg.
68603–02–1	Distillates (petroleum), thermal cracked naphtha and gas oil, dimerized
68603–03–2	Distillates (petroleum), thermal cracked naphtha and gas oil, extractive
68603–08–7	Naphtha (petroleum), arom.-contg.
68603–09–8	Hydrocarbon waxes (petroleum), oxidized, calcium salts
68603–10–1	Hydrocarbon waxes (petroleum), oxidized, Me esters, barium salts
68603–11–2	Hydrocarbon waxes (petroleum), oxidized, Me esters, calcium salts
68603–12–3	Hydrocarbon waxes (petroleum), oxidized, Me esters, sodium salts
68603–13–4	Petrolatum (petroleum), oxidized, ester with sorbitol
68603–14–5	Residual oils (petroleum), oxidized, calcium salts
68603–31–6	Alkenes, C10, tert-amylene concentrator by-product
68603–32–7	Alkenes, C15-20 .alpha.-, isomerized
68606–09–7	Fuel gases, expander off
68606–10–0	Gasoline, pyrolysis, debutanizer bottoms
68606–11–1	Gasoline, straight–run, topping-plant
68606–24–6	Hydrocarbons, C4, butene concentrator by-product
68606–25–7	Hydrocarbons, C2-4
68606–26–8	Hydrocarbons, C3
68606–27–9	Gases (petroleum), alkylation feed
68606–28–0	Hydrocarbons, C5 and C10-aliph. and C6-8-arom.

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
68606–31–5	Hydrocarbons, C3-5, butadiene purifn. by-product
68606–34–8	Gases (petroleum), depropanizer bottoms fractionation off
68606–36–0	Hydrocarbons, C5-unsatd. rich, isoprene purifn. by-product
68607–11–4	Petroleum products, refinery gases
68607–30–7	Residues (petroleum), topping plant, low-sulfur
68608–56–0	Waste gases, from carbon black manuf.
68647-60–9	Hydrocarbons, C>4
68647–61–0	Hydrocarbons, C4-5, tert-amylene concentrator by-product
68647–62–1	Hydrocarbons, C4-5, butene concentrator by-product, sour
68650–36–2	Aromatic hydrocarbons, C8, *o*-xylene-lean
68650–37–3	Paraffin waxes (petroleum), oxidized, sodium salts
68782–97–8	Distillates (petroleum), hydrofined lubricating-oil
68782–98–9	Extracts (petroleum), clarified oil solvent, condensed-ring-arom.-contg.
68782–99–0	Extracts (petroleum), heavy clarified oil solvent, condensed-ring-arom.-contg.
68783–00–6	Extracts (petroleum), heavy naphthenic distillate solvent, arom. conc.
68783–01–7	Extracts (petroleum), heavy naphthenic distillate solvent, paraffinic conc.
68783–02–8	Extracts (petroleum), intermediate clarified oil solvent, condensed-ring-arom.-contg.
68783–04–0	Extracts (petroleum), solvent-refined heavy paraffinic distillate solvent
68783–05–1	Gases (petroleum), ammonia-hydrogen sulfide, water-satd.
68783–06–2	Gases (petroleum), hydrocracking low-pressure separator
68783–07–3	Gases (petroleum), refinery blend
68783–08–4	Gas oils (petroleum), heavy atmospheric
68783–09–5	Naphtha (petroleum), catalytic cracked light distd.
68783–12–0	Naphtha (petroleum), unsweetened
68783–13–1	Residues (petroleum), coker scrubber, condensed-ring-arom.-contg.
68783–15–3	Alkenes, C6-7 .alpha.-
68783–61–9	Fuel gases, refinery, sweetened
68783–62–0	Fuel gases, refinery, unsweetened
68783–64–2	Gases (petroleum), catalytic cracking
68783–65–3	Gases (petroleum), C2-4, sweetened
68783–66–4	Naphtha (petroleum), light, sweetened
68814–47–1	Waste gases, refinery vent
68814–67–5	Gases (petroleum), refinery
68814–89–1	Extracts (petroleum), heavy paraffinic distillates, solvent-deasphalted
68814–87–9	Distillates (petroleum), full-range straight-run middle
68814–90–4	Gases (petroleum), platformer products separator off
68814–91–5	Alkenes, C5-9 .alpha.-
68855–57–2	Alkenes, C6-12 .alpha.-
68855–58–3	Alkenes, C10-16 .alpha.-
68855–59–4	Alkenes, C14-18 .alpha.-
68855–60–7	Alkenes, C14-20 .alpha.-
68911–58–0	Gases (petroleum), hydrotreated sour kerosine dependanizer stabilizer off
68911–59–1	Gases (petroleum), hydrotreated sour kerosine flash drum
68915–96–8	Distillates (petroleum), heavy straight-run
68915–97–9	Gas oils (petroleum), straight-run, high-boiling
68918–69–4	Petrolatum (petroleum), oxidized, zinc salt
68918–73–0	Residues (petroleum), clay-treating filter wash
68918–93–4	Paraffin waxes and Hydrocarbon waxes, oxidized, alkali metal salts
68918–98–9	Fuel gases, refinery, hydrogen sulfide-free
68918–99–0	Gases (petroleum), crude oil fractionation off
68919–00–6	Gases (petroleum), dehexanizer off
68919–01–7	Gases (petroleum), distillate unifiner desulfurization stripper off
68919–02–8	Gases (petroleum), fluidized catalytic cracker fractionation off
68919–03–9	Gases (petroleum), fluidized catalytic cracker scrubbing secondary absorber off
68919–04–0	Gases (petroleum), heavy distillate hydrotreater desulfurization stripper off
68919–05–1	Gases (petroleum), light straight run gasoline fractionation stabilizer off
68919–06–2	Gases (petroleum), naphtha unifiner desulfurization stripper off
68919–07–3	Gases (petroleum), platformer stabilizer off, light ends fractionation
68919–08–4	Gases (petroleum), preflash tower off, crude distn.
68919–09–5	Gases (petroleum), straight-run naphtha catalytic reforming off
68919–10–8	Gases (petroleum), straight-run stabilizer off
68919–11–9	Gases (petroleum), tar stripper off
68919–12–0	Gases (petroleum), unifiner stripper off
68919–15–3	Hydrocarbons, C6-12, benzene-recovery
68919–17–5	Hydrocarbons, C12-20, catalytic alkylation by-products
68919–19–7	Gases (petroleum), fluidized catalytic cracker splitter residues
68919–20–0	Gases (petroleum), fluidized catalytic cracker splitter overheads
68919–37–9	Naphtha (petroleum), full-range reformed
68920–06–9	Hydrocarbons, C7-9
68920–07–0	Hydrocarbons, C<10-linear
68920–64–9	Disulfides, di-C1-2-alkyl

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES TERMED ''PETROLEUM PROCESS STREAMS'' FOR PURPOSES OF INVENTORY UPDATE REPORTING—Continued

CAS No.	Product
68921–07–3	Distillates (petroleum), hydrotreated light catalytic cracked
68921–09–5	Distillates (petroleum), naphtha unifiner stripper
68921–08–4	Distillates (petroleum), light straight-run gasoline fractionation stabilizer overheads
68921–67–5	Hydrocarbons, ethylene-manuf.-by-product distn. residues
68952–76–1	Gases (petroleum), catalytic cracked naphtha debutanizer
68952–77–2	Tail gas (petroleum), catalytic cracked distillate and naphtha stabilizer
68952–78–3	Tail gas (petroleum), catalytic hydrodesulfurized distillate fractionation stabilizer, hydrogen sulfide-free
68952–79–4	Tail gas (petroleum), catalytic hydrodesulfurized naphtha separator
68952–80–7	Tail gas (petroleum), straight-run naphtha hydrodesulfurizer
68952–81–8	Tail gas (petroleum), thermal-cracked distillate, gas oil and naphtha absorber
68952–82–9	Tail gas (petroleum), thermal cracked hydrocarbon fractionation stabilizer, petroleum coking
68953–80–0	Benzene, mixed with toluene, dealkylation product
68955–27–1	Distillates (petroleum), petroleum residues vacuum
68955–28–2	Gases (petroleum), light steam-cracked, butadiene conc.
68955–31–7	Gases (petroleum), butadiene process, inorg.
68955–32–8	Natural gas, substitute, steam-reformed desulfurized naphtha
68955–33–9	Gases (petroleum), sponge absorber off, fluidized catalytic cracker and gas oil desulfurizer overhead fractionation
68955–34–0	Gases (petroleum), straight-run naphtha catalytic reformer stabilizer overhead
68955–35–1	Naphtha (petroleum), catalytic reformed
68955–36–2	Residues (petroleum), steam-cracked, resinous
68955–76–0	Aromatic hydrocarbons, C9-16, biphenyl deriv.-rich
68955–96–4	Disulfides, dialkyl and di-Ph, naphtha sweetening
68956–47–8	Fuel oil, isoprene reject absorption
68956–48–9	Fuel oil, residual, wastewater skimmings
68956–52–5	Hydrocarbons, C4-8
68956–54–7	Hydrocarbons, C4-unsatd.
68956–55–8	Hydrocarbons, C5-unsatd.
68956–70–7	Petroleum products, C5-12, reclaimed, wastewater treatment
68988–79–4	Benzene, C10-12-alkyl derivs., distn. residues
68988–99–8	Phenols, sodium salts, mixed with sulfur compounds, gasoline alk. scrubber residues
68989–88–8	Gases (petroleum), crude distn. and catalytic cracking
68990–35–2	Distillates (petroleum), arom., hydrotreated, dicyclopentadiene-rich
68991–49–1	Alkanes, C10-13, arom.-free desulfurized
68991–50–4	Alkanes, C14-17, arom.-free desulfurized
68991–51–5	Alkanes, C10-13, desulfurized
68991–52–6	Alkenes, C10-16
69013–21–4	Fuel oil, pyrolysis
69029–75–0	Oils, reclaimed
69430–33–7	Hydrocarbons, C6-30
70024–88–3	Ethene, thermal cracking products
70528–71–1	Distillates (petroleum), heavy distillate solvent ext. heart-cut
70528–72–2	Distillates (petroleum), heavy distillate solvent ext. vacuum overheads
70528–73–3	Residues (petroleum), heavy distillate solvent ext. vacuum
70592–76–6	Distillates (petroleum), intermediate vacuum
70592–77–7	Distillates (petroleum), light vacuum
70592–78–8	Distillates (petroleum), vacuum
70592–79–9	Residues (petroleum), atm. tower, light
70693–00–4	Hydrocarbon waxes (petroleum), oxidized, sodium salts
70693–06–0	Aromatic hydrocarbons, C9-11
70913–85–8	Residues (petroleum), solvent-extd. vacuum distilled atm. residuum
70913–86–9	Alkanes, C18-70
70955–08–7	Alkanes, C4-6
70955–09–8	Alkenes, C13-14 .alpha.-
70955–10–1	Alkenes, C15-18 .alpha.-
70955–17–8	Aromatic hydrocarbons, C12-20
71243–66–8	Hydrocarbon waxes (petroleum), clay-treated, microcryst., oxidized, potassium salts
71302–82–4	Hydrocarbons, C5-8, Houdry butadiene manuf. by-product
71329–37–8	Residues (petroleum), catalytic cracking depropanizer, C4-rich
71808–30–5	Tail gas (petroleum), thermal cracking absorber
72230–71–8	Distillates (petroleum), cracked steam-cracked, C5-17 fraction
72623–83–7	Lubricating oils (petroleum), C>25, hydrotreated bright stock-based
72623–84–8	Lubricating oils (petroleum), C15-30, hydrotreated neutral oil-based, contg. solvent deasphalted residual oil
72623–85–9	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based, high-viscosity
72623–86–0	Lubricating oils (petroleum), C15-30, hydrotreated neutral oil-based
72623–87–1	Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based
93762–80–2	Alkenes, C15-18

(2) *Specific exempted chemical substances*—(i) *Exemption.* EPA has determined that, at this time, the information in § 710.52(c)(4) associated with the chemicals listed in paragraph (b)(2)(iv) of this section is of low current interest.

(ii) *Considerations.* In making its determination of whether this partial exemption should apply to a particular chemical substance, EPA will consider the totality of information available for the chemical substance in question, including but not limited to, one or more of the following considerations:

(A) Whether the chemical qualifies or has qualified in past IUR collections for the reporting of the information described in § 710.52(c)(4) (i.e., at least one site manufactures 300,000 pounds or more of the chemical).

(B) The chemical substance's chemical and physical properties or potential for persistence, bioaccumulation, health effects, or environmental effects (considered independently or together).

(C) The information needs of EPA, other federal agencies, tribes, states, and local governments, as well as members of the public.

(D) The availability of other complementary risk screening information.

(E) The availability of comparable processing and use information.

(F) Whether the potential risks of the chemical substance are adequately managed by EPA or another agency or authority.

(iii) *Amendments.* EPA may amend the chemical list in paragraph (b)(2)(iv) of this section on its own initiative or in response to a request from the public based on EPA's determination of whether the information in § 710.52(c)(4) is of low interest.

(A) Any person may request that EPA amend the chemical list in paragraph (b)(2)(iv) of this section. Your request must be in writing and must be submitted to the address provided in § 710.59(d). Requests must identify the chemical in question, as well as its CAS Number or other chemical identification number as identified in § 710.52(c)(3)(i). Your request should provide sufficient information for EPA to determine whether collection of the information in § 710.52(c)(4) for the chemical in question is of low interest. In preparing your request, please refer to the considerations outlined in paragraph (b)(2)(ii) of this section. If a request related to a particular chemical is resubmitted, any subsequent request must clearly identify new information contained in the request. EPA may request other information that it believes necessary to evaluate the request. EPA will issue a written response to each request within 120 days of receipt of the request, and will maintain copies of these responses in a public docket that will be established for each reporting cycle.

(B) As needed, the Agency will initiate rulemaking to make revisions to the list in paragraph (b)(2)(iv) of this section.

(C) To assist EPA in reaching a decision regarding a particular request prior to a given reporting year, requests must be submitted to EPA no later than 12 months prior to the start of the reporting year, i.e., by January 1, 2004, or by each January 1 at 4–year intervals thereafter.

(iv) *List of chemical substances.* EPA has designated the following chemical substances, listed by CAS Number, as partially exempt from reporting under the IUR.

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES UNDER § 710.46(B)(2)

CAS No.	Chemical
50–70–4	D-Glucitol
50–81–7	L-Ascorbic acid
50–99–7	D-Glucose
56–87–1	L-Lysine
57–50–1	.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl
58–95–7	2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12- trimethyltridecyl]-, acetate, (2R)-
59–02–9	2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12- trimethyltridecyl]-, (2R)-
59–51–8	Methionine
69–65–8	D-Mannitol
87–79–6	L-Sorbose
123–94–4	Octadecanoic acid, 2,3-dihydroxypropyl ester
124–38–9	Carbon dioxide
137–08–6	.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium alt (2:1)
142–47–2	L-Glutamic acid, monosodium salt
150–30–1	Phenylalanine
1317–65–3	Limestone
1333–74–0	Hydrogen
1592–23–0	Octadecanoic acid, calcium salt
7440–37–1	Argon
7440–44–0	Carbon
7727–37–9	Nitrogen
7782–42–5	Graphite
7782–44–7	Oxygen
8001–21–6	Sunflower oil
8001–22–7	Soybean oil
8001–23–8	Safflower 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
8002–13–9	Rape oil
8002–43–5	Lecithins
8002–75–3	Palm oil

CAS NUMBERS OF PARTIALLY EXEMPT CHEMICAL SUBSTANCES UNDER § 710.46(B)(2)—Continued

CAS No.	Chemical
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
9004–53–9	Dextrin
9005–25–8	Starch
9050–36–6	Maltodextrin
11103–57–4	Vitamin A
16291–96–6	Charcoal
26836–47–5	D-Glucitol, monooctadecanoate
61789–44–4	Fatty acids, castor-oil
61789–97–7	Tallow
61789–99–9	Lard
64147–40–6	Castor oil, dehydrated
64755–01–7	Fatty acids, tallow, calcium salts
65996–63–6	Starch, acid-hydrolyzed
65996–64–7	Starch, enzyme-hydrolyzed
67701–01–3	Fatty acids, C12-18
68002–85–7	Fatty acids, C14-22 and C16-22-unsatd.
68131–37–3	Syrups, hydrolyzed starch, dehydrated
68188–81–8	Grease, poultry
68308–54–3	Glycerides, tallow mono-, di- and tri-, hydrogenated
68334–00–9	Cottonseed oil, hydrogenated
68334–28–1	Fats and glyceridic oils, vegetable, hydrogenated
68409–76–7	Bone meal, steamed
68424–45–3	Fatty acids, linseed-oil
68424–61–3	Glycerides, C16-18 and C18-unsatd. mono- and di-
68425–17–2	Syrups, hydrolyzed starch, hydrogenated
68439–86–1	Bone, ash
68442–69–3	Benzene, mono-C10-14-alkyl derivs.
68476–78–8	Molasses
68514–27–2	Grease, catch basin
68514–74–9	Palm oil, hydrogenated
68525–87–1	Corn oil, hydrogenated
68648–86–2	Benzene, C14-16-alkyl derivs.
68648–87–3	Benzene, C10-16-alkyl derivs.
68918–42–3	Soaps, stocks, soya
68952–94–3	Soaps, stocks, vegetable-oil
68989–98–0	Fats and glyceridic oils, vegetable, residues
73138–67–7	Lard, hydrogenated
129813–58–7	Benzene, mono-C10-13-alkyl derivs.
129813–59–8	Benzene, mono-C12-14-alkyl derivs.
129813–60–1	Benzene, mono-C14-16-alkyl derivs.

(3) *Inorganic chemical substances.* For purposes of this subpart, an inorganic chemical substance is any chemical substance which does not contain carbon or contains carbon only in the form of carbonato [=CO3], cyano [--CN], cyanato [--OCN], isocyano [--NC], or isocyanato [--NCO] groups or the chalcogen analogues of such groups. During the 2006 submission period, manufacturers are excluded only from the reporting requirements under § 710.52(c)(4) for inorganic chemical substances. During the 2006 submission period, manufacturers of inorganic chemical substances are not excluded from the other reporting requirements under this part. During submission periods following the 2006 submission period, manufacturers of inorganic chemical substances are subject to all of the reporting requirements in this subpart.

§ 710.48 Persons who must report.

Except as provided in § § 710.49 and 710.50, the following persons are subject to the requirements of this subpart. 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. (11,340 kg) or more of a chemical substance described in § 710.45 at any single site owned or controlled by that person at any time during calendar year 2005 or during the calendar year at 4–year intervals thereafter is subject to reporting.

(b) *Special provisions for importers.* For purposes of this section, the site for a person who imports a chemical substance described in § 710.45 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 § 710.55(b)).

§ 710.49 Persons not subject to this subpart.

A person described in § 710.48 is not subject to the requirements of this subpart if that person qualifies as a small manufacturer as that term is defined in § 704.3 of this chapter. Notwithstanding this exclusion, a

person who qualifies as a small manufacturer is subject to this subpart with respect to any chemical substance that is the subject of a rule proposed or promulgated under section 4, 5(b)(4), or 6 of the Act, or is the subject of an order in effect under section 5(e) 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.

§ 710.50 Activities for which reporting is not required.

A person described in § 710.48 is not subject to the requirements of this subpart with respect to any chemical substance described in § 710.45 that the person solely manufactured or imported under the following circumstances:

(a) The person manufactured or imported the chemical substance described in § 710.45 solely in small quantities for research and development.

(b) The person imported the chemical substance described in § 710.45 as part of an article.

(c) The person manufactured the chemical substance described in § 710.45 in a manner described in § 720.30(g) or (h) of this chapter.

§ 710.52 Reporting information to EPA.

Any person who must report under this subpart, as described in § 710.48, must submit the information described in this section for each chemical substance described in § 710.45 that the person manufactured (including imported) for commercial purposes in an amount of 25,000 lbs. (11,340 kg) or more at any one site during calendar year 2005 or during the calendar year at 4–year intervals thereafter. (See § 710.48(b) for the ''site'' for importers). A separate form must be submitted for each chemical substance at each site for which the submitter is required to report. A submitter of information under this subpart must report information as described in paragraphs (c)(1), (c)(2), and (c)(3) of this section to the extent that such information is *known to or reasonably ascertainable by* that person whereas a submitter must report information as described in paragraph (c)(4) of this section only to the extent that such information is *readily obtainable* by that person. A submitter under this subpart must report information that applies to the calendar year for which the person is required to report (i.e., calendar year 2005 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 § 710.59. The form must include all information described 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 described 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 § 710.59.

(c) *Information to be reported.* Manufacturers (including importers) of a reportable chemical substance in an amount of 25,000 lbs. (11,340 kg) or more at a site during a reporting year must report the information described in paragraphs (c)(1), (c)(2), and (c)(3) of this section. Manufacturers (including importers) of a reportable chemical substance in an amount of 300,000 lbs. (136,077 kg) or more at a site during a reporting year must report the information described in paragraph (c)(4) of this section in addition to the information described in paragraphs (c)(1), (c)(2), and (c)(3) of this section. As described in § 710.46(b)(3), manufacturers of certain inorganic chemical substances are not required to report the information described in paragraph (c)(4) of this section during the 2006 submission period, but are required to report this information during subsequent submission periods. As described in § 710.46(b)(1) and (b)(2), manufacturers of certain chemicals are not required to report the information described in paragraph (c)(4) 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 as described in § 710.59.

(2) *Company and plant site information.* The following company and plant site information must be reported for each site at which at least 25,000 lbs. (11,340 kg) of a reportable chemical substance is manufactured (including imported) during calendar year 2005 or during the calendar year at 4–year intervals thereafter (see § 710.48(b) for the ''site'' for importers):

(i) The name 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, the parent company name and Dun and Bradstreet Number, the contact person's full mailing address, the contact person's telephone number and the contact person's e-mail address.

(ii) The name and full street address of each site. A submitter under this subpart must include the appropriate Dun and Bradstreet Number for each plant site reported, and the county or parish (or other jurisdictional indicator) in which the plant site is located.

(3) *Specific information for chemicals manufactured in amounts of 25,000 lbs. or more.* The following chemical-specific information must be reported for each reportable chemical substance manufactured at (including imported into) each site in amounts of 25,000 lbs. (11,340 kg) or more during calendar year 2005 or during the calendar year at 4–year intervals thereafter:

(i) The specific chemical name and CAS Number of each reportable chemical substance at each site. A submitter under this subpart may use an EPA-designated Accession Number for confidential substances, or a premanufacture notice (PMN) case number (see § 720.65 of this chapter) in lieu of a CAS Number when a CAS Number is not known to or reasonably ascertainable by the submitter. In addition to reporting the number itself, submitters must specify the type of number they are reporting by selecting from among the following codes:

CODES TO SPECIFY TYPE OF CHEMICAL IDENTIFYING NUMBER

Codes	Number Type
A	Accession Number
C	CAS Registry Number
P	PMN Number

(ii) A statement indicating, for each reportable chemical substance at each site, 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 at each site, 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 that the volume reported under paragraph (c)(3)(iv) of this section is confidential

business information under § 710.58 must indicate, for each reportable chemical substance at each site, whether the total volume range (in pounds) which corresponds with the specific volume figure reported in response to paragraph (c)(3)(iv) of this section is also confidential. Volume ranges are listed in the following table:

VOLUME RANGES

From	To
25,000 lbs.	300,000 lbs.
300,000 lbs.	1,000,000 lbs.
1,000,000 lbs.	10,000,000 lbs.
10,000,000 lbs.	50,000,000 lbs.
50,000,000 lbs.	100,000,000 lbs.
100,000,000 lbs.	500,000,000 lbs.
500,000,000 lbs.	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. For each reportable substance at each site, the submitter must select from among the ranges of workers listed in the following table and report the corresponding code (i.e., W1 through W8):

CODES FOR REPORTING NUMBER OF WORKERS REASONABLY LIKELY TO BE EXPOSED

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

(vii) The maximum concentration, measured by percentage of weight, of each reportable chemical substance at the time it is sent off-site from each site. If the chemical is site-limited, you must report the maximum concentration, measured by percentage of weight, of the reportable chemical substance at the time it is reacted on-site to produce a different chemical substance. This information must be reported regardless of the physical form(s) in which the substance is sent off-site/reacted on-site. For each substance at each site, select the maximum concentration of the substance from among the ranges listed in the following table and report the corresponding code (i.e., M1 through M5):

CODES FOR REPORTING MAXIMUM CONCENTRATION OF CHEMICAL SUBSTANCE

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

(viii) The physical form(s) of the reportable chemical substance as it is sent off-site from each site. If the chemical is site-limited, you must report the physical form(s) of the reportable chemical substance at the time it is reacted on-site to produce a different chemical substance. For each substance at each site, the submitter must report as many physical forms as apply from among the physical forms listed below:

(A) Dry powder.

(B) Pellets or large crystals.

(C) Water- or solvent-wet solid.

(D) Other solid.

(E) Gas or vapor.

(F) Liquid.

(ix) Submitters must report the percentage, rounded off to the closest 10%, of total production volume of the reportable chemical substance, reported in response to paragraph (c)(3)(iv) of this section, that is associated with each physical form reported under paragraph (c)(3)(viii) of this section. The sum of the percentages reported must not add up to more than 100%.

(4) Specific information for chemical substances manufactured in amounts of 300,000 lbs. or more. In addition to the information required under paragraphs (c)(1), (c)(2), and (c)(3) of this section, the following information must be reported for each reportable chemical substance manufactured (including imported) in an amount of 300,000 lbs. (136,077 kg) or more at any one site during calendar year 2005 or during the calendar year at 4–year intervals thereafter. Persons subject to paragraph (c)(4) of this section must report the information described in paragraphs (c)(4)(i) and (c)(4)(ii) of this section 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 reported in response to this paragraph must be reported only to the extent that it is readily obtainable by the submitter. If information responsive to a given data requirement under this paragraph, including information in the form of an estimate, is not readily obtainable, the submitter is not required to respond to the requirement.

(i) Industrial processing and use information.

(A) A designation indicating the type of industrial processing or use operation(s) at each site that receives a reportable substance from the submitter site directly or indirectly (whether the recipient site(s) are controlled by the submitter site or not). For each chemical substance, report the letters which correspond to the appropriate processing or use operation(s). A particular designation may need to be reported more than once, to the extent that a submitter reports more than one NAICS code (under paragraph (c)(4)(i)(B) of this section) that applies to a given designation under this paragraph.

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) of this section. Information about how to find these codes is provided in the instruction booklet available from EPA at the address set forth in § 710.59. A particular NAICS code may need to be reported more than once, to the extent that a submitter reports more than one industrial function code (under paragraph (c)(4)(i)(C) of this section) that applies to a given NAICS code under this paragraph.

(C) For each NAICS code reported under paragraph (c)(4)(i)(B) of this section, code(s) from the following list must be selected to designate the industrial function category(ies) that best represents the specific manner in which the chemical substance is used. A particular industrial function category may need to be reported more than once, to the extent that a submitter reports more than one industrial processing or use operation/NAICS code

combination (under paragraphs (c)(4)(i)(A) and (c)(4)(i)(B) of this section) that applies to a given industrial function category under this paragraph. If more than 10 unique combinations of industrial processing or use operations/NAICS codes/industrial function categories apply to a chemical substance, submitters need only report the 10 unique combinations for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight.

CODES FOR REPORTING INDUSTRIAL FUNCTION CATEGORIES

Codes	Category
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 estimated percentage, rounded off to the closest 10%, of total production volume of the reportable chemical substance associated with each combination of industrial processing or use operation, NAICS code and industrial function category. Where a particular combination of industrial processing or use operation, NAICS code and industrial function category accounts for 5% or less of the submitter's site's total production volume of a reportable chemical substance, the percentage must not be rounded off to zero % if the production volume attributable to that industrial processing or use operation, NAICS code and industrial function category combination is 300,000 lbs. (136,077 kg) or more during the reporting year. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1%, of the submitter's site's total production volume of the reportable chemical substance associated with the particular combination of industrial processing or use operation, NAICS code and industrial function category.

(E) For each combination of industrial processing or use operation, NAICS code and industrial function category, the submitter must estimate the number of sites at which each reportable chemical substance is processed or used. For each combination associated with each substance, the submitter must select from among the ranges of sites listed in the following table and report the corresponding code (i.e., S1 through S7):

CODES FOR REPORTING NUMBERS OF SITES

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

(F) For each combination of industrial processing or use operation, NAICS code and industrial function category, the submitter must estimate the number of workers reasonably likely to be exposed to each reportable chemical substance. For each combination associated with each substance, the submitter must select from among the worker ranges listed in paragraph (c)(3)(vi) of this section and report the corresponding code (i.e., W1 though W8).

(ii) *Commercial and consumer use information.*

(A) Using the codes listed in this paragraph, submitters must designate the commercial and consumer product category or categories that best describe the commercial and consumer products in which each reportable chemical substance is used (whether the recipient site(s) are controlled by the submitter site or not). If more than 10 codes apply to a chemical substance, submitters need only report the 10 codes for the chemical substance that cumulatively represent the largest percentage of the submitter's production volume for that chemical, measured by weight:

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) Submitters must determine, within each commercial and consumer product category reported under paragraph (c)(4)(ii)(A) of this section, whether any amount of each reportable chemical substance manufactured (including imported) by the submitter is present in (for example, a plasticizer chemical used to make pacifiers) or on (for example, as a component in the paint on a toy) any consumer products intended for use by children up to the age of 14, regardless of the concentration of the substance remaining in or on the product. Submitters must select from the following options: the chemical substance is used in or on any consumer products intended for use by children, the chemical substance is not used in or on any consumer products intended for use by children, or information as to whether the chemical substance is used in or on any consumer products intended for use by children is not readily obtainable.

(C) The estimated percentage, rounded off to the closest 10%, of the submitter's site's 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 must not be rounded off to zero % if the production volume attributable to that commercial and consumer product category is 300,000 lbs. (136,077 kg) or more during the reporting year. Instead, in such a case, submitters must report the percentage, rounded off to the closest 1%, of the submitter's site's total production volume of the reportable chemical substance associated with the particular commercial and consumer product category.

(D) Where the reportable chemical substance is used in commercial or consumer products, the estimated typical maximum concentration, measured by weight, of the chemical substance in each commercial and consumer product category reported under paragraph (c)(4)(ii)(A) of this section. For each substance in each commercial and consumer product category reported under paragraph (c)(4)(ii)(A) of this section, submitters must select from among the ranges of concentrations listed in the table in paragraph (c)(3)(vii) of this section and report the corresponding code (i.e., M1 through M5).

§ 710.53 When to report.

All information reported to EPA in response to the requirements of this subpart must be submitted during an applicable submission period. The first submission period is from August 25, 2006, to December 23, 2006. Subsequent recurring submission periods are from August 25 to December 23 at 4–year intervals after the first submission period. Any person described in § 710.48(a) must report during each submission period for each chemical substance described in § 710.45 that the person manufactured (including imported) during the preceding calendar year (i.e., the ''reporting year'').

§ 710.55 Duplicative reporting.

(a) *With regard to section 8(a) rules.* Any person subject to the requirements of this part who previously has complied with reporting requirements of a rule under section 8(a) of the Act by submitting the information described in § 710.52 for a chemical substance described in § 710.45 to EPA, and has done so within 1 year of the start of a submission period described in § 710.53, is not required to report again on the manufacture of that substance at that site during that submission period.

(b) *With regard to importers.* This part requires that only one report be submitted on each import transaction involving a chemical substance described in § 710.45. When two or more persons are involved in a particular import transaction and each person meets the Agency's definition of ''importer'' as set forth in § § 710.3 and 704.3 of this chapter, they may determine among themselves who should submit the required report; if no report is submitted as required under this part, EPA will hold each such person liable for failure to report.

§ 710.57 Recordkeeping requirements.

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

§ 710.58 Confidentiality.

(a) Any person submitting information under this subpart 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 submission period. Guidance for asserting confidentiality claims is provided in the instruction booklet identified in § 710.59. 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) Chemical identity. 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 subpart. The following steps must be taken to assert a claim of confidentiality for the identity of a reportable chemical substance:

(1) The submitter 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 subpart? 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? 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 listed in paragraph (b)(1) of this section is asserted to contain confidential business information, the submitter must clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(c) Site identity. A submitter may assert a claim of confidentiality for a site only if the linkage of the site with a reportable chemical is confidential and not publicly available. The following steps must be taken to assert a claim of confidentiality for a site identity:

(1) The submitter 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 being disclosed in connection with reporting under this subpart? 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 listed in paragraph (c)(1) of this section is asserted to contain confidential business information, the submitter must clearly identify the information that is claimed confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(d) If no claim of confidentiality is indicated on the reporting form submitted to EPA under this subpart, 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.

§ 710.59 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 and from the EPA Internet Home Page at http://www.epa.gov/oppt/iur.

(b) *Follow the reporting instructions.* Guidance for completing the reporting form and preparing an electronic (magnetic media) report will be made available prior to each submission period.

(c) *Obtain the reporting package and copies of the form.* EPA will send a reporting package (consisting of a copy of Form U and a copy of the reporting instructions) to those submitters that reported in the IUR submission period that occurred immediately prior to the current submission period. Failure to receive a reporting package does not obviate or otherwise affect the requirement to submit a timely report. 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 telephone.* Call the EPA TSCA Hotline at 202–554–1404.

(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, Mailcode 7408M, ATTN: Inventory Update Rule, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(4) *By Internet.* To download a copy of the form and/or instructions go to: http://www.epa.gov/oppt/iur.

(d) *Submit the completed reports.* You must submit your completed reporting form(s) and/or magnetic media to EPA at the following address: OPPT Document Control Officer (DCO), Mailcode 7407M, ATTN: Inventory Update Rule, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Part 723 is amended as follows:

PART 723—[AMENDED]

a. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

b. In § 723.175, revise paragraph (b)(3) to read as follows:

§ 723.175 Premanufacture Notification Exemptions

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(b) Definitions. * * *

(3) The terms *byproduct*, *EPA*, *impurities*, *person*, and *site* have the same meanings as in § 710.3 of this chapter.

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