

PREPUBLICATION COPY NOTICE:

The Assistant Administrator for Chemical Safety and Pollution Prevention signed the following final rule on **August 1, 2011**.

This is a prepublication version of the final rule that EPA is submitting for publication in the *Federal Register*. While the Agency has taken steps to ensure the accuracy of this Internet version of the final rule, it is not the official version of the final rule for purposes of judicial review. Please refer to the official version of the final rule that will appear in a forthcoming *Federal Register* publication, which is currently expected to occur in the week of August 7th.

Once the official version of the final rule publishes in the *Federal Register*, this advance publication version of the final rule will be replaced with a link to the final rule that appears in the *Federal Register* publication. At that time, you will also be able to access the on-line docket for this rulemaking at <http://www.regulations.gov>. You can then use EPA's electronic docket and comment system at www.regulations.gov, to access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. The docket number for this rulemaking is **EPA-HQ-OPPT-2009-0187**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 704, 710, and 711

[EPA-HQ-OPPT-2009-0187; FRL-8872-9]

RIN 2070-AJ43

TSCA Inventory Update Reporting Modifications; Chemical Data Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending the Toxic Substances Control Act (TSCA) section 8(a) Inventory Update Reporting (IUR) rule and changing its name to the Chemical Data Reporting (CDR) rule. The CDR enables EPA to collect and publish information on the manufacturing, processing, and use of commercial chemical substances and mixtures (referred to hereafter as chemical substances) on the TSCA Chemical Substance Inventory (TSCA Inventory). This includes current information on chemical substance production volumes, manufacturing sites, and how the chemical substances are used. This information helps the Agency determine whether people or the environment are potentially exposed to reported chemical substances. EPA publishes submitted CDR data that is not Confidential Business Information (CBI). EPA is amending this rule to require submission of information that will better address Agency and public information needs, improve the usability and reliability of the reported data, and ensure that data are available in a timely manner. EPA is requiring electronic reporting of CDR information and modifying reporting requirements, including certain circumstances that trigger

11T-0566

reporting, the specific data to be reported, the reporting standard for processing and use information, and CBI reporting procedures.

DATES: This final rule is effective [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2009-0187. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

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SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture (including manufacture as a byproduct) or import, for commercial purposes, chemical substances listed on the TSCA Inventory (under TSCA section 3, “import” is included in the definition of manufacture). Potentially affected entities may include, but are not limited to:

- Chemical substance manufacturers and importers (NAICS codes 325 and 324110; e.g., chemical substance manufacturing and processing and petroleum refineries).
- Chemical substance users and processors who, in addition to manufacturers described in this unit, may manufacture a byproduct chemical substance (NAICS codes 22, 322, 331, and 3344; e.g., utilities, paper manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing).

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. The North American Industrial Classification

System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What Action is the Agency Taking?

In this action, EPA is promulgating several amendments to the IUR rule, taking into consideration comments received on the proposed rule and is changing its name to the CDR rule. The amendments were proposed in the **Federal Register** issue of August 13, 2010 (Ref. 1). The amendments contained in this final rule, as well as the TSCA Inventory update provisions of 40 CFR part 710, subpart C, unchanged by these amendments, appear in a new part, 40 CFR part 711. The following is a brief listing of the primary amendments. These amendments are described in more detail in Unit III.

1. EPA is amending 40 CFR 710.59, which appears in the new 40 CFR part 711 as 40 CFR 711.35, to require electronic reporting of the CDR data, using an Agency-provided, web-based reporting tool (e-CDRweb) to submit CDR reports through the Internet to EPA's Central Data Exchange (CDX). After the final rule's effective date (see **DATES**), paper submissions will no longer be accepted.

2. EPA is adding a new definition section, which appears in the new 40 CFR part 711 as 40 CFR 711.3, revising the definition for *manufacture* and *site*; and making other needed definitional modifications and additions.

3. EPA is amending 40 CFR 710.53, which appears in the new 40 CFR part 711 as 40 CFR 711.20, to change the reporting frequency from every 5 years to every 4 years.

4. EPA is amending 40 CFR 710.48(a), which appears in the new 40 CFR part 711 as 40 CFR 711.8(a), to modify the method used to determine whether a manufacturer (including importer) is subject to CDR reporting. The method will be effective after the 2012 submission period. Subsequent to 2012, reporting is required if the production volume of a chemical substance met or exceeded the 25,000 pound (lb) threshold in any calendar year since the last principal reporting year (e.g., 2011).

5. EPA is amending 40 CFR 710.52(c), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b), to replace the 300,000 lb reporting threshold for processing and use information by phasing in a lower threshold. For the 2012 submission period, the threshold for reporting processing and use information is 100,000 lb. In subsequent submission periods, the reporting threshold will be 25,000 lb.

6. EPA is amending 40 CFR 710.48(a), which appears in the new 40 CFR part 711 as 40 CFR 711.8(b), to replace the 25,000 lb threshold for specific chemical substances that are the subject of particular TSCA rules and/or orders. The new reporting threshold for these chemical substances is 2,500 lb, which is effective for the 2016 submission period and subsequent submission periods.

7. EPA is amending 40 CFR 710.46, which appears in the new 40 CFR part 711 as 40 CFR 711.6, to make chemical substances for which an enforceable consent agreement (ECA) to conduct testing has been made under 40 CFR part 790 ineligible for exemptions, to provide a full exemption from CDR requirements for water, and to remove polymers, which are already fully exempt from the partially exempt list of chemical substances at 40 CFR 710.46(b)(2)(iv), which appears in the new 40 CFR part 711 as 40 CFR 711.6(b)(2)(iv).

8. EPA is amending 40 CFR 710.52(c), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b), to modify the reporting requirements for certain manufacturing data elements. Specifically, manufacturers (including importers) are required to report:

- a. The name and address belonging to the parent company.
- b. The current Chemical Abstracts (CA) Index Name, as used to list the chemical substance on the TSCA Inventory, as part of the chemical identity.
- c. For the 2012 submission period only, the production volume for calendar year 2010.
- d. The production volume for each of the years since the last principal reporting year. This requirement will be effective after the 2012 reporting cycle (i.e., for the 2016 submission period and subsequent submission periods).
- e. The volume of a manufactured (including imported) chemical substance used at the reporting site.
- f. Whether an imported chemical substance is physically present at the reporting site.
- g. The volume directly exported and not domestically processed or used.
- h. When a manufactured chemical substance, such as a byproduct, is being recycled, remanufactured, reprocessed, or reused.

9. EPA is replacing the “readily obtainable” reporting standard used for the reporting of processing and use information required by 40 CFR 710.52(c)(4), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(4), with the “known to or reasonably ascertainable by” reporting standard.

10. EPA is amending 40 CFR 710.58, which appears in the new 40 CFR part 711 as 40 CFR 711.30, to require upfront substantiation when processing and use information required by 40 CFR 710.52(c)(4), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(4), is claimed as CBI.

11. EPA will disallow confidentiality claims for processing and use data elements identified as not “known to or reasonably ascertainable by” (40 CFR 710.52(c)(4)), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(4).

12. EPA is revising the list of industrial function categories for the reporting of processing and use information. EPA is also amending 40 CFR 710.52(c)(4)(i)(C), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(4)(i)(B), to replace the 5-digit NAICS codes with 48 Industrial Sector (IS) codes.

13. EPA is amending 40 CFR 710.52(c)(4)(ii), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(4)(ii), to revise the list of consumer and commercial product categories for the reporting of consumer and commercial use information. EPA is also requiring the separate reporting for consumer or commercial categories and the reporting of the number of commercial workers reasonably likely to be exposed to the subject chemical substance.

14. EPA is eliminating the gaps in the ranges used to report concentration in 40 CFR 710.52(c)(3) and (c)(4), which appear in the new 40 CFR part 711 as 40 CFR 711.15(b)(3) and (b)(4).

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 manufactured or processed in the

United States. This inventory is known as the TSCA Chemical Substance Inventory (TSCA Inventory). The Agency maintains the Master Inventory File as the authoritative list of all the chemical substances reported to EPA for inclusion on the TSCA Inventory. In 1977, EPA promulgated a rule published in the **Federal Register** issue of December 23, 1977 (Ref. 2) 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 rule under TSCA section 8(a) at 40 CFR part 710, published in the **Federal Register** issue of June 12, 1986 (Ref. 3), to facilitate the periodic updating of information on chemical substances listed on the TSCA Inventory and to support activities associated with the implementation of TSCA. In 2003, EPA promulgated extensive amendments to the IUR rule, published in the **Federal Register** issue of January 7, 2003 (2003 IUR Amendments) (Ref. 4), to collect exposure-related information associated with the manufacturing, processing, and use of eligible chemical substances and to make certain other changes.

Section 8(a)(1) of TSCA authorizes the EPA Administrator to promulgate rules under which manufacturers and processors of chemical substances must maintain such records and submit such information as the EPA Administrator may reasonably require. Section 8(a) of TSCA 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)(A)(ii) 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 in effect under TSCA section 5(e), or that is the subject of relief

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 part 710, which appears in the new 40 CFR part 711, is found at 40 CFR 704.3. Processors are not currently subject to the rules at 40 CFR part 710, which appears in the new 40 CFR part 711.

This document renames the IUR as CDR and promulgates the CDR as 40 CFR part 711, which includes provisions copied from the existing regulations in 40 CFR part 710, subpart C, that are not substantively changed as a part of this rulemaking, and the new 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 Was the TSCA Inventory Update Reporting (IUR) Rule Prior to These Modifications?

The IUR rule, as modified by the 2003 IUR Amendments, required U.S. manufacturers (including importers) of chemical substances listed on the TSCA Inventory to report the identity of chemical substances manufactured (including imported) during the reporting year in quantities of 25,000 lb or greater at any single site they own or control to EPA every 5 years. IUR data were collected five times prior to the 2003 IUR Amendments: 1986, 1990, 1994, 1998, and 2002, and one time after the 2003 IUR Amendments, in 2006. EPA uses the TSCA Inventory and data reported under the IUR rule to support many TSCA-related activities and to support a number of EPA and other Federal health, safety, and environmental protection activities. The Agency also makes the data available to the public, to the extent possible given CBI claims.

Persons manufacturing (including importing) chemical substances were required to report information such as company name, site location and other identifying information, production volume of the reportable chemical substance, and exposure-related information associated with the manufacture of each reportable chemical substance. This exposure-related information included the physical form and maximum concentration of the chemical substance and the number of potentially exposed workers. Several groups of chemical substances were and will continue to be generally excluded from the reporting requirements: e.g., polymers, microorganisms, naturally occurring chemical substances, and certain natural gas substances.

Manufacturers (including importers) of chemical substances in larger volumes (i.e., 300,000 lb or greater manufactured (including imported) during the reporting year at any single site) were required also to report certain processing and use information for the 2006 submission. This information includes process or use category; NAICS code; industrial function category; percent production volume associated with each process or use category; number of use sites; number of potentially exposed workers; and consumer/commercial information such as use category, use in or on products intended for use by children, and maximum concentration.

The 2006 submission was the first instance where manufacturers (including importers) of inorganic chemical substances were required to report under the IUR rule. For the 2006 submission only, inorganic chemical substances were partially exempted from the IUR rule, and manufacturers of such chemical substances were required to report the manufacturing information and not the processing and use information, regardless of production volume. Under the previous rule, for future collections (i.e., for

2011 or 2016 collections, etc.), the partial exemption for inorganic chemical substances would have no longer been applicable and submitters would have reported in the same manner as was required for organic chemical substances, including processing and use information. In addition, starting with the 2006 collection and for future collections, specifically listed petroleum process streams and other specifically listed chemical substances were partially exempt, and manufacturers of such chemical substances were not required to report processing and use information. These partial exemptions will continue in subsequent submission periods under the CDR as revised in this final rule (including the 2012 collection), for as long as the chemical substances remain on these partial exemption lists 40 CFR 711.6(b)(1) and (b)(2).

Non-confidential data, including both searchable and separately downloadable databases, and the 2006 IUR data summary report are available to the public on the CDR website (<http://www.epa.gov/iur>).

D. Why is the Agency Amending the IUR Rule?

EPA has modified the IUR rule to meet four primary goals:

1. To tailor the information collected to better meet the Agency's overall information needs.
2. To increase its ability to effectively provide public access to the information.
3. To obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory.
4. To improve the usefulness of the information reported.

EPA believes that expanding the range of chemical substances for which more in-depth processing and use information is to be reported and adjusting the specific reported

information, the method and frequency of collecting the information, and CBI requirements will accomplish these goals.

These goals are supported by a policy outlined in TSCA section 2, which is that “adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures” (TSCA section 2(b)(1)). Modifications to the IUR requirements by the 2003 IUR Amendments provided many improvements to the data collected through that rule, and EPA’s efforts to use the 2006 IUR data identified areas where further improvements are needed. The modifications described in this final rule change some of the reporting requirements in an effort by EPA to ensure the required information is properly reported and that the information in the Agency’s database reflects the information provided in the IUR reports; increase the usability of the collected information; increase the availability of information for the public; and focus reporting on information that is most needed by the Agency.

In addition, these changes will enable EPA and other Federal agencies to improve their risk screening capabilities, enabling them to better assess and manage risk, and improve public awareness of basic information about a large number of chemical substances.

EPA provided reporting software for the 2006 IUR submission period and encouraged electronic reporting through the Internet, using the Agency’s CDX. EPA’s experience with populating the IUR database and with using the 2006 IUR data provided insight into how well both the reporting software and submission methods worked. For

instance, because of validations built into the reporting software, electronic submissions were able to be quickly assimilated into the IUR database. Other forms of submission required the documents to be scanned in or hand entered, and resulted in many introduced errors during the data entry process. Additionally, for the 2006 IUR, certain types of submissions (e.g., joint submissions) could not be reported electronically. Other problems, such as incorrect chemical identities, delayed the inclusion of the data into the database, resulting in the Agency's inability to begin using the 2006 IUR data and providing public access in a timely manner. The modifications in this final rule associated with reporting methods and changes to the reporting software will better ensure the information reported to the Agency is accurate and in compliance with the IUR requirements.

During the development of the 2003 IUR Amendments, the Agency considered the data accuracy and reliability needed for screening level exposure analyses and took several steps to ensure the IUR data met those needs. Screening level data need not be precise, but should be accurate and reliable enough for the Agency to develop screening level assessments. The 2003 IUR Amendments supplied exposure-related information the Agency did not previously possess, recognizing that industry has a greater knowledge than EPA about its own operations and the uses of chemical substances it manufactures and sells.

EPA's extensive use of the 2006 IUR data in the Agency's Existing Chemicals Program is consistent with how EPA envisioned the data would be used when the 2003 IUR Amendments were promulgated. In 2007, the Agency began to develop and post screening-level hazard, exposure, and risk characterizations for high production volume

(HPV) chemical substances, which are those chemical substances produced nationally at aggregated volumes of one million lb or more per year. In developing these characterizations, EPA identified areas where the IUR data collection can be improved and enhanced. Improvements would allow EPA to better identify and take follow-up action on chemical substances that may pose potential risks to human health or the environment.

During its review of the IUR data, EPA identified numerous examples of CBI claims where the same or similar information to that claimed as CBI was already available to the public. In several cases, information on production volume and uses for a chemical substance or group of chemical substances was claimed CBI on Form U, while the same or similar information was submitted voluntarily by the company without such a claim under the HPV Challenge Program. In those cases, EPA had previously made the information publicly available through the High Production Volume Information System (HPVIS) or on EPA's Existing Chemicals Program website. More detailed CBI substantiation requirements will encourage the correct designation of non-confidential reported information, thereby facilitating reporting of this information to the public.

EPA Administrator Lisa P. Jackson has made it a priority to strengthen the Agency's chemical management program, including the development of new regulatory risk management actions, the development of Chemical Action Plans targeting the Agency's risk management efforts, requiring the reporting of information needed to understand chemical substance risks, and increasing public access to information about chemical substances (Ref. 5). The IUR provides exposure-related data needed to understand chemical substance risks. The modifications to the IUR rule will enhance the

capabilities of the Agency to ensure risk management actions are taken on chemical substances which may pose the greatest concern. More in-depth reporting of the processing and use data, more careful consideration of the need for confidentiality claims, and adjustments to the specific data elements are important aspects of this action. By enhancing the data supplied to the Agency, EPA expects to more effectively and expeditiously identify and address potential risks posed by chemical substances and provide improved access and information to the public.

An important and anticipated result of this action is that EPA will receive more publicly available, non-CBI information, therefore increasing the transparency and public accessibility of the chemical substance use, and exposure information and ensuring consistency with the President's policy goals for government reliance on and public availability of scientific information.

As part of this action, EPA is also renaming the IUR to CDR. This name change is intended to better reflect the distinction between this data collection (which includes exposure-related data) and the TSCA Inventory itself (which only involves chemical identification information). Identifying this data collection as "CDR" will make it easier for the public to understand what information is available to them through the data collection. The name change thereby contributes to the Agency's current chemicals management program by increasing transparency and facilitating public access to information about chemical substances.

E. When is Reporting Required?

EPA promulgated a final rule, published in the **Federal Register** issue of May 11, 2011 (Ref. 6), to suspend the 2011 submission period. EPA suspended the submission

period to allow additional time to finalize the proposed modifications, and to provide sufficient time for companies to comply with the CDR reporting requirements. This action supersedes the suspension of the 2011 submission period by establishing a new sequence of submission periods, beginning with a submission period in 2012. For the 2012 CDR, all information reported to EPA in response to 40 CFR part 711 must be submitted between February 1, 2012, and June 30, 2012. Beginning in 2016 and for each subsequent submission period, the submission period will begin June 1 and end September 30 (40 CFR 711.20).

III. What Are the Revised Requirements of the CDR?

EPA is making a number of revisions to the IUR, as described in this unit. The regulatory text of this document describes the full specific CDR reporting requirements and includes both the modified and the unmodified portions of the regulatory text (see 40 CFR part 711). EPA has also developed guidance documents with specific reporting instructions, questions and answers, and case studies, and intends to conduct a webinar to help potential CDR submitters become familiar with the revised reporting form (Form U) and amended reporting requirements. Guidance documents and information on the webinar are available on the CDR website (<http://www.epa.gov/iur>).

A. What Technical Modifications Have Been Made to the Regulatory Text?

The Agency is making several technical modification related to moving the regulatory text to its own part in the CFR. The chemical substances that are covered by the CDR rule are on the Master Inventory File, which includes chemical substances from the original TSCA Inventory compilation and those added subsequently through the notice requirements of TSCA section 5. Because the CDR rule applies to a list of

chemical substances included on the original TSCA Inventory plus additional chemical substances added subsequently, and because the Agency from time to time has modified the CDR rule, the Agency believes the regulatory text associated with the CDR rule should be in its own part in the CFR, distinct from both the original TSCA Inventory rules and from the TSCA section 5 requirements.

1. *Move the IUR regulatory text from 40 CFR part 710, subpart C, to 40 CFR part 711 and eliminate subpart divisions.* Subpart C (40 CFR 710.43 to 710.59) of 40 CFR part 710 contains the IUR regulatory text. EPA is moving all of the subpart C text from 40 CFR part 710 to a new 40 CFR part 711 and adding a new scope and compliance section (40 CFR 711.1).

Table 1.--Distribution Table for 40 CFR Part 710, Subpart C, Regulatory Text

Old CFR Citation	New CFR Citation
40 CFR 710.43	40 CFR 711.3
40 CFR 710.45	40 CFR 711.5
40 CFR 710.46	40 CFR 711.6
40 CFR 710.48	40 CFR 711.8
40 CFR 710.49	40 CFR 711.9
40 CFR 710.50	40 CFR 711.10
40 CFR 710.52	40 CFR 711.15
40 CFR 710.53	40 CFR 711.20
40 CFR 710.55	40 CFR 711.22
40 CFR 710.57	40 CFR 711.25
40 CFR 710.58	40 CFR 711.30
40 CFR 710.59	40 CFR 711.35

Because all of the text of subpart C was moved to 40 CFR part 711, 40 CFR part 710 no longer has a subpart C. Neither 40 CFR part 710 nor 40 CFR part 711 have any subparts.

2. *Consolidate definitions.* As part of moving the regulatory text from 40 CFR part 710, subpart C, to 40 CFR part 711, EPA is consolidating definitions copied from 40 CFR 710.3 and 40 CFR 710.43 into the new 40 CFR 711.3, except where an appropriate definition is already in place in TSCA section 3 or at 40 CFR 704.3, and an additional definition of the term in 40 CFR 711.3 was therefore unnecessarily duplicative. The definitions in TSCA section 3 and at 40 CFR 704.3 are included in 40 CFR 711.3, except insofar as 40 CFR 711.3 provides a modified definition of a term also defined at 40 CFR 704.3.

The term *mixture* is defined in both 40 CFR 710.3 and TSCA section 3. For purposes of the CDR rule, EPA is including the definition of *mixture* from TSCA section 3 with the definitions at 40 CFR 711.3. The TSCA mixture definition differs from the definition in 40 CFR 710.3 and 40 CFR 720.3, the regulations used to determine the chemical substances listed on the TSCA Inventory, in that it does not specifically address hydrates. A hydrate is a mixture of water and an anhydrous chemical substance. Because they are mixtures, hydrates are not listed as such on the TSCA Inventory. For this reason, EPA believes it is superfluous to include a specific discussion of hydrates in the CDR definition of mixture. Please see the Instructions for the 2012 TSCA Chemical Data Reporting (Instructions document) for additional discussion (Ref. 7).

Unit III.C. contains further discussions about changes to specific definitions, in relation to the modifications included in this final rule. A summary of all CDR-related definitions is available in the docket (Ref. 8).

3. *Remove “non-isolated intermediate” definition from 40 CFR 710.3.* EPA added a definition to 40 CFR 710.43 for the term *non-isolated intermediate* as part of the 2003 IUR Amendments. Subsequently, as part of the IUR Revisions Rule, published in the **Federal Register** issue of December 19, 2005 (Ref. 9), EPA erroneously moved the definition to 40 CFR 710.3 from 40 CFR 710.43. EPA is removing the definition from 40 CFR 710.3 as this definition was not associated with the original TSCA Inventory, and therefore does not belong in 40 CFR 710.3. A definition of this term, codified elsewhere at 40 CFR 704.3, is included with the CDR definitions at 40 CFR 711.3.

4. *Remove 40 CFR part 710, subpart B.* EPA is removing the regulatory text contained in 40 CFR part 710, subpart B (40 CFR 710.23 to 710.39). This text refers to IUR submission periods of 2002 and earlier and is obsolete. As noted in 40 CFR 710.1, the Agency expressed its intent to remove 40 CFR part 710, subpart B, once the 2002 update was complete.

5. *Remove superfluous text associated with reporting production volumes.* EPA is removing the phrase “provided that the reported figures are within $\pm 10\%$ of the actual volume” from the production volume reporting requirements found in 40 CFR 710.52(c)(3)(iv), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(3)(iv). The revised wording would be “This amount must be reported to two significant figures of accuracy.” The phrase that was removed is superfluous because any number reported accurately to two significant figures is within 10% of the correct value.

6. *Correct text associated with reporting number of sites and number of workers.*

EPA is replacing the phrase “less than” with the phrase “fewer than” in the ranges used to report the number of workers found in the table in 40 CFR 710.52(c)(3)(v), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(3)(vii) and the number of sites found in the table in 40 CFR 710.52(c)(4)(i)(E), which appears in the new 40 CFR part 711 as 40 CFR 711.15(b)(4)(i)(E). This change makes the phrases describing the ranges grammatically correct.

B. What Are the Changes to the Method of Submission?

EPA is requiring the mandatory use of Agency-provided, web-based reporting tool (e-CDRweb) and CDX to submit the completed Form U to the Agency. After the final rule’s effective date, EPA will no longer accept paper submissions or electronic media (i.e., as a file on a CD-ROM) for any CDR submission.

In order to submit electronically to EPA via CDX, individuals acting on behalf of the submitter must first register with CDX. CDX registration is a requirement for all electronic submissions using CDX; this requirement predates this final rule. EPA has modified the 2006 Electronic Signature Agreement (ESA) Form to identify more clearly the individual(s) required to sign the ESA Form (Ref. 10). Each CDR submission must have an authorized official associated with the submission, who is the person signing the certification statement and submitting the CDR report via CDX. The authorized official must complete both an ESA Form and the CDX registration process. Companies can access the reporting tool upon completion of their CDX registration. The instruction manual and other guidance materials are available on EPA’s website (<http://www.epa.gov/iur>).

C. What Definitions Have Been Modified or Added To Clarify the Reporting Requirements?

As part of developing the definition section for 40 CFR part 711, EPA is modifying six definitions associated with the CDR rule and adding four new definitions. In 40 CFR 704.3 and 40 CFR 710.3, EPA is also modifying the definition of *importer* by removing the citation to 19 CFR 1.11.

1. *Manufacture and manufacturer.* To improve the information submitted through the CDR rule, EPA is modifying the definition of *manufacture* by including elements from the 40 CFR 720.3 definition for *manufacturer*. The Agency is also adding a simple definition for the term *manufacturer* to 40 CFR 711.3. In addition to the change to the definition of *manufacture*, EPA is adding a paragraph (c) to the regulation at 40 CFR 711.22 to clarify the reporting relationship between the contracting company and the toll manufacturer. The contracting company and the toll manufacturer should confer with each other to avoid duplicate reporting, and both the contracting company and the toll manufacturer are liable if no report is made. EPA agreed with comments that the “primarily responsible” language that was proposed was confusing and needed to be revised. As a result, EPA modified paragraph (c) of 40 CFR 711.22 to clarify that the contracting company and the toll manufacturer should determine among themselves who should submit the required report for the site. EPA also added “per site” in two places in paragraph (c) of 40 CFR 711.22 to specify that there is supposed to be one report per chemical substance, per site. See Unit III.C.2., for further discussion of the site for contract manufacturing situations.

This final rule defines the term *manufacture* under the CDR to mean:

to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or a complex combination of substances. When a chemical substance, manufactured other than by import, is:

(1) Produced exclusively for another person who contracts for such production, and

(2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

This final rule defines the term *manufacturer* under the CDR to mean “a person who manufactures a chemical substance.”

2. *Site*. EPA is amending the definition of *site* to clarify that the importer’s site must be a U.S. address; accommodate manufacturing under contract; and accommodate portable manufacturing units. See Unit III.J., for a further discussion of this final rule as it relates to importers.

This final rule defines the term *site* under the CDR to mean:

a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. More than one plant may be located on a single site.

(1) For chemical substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured.

(2) The site for an importer who imports a chemical substance described in 40 CFR 711.5 is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

(3) For portable manufacturing units sent out to different locations from a single distribution center, the distribution center shall be considered the site.

3. *Electronic-reporting related definitions.* EPA is adding two new terms, *Central Data Exchange (CDX)* and *e-CDRweb*. The Agency is adding these terms to provide clarity to the requirement for electronic reporting of CDR data. The term *CDX* means “EPA’s centralized electronic document receiving system, or its successors.” The term *e-CDRweb* means the “electronic, web-based CDR tool provided by EPA for the completion and submission of the CDR data.”

4. *Processing and use-related definitions.* EPA is amending the definitions of the terms *commercial use* and *consumer use* in order to make them more consistent with the definitions developed collaboratively by the United States and Canada. See Unit III.G.8.a., for further information. While the definitions for these two terms differ in their precise wording from the Canadian version (to preserve the use of terminology defined in CDR and related regulations), EPA does not expect the basic application of these two terms to differ from the basic application of the Canadian definitions (Ref. 11). The term *commercial use* means “the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.” Examples included in the 40 CFR 710.43 definition have been eliminated. The slightly modified definition of *consumer use* is “the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.” The restrictions associated with where a consumer would use the product have been removed.

EPA is adding a definition for the term *industrial function*. For the 2006 IUR, EPA defined *industrial use* and did not define *industrial function*. The inclusion of both definitions provides clarity for the industrial processing and use reporting requirements

and makes the Agency's requirements consistent with those collaboratively developed with Canada (Ref. 11). Additional discussion of those requirements is in Unit III.G.7. With this final rule, *industrial function* means “the intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used.”

5. *Principal reporting year and submission period.* As described in Unit II.A., EPA is changing the reporting frequency from every 5 years to every 4 years and requiring the reporting of production volumes for each calendar year since the last principal reporting year. EPA is modifying the terms *reporting year* and *submission period* to reflect these changes.

The term *reporting year* is modified to add the term “principal” and to replace the word “information” with “manufacturing, processing and use data.” These changes are to indicate that the principal reporting year is the year in which most of the reported data are based. Under the final rule, the principal reporting year is the latest complete calendar year preceding the submission period. Additionally, EPA is removing the reference to “the calendar year at 5-year intervals thereafter” and removing the reference to “calendar year 2005.” With these changes, the term *principal reporting year* is defined as “the latest complete calendar year preceding the submission period.”

The term *submission period* is modified by removing the phrase “generated during the reporting year.” With this change, the definition of *submission period* reflects that data for years in addition to the principal reporting year would be reported. With this

change, the definition of *submission period* means “the period in which manufacturing, processing, and use data are submitted to EPA.”

D. Has the Reporting Frequency Been Changed?

As proposed, EPA has changed the reporting frequency to every 4 years. The Agency has determined that reporting every 5 years is too infrequent and believes that returning reporting to every 4 years will provide data sufficiently current to meet Agency and public needs. After the 2012 submission period, the next submission period under the CDR rule will occur in 2016. The submission period will continue to occur in the year following the principal reporting year.

E. How Have the Reporting Thresholds Changed?

Reporting thresholds are used to determine when CDR reporting is required for a subject chemical substance at a manufacturing (including importing) site. EPA has made three changes related to the reporting thresholds:

- Determination of whether you meet the 25,000 lb threshold.
- Replacement of the 300,000 lb threshold for reporting information in Part III of

Form U.

- Reduction of the 25,000 lb threshold for certain chemical substances.

1. *Method for determining whether a person is subject to CDR reporting requirements.* For the 2012 submission period, manufacturers (including importers) are required to report under the CDR rule if they manufacture (including import) a chemical substance listed on the TSCA Inventory during the principal reporting year (i.e., 2011 for the 2012 submission period); the chemical substance is not otherwise exempt; and the associated production volume (domestically manufactured plus imported volumes) at a

site met or exceeded 25,000 lb during the principal reporting year (i.e., 2011 for the 2012 submission period).

For submission periods subsequent to the 2012 submission period, the determination of the need to report is based on whether, for any calendar year since the last principal reporting year, a chemical substance was manufactured (including imported) at a site in production volumes of 25,000 lb or greater. For example, for the 2016 submission period, it would be necessary to examine the annual production volumes for the calendar years 2012 to 2015 for the site. If the production volume for a reportable chemical substance were 25,000 lb or greater for any calendar year during that 4-year period, then it would be necessary to report the chemical substance, unless it were otherwise exempt. For instance, a subject chemical substance with production volumes of 5,000 lb in 2015 and 35,000 lb in 2012 would be reported for the 2016 CDR. Regardless of the 2015 production volume, in this example scenario the 2016 CDR submission would contain detailed information based on the production volume during the 2015 calendar year and production volume information only for the years 2012 through 2014. See Unit III.D.1. of the proposed rule (Ref. 1) for further discussion.

EPA is finalizing this change because of the mounting evidence that many chemical substances, even larger production volume chemical substances, often experience wide fluctuations in production volume from year to year. (See Unit III.D.1. of the proposed rule (Ref. 1).) This can result in the production volume of a chemical substance exceeding the threshold for several years, then falling below the threshold during the CDR principal reporting year. EPA believes that using production volume reporting for all years since the last principal reporting year to determine reporting

obligations will yield a much more accurate picture of the chemical substances currently in commerce, ensuring proper review under EPA's risk screening, assessment, and management activities and providing better information to the public. This issue is addressed further in Unit V.C. as well as in the "Summary of EPA's Responses to Public Comments Submitted in Response to Proposed TSCA Inventory Update Reporting Modifications Rule" (Responses to Comments document) (Ref. 12).

2. Replacement of the 300,000 lb threshold for processing and use information.

EPA is replacing the 300,000 lb threshold for processing and use information by phasing in a lower reporting threshold. For the 2012 CDR, all submitters of non-excluded chemical substances are required to report processing and use information if they manufactured (including imported) 100,000 lb or more of a chemical substance in 2011. Subsequent to the 2012 submission period, the reporting threshold will be 25,000 lb (or 2,500 lb for chemical substances subject to 40 CFR 711.8(b)). EPA is replacing the 300,000 lb reporting threshold in order to collect information necessary to complete screening-level exposure characterizations for CDR reportable chemical substances. EPA is phasing in the lower threshold in order to give chemical manufacturers time to comply with the modified reporting requirements.

In order to select a threshold for processing and use reporting, EPA considered the burden of reporting as well as the Agency's needs for processing and use information on the maximum number of chemical substances. As discussed elsewhere in this preamble and other supporting documents, EPA identified that the processing and use data received from the 2006 IUR was not sufficient in part because it did not include information on many HPV and most moderate production volume (MPV) chemical substances that EPA

was trying to assess. Therefore, in its proposal, EPA proposed lowering the processing and use reporting threshold from 300,000 lb to 25,000 lb in order to enable the Agency to collect exposure-related information needed to screen and prioritize the HPV and MPV chemical substances. EPA received comments suggesting that the Agency adopt a phased-in approach for reducing the threshold, similar to the approach used for introducing the requirement for reporting information for inorganic chemical substances. Manufacturers reporting for inorganic chemical substances were provided a one-time partial exemption for those substances for the 2006 IUR, thereby phasing in reporting. Other commenters suggested that because reporting of processing and use information for inorganic chemicals was not required for the 2006 IUR, the industry sector is still inexperienced with reporting such information and therefore should be given an opportunity to report under the existing thresholds. Another commenter suggested that EPA lower the processing and use threshold to 100,000 lb, which is consistent with one of the triggers for the small business exemption.

EPA agrees with a phased-in approach because it provides submitters with an opportunity to become familiar with the reporting requirements, while at the same time providing much needed and more complete processing and use information on chemical substances of interest to the Agency. Future reporting of the processing and use information by all submitters will provide EPA and others with needed additional information for those chemical substances with production volumes of 25,000 lb or more at a site. In the future, EPA may find it necessary to collect information on chemical substances at reporting thresholds below the thresholds introduced in this action.

Using the 2006 IUR data, EPA looked at the effect of setting the processing and use reporting threshold at various levels. Based on this information, lowering the threshold to 25,000 lb would not have brought in a significant number of new reporters for the 2012 submission period, because about 89% of companies and 86% of sites reported at least one chemical substance with a production volume of 300,000 lb or more in 2006 (Ref. 13). Therefore, most companies would be expected to be generally aware of the processing and use reporting requirements because the company would have reported such information on at least one chemical substance.

On a chemical-by-chemical basis, EPA's examination of the 2006 IUR data revealed that approximately 66% of the individual reports were above the 300,000 lb threshold, and that these reports covered approximately 60% of the chemical substances reported for the 2006 IUR. Lowering the threshold to 25,000 lb would result in processing and use information on 40% more chemicals and would have greatly informed EPA's Existing Chemicals Program. As discussed earlier, EPA recognized the need to allow companies time to become familiar with reporting the processing and use information, and therefore considered alternate reporting thresholds for the 2012 CDR. Lowering the threshold to 100,000 lb results in processing and use information on approximately 23% more chemical substances than the 300,000 lb threshold, while increasing the number of reports by only approximately 18%. EPA believes that the 100,000 lb threshold, as an interim threshold, provides an appropriate balance between increasing the number of chemicals with processing and use information and increasing the reporting burden on industry. See the "Economic Analysis for the Final Inventory

Update Reporting (IUR) Modifications Rule” (Economic Analysis) (Ref. 14) for further discussion.

The exposure information is an essential part of developing risk evaluations and, based on its experience in using this information, the Agency believes that collecting this exposure information is critical to its mission of characterizing exposure, identifying potential risks, and noting uncertainties for these lower production volume chemical substances. In addition, the lower thresholds will provide the public with information on a greater number of chemical substances. This issue is addressed further in Unit V.C.2., as well as in the Responses to Comments document (Ref. 12).

3. Reduction of the 25,000 lb threshold for specific regulated chemical substances. For the 2012 CDR, EPA is maintaining the 25,000 lb reporting threshold for chemical substances that are the subject of particular TSCA rules and/or orders. For future CDR collections, EPA is reducing the threshold (including the threshold for the collection of processing and use information) to 2,500 lb for those chemical substances (40 CFR 711.8(b)).

EPA proposed to eliminate the threshold, which would have required manufacturers (including importers) of such chemical substances to report under the CDR rule, regardless of the production volume. A number of commenters supported the proposal to eliminate the reporting threshold while others felt the requirement would be overly burdensome, especially for imported chemical substances or mixtures. In its proposal, EPA specifically asked for comment on whether a *de minimis* production volume threshold should be set for these chemical substances and how best to set such a

de minimis threshold. Some commenters opposed setting a *de minimis* threshold and others suggested a variety of methods for establishing one.

For many of the reasons identified by commenters (e.g., the expense and burden of collecting the information, and difficulty in knowing whether low-concentration chemical substances are present in formulated mixtures), EPA has decided to set a *de minimis* threshold and to delay its implementation. Beginning with the 2016 submission period, the reporting threshold will be reduced to 2,500 lb for those chemical substances that are:

- The subject of a rule proposed or promulgated under TSCA section 5(a)(2), 5(b)(4), or 6,
- The subject of an order issued under TSCA section 5(e) or 5(f), or
- The subject of relief that has been granted under a civil action under TSCA section 5 or 7.

(40 CFR 711.8(b))

For the 2016 submission period and submission periods thereafter, a manufacturer (including importer) of such chemical substances is required to report manufacturing information on the chemical substances if they are manufactured (including imported) in volumes of 2,500 lb or more during any of the years since the last principal reporting year (e.g., 2011). Information on the processing and use of the chemical substances must be reported if they were manufactured (including imported) in volumes of 2,500 lb or more during any of the years since the last principal reporting year. In addition to the manufacturing, processing, and use information for the principal reporting year (e.g., 2015), the production volumes for each year since the last principal reporting year must

also be reported. For the 2016 submission period, for example, a manufacturer (including importer) must consider the manufactured or imported volume during the years 2012 through 2015 to determine the need to report; must report the production volumes for each year from 2012 to 2015; and must report the full manufacturing, processing, and use information for 2015.

Chemical substances that are the subject of these particular TSCA actions are of demonstrated high interest to the Agency. EPA is promulgating this change to help reduce the reporting burden for submitters and to ensure the availability of current information when the Agency has expressed a concern in the form of regulatory action on those chemical substances. EPA will use the CDR data associated with these specific regulated chemical substances to monitor chemical substance production and compliance with the particular TSCA actions. In the future, EPA may find it necessary to collect information on chemical substances at a reporting threshold below the 2,500 lb threshold introduced in this action. Although the 2,500 lb threshold is higher than the proposed threshold of zero, the enhanced information that will be gathered during the 2016 submission period will enable the Agency and others to more efficiently identify those chemical substances warranting further, more in-depth review, as well as chemical substances of lesser concern. See Unit V.C.3., for further discussion.

As under the 2006 IUR, if a manufacturer qualifies for the small manufacturer exemption at 40 CFR 711.9, it is exempt from CDR reporting. Nothing in this final rule affects the scope of this exemption at 40 CFR 711.9. However, because the reduction in the reporting threshold to 2,500 lb is generally applicable to all manufacturers of the subject chemical substances, for the 2016 submission period and subsequent submission

periods, it may affect small manufacturers to the extent they are non-exempt under 40 CFR 711.9. As under the 2006 IUR, small manufacturers are generally exempt from CDR reporting but are specifically subject to reporting 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 is the subject of an order in effect under TSCA section 5(e), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7 (40 CFR 711.9). With the exception of rules proposed or promulgated under TSCA section 4, the same TSCA actions that make small manufacturers ineligible for a CDR exemption under 40 CFR 711.9 (with respect to the particular chemical substance that is the subject of the action) will also make those small manufacturers subject to the 2,500 lb reporting threshold in the 2016 submission period and subsequent submission periods (40 CFR 711.8(b)). The proposal or promulgation of a rule under TSCA section 4 affects the small manufacturer exemption but it does not affect the applicable reporting threshold under CDR.

In the proposed rule, EPA specifically sought comment on whether circumstances triggering an exception to the 25,000 lb reporting threshold for a chemical substance should include the proposal of certain rules for the chemical substance, under TSCA section 5(a)(2), 5(b)(4), or 6. EPA explained that such an approach would more closely parallel the exception language in the introductory paragraph to 40 CFR 711.6 and in 40 CFR 711.9. (See Unit III.D.3. of the proposed rule (Ref. 1)). Including these types of proposed rules in the list of triggering circumstances is also more consistent with reporting obligations under other parts of TSCA, such as 12(b). Among other situations, reporting under TSCA 12(b) is required when any rule under TSCA section 5 or 6 is

proposed or promulgated. In response to the comments received, EPA has determined that chemical substances subject to a rule proposed under TSCA section 5(a)(2), 5(b)(4), or 6 will be excepted from the 25,000 lb reporting threshold, and thus will be reportable at 2,500 lb beginning with the 2016 CDR. See Unit V.C.3., for further discussion.

F. What Are the Changes to the Chemical Substances Covered by CDR?

1. *Water.* EPA is fully exempting all (both naturally occurring and manufactured) water (Chemical Abstracts Service Registry Number (CASRN) 7732-18-5) (40 CFR 711.6(a)(4)) from reporting under the CDR rule.

2. *Fully exempt polymers removed from partially exempt list.* Polymers are a class of chemical substances for which CDR reporting is not required (40 CFR 711.6(a)(1)). However, three polymers were previously listed in the partially exempt list of chemical substances at 40 CFR 710.46(b)(2)(iv): Starch (CASRN 9005-25-8), dextrin (CASRN 9004-53-9), and maltodextrin (CASRN 9050-36-6). EPA has removed from the partially exempt list of chemical substances at 40 CFR 711.6(b)(2)(iv) these three chemical substances which, as polymers, are fully exempt from reporting.

3. *Chemical substances that are the subject of an ECA are ineligible for exemptions.* EPA may enter into an ECA, pursuant to procedures at 40 CFR part 790, with a manufacturer of a chemical substance to obtain testing where a consensus exists among EPA, affected manufacturers and/or processors, and interested members of the public concerning the need for and scope of testing. Chemical substances that are the subject of an ECA are now included in the list of chemical substances that are ineligible for a CDR exemption, in the introductory paragraph of 40 CFR 711.6, along with the other chemical substances that are likewise not eligible for a CDR exemption. The

paragraph states that a chemical substance “is not exempted from any of the reporting requirements of this part if that substance is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Act, or is the subject of a consent agreement developed under the procedures of 40 CFR part 790, 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.”

G. What Changes Have Been Made to Reportable Data Elements?

1. *Parent company and site identity.* Manufacturers (including importers) are required to report the company name and Dun & Bradstreet D-U-N-S® ((D&B) number) to identify the company associated with the plant site, and also to report the site name, address, and D&B number. If the company associated with the plant site does not have a D&B number, the manufacturer (including importer) must obtain one for the company. Likewise, if the plant site does not have a D&B number, the manufacturer (including importer) must obtain one for the site. EPA received a variety of questions concerning the correct company name to report during the 2006 IUR submission period. EPA is now clarifying what is meant by company name, by requiring at 40 CFR 711.15(b)(2)(ii) that the company name provided be the U.S. parent company name and defining “U.S. parent company,” at 40 CFR 711.3, to mean “the highest level company, located in the United States, that directly owns at least 50% of the voting stock of the manufacturer.” As noted in the proposed rule (Ref. 1), EPA believes that using an approach that is consistent with the Toxics Release Inventory (TRI) reporting requirements would be most clear both for reporters and users of the data. The CDR definition of “U.S. parent company name” is consistent with the use of the term of “parent company” in section 5 of the 2009 Toxic

Chemical Release Inventory Reporting Forms and Instructions (Ref. 15). The 2006 IUR submissions from different reporting sites contained varying D&B numbers for parent companies that appeared to be the same company. In order to better identify when reporting sites are under the same parent company, EPA is requiring the address as well as the D&B number of the parent company.

2. *Technical contact.* Manufacturers (including importers) are required to provide a technical contact for their CDR submission. The technical contact does not have to be a person located at the manufacturing (including importing) site, but must be a person who can answer questions EPA may have about the reported chemical substance. In the proposed rule, EPA had stated that the technical contact should be a person located at the manufacturing (including importing) site. EPA has decided, however, to not impose limitations on where the technical contact can be located. Therefore, companies may use their discretion in selecting a technical contact or multiple technical contacts, as provided by the new e-CDRweb tool. Submitters should consider, in selecting the technical contact, that EPA may have follow-up questions about a CDR submission, one or more years after the submission date.

3. *Chemical identification.* Manufacturers (including importers) are required to submit the correct chemical identity for each subject chemical substance.

a. *Chemical name.* EPA is requiring the reporting of the Chemical Abstracts (CA) Index Name currently used to list the chemical substance on the TSCA Inventory as the chemical name reported for CDR. The reporting tool will be directly linked to the non-confidential portion of the TSCA Inventory through the Agency's Substance Registry Services (SRS) database, which lists all chemical substances on the TSCA Inventory.

This link will enable submitters to select the correct CA Index Name for their reportable chemical substance(s) from SRS. EPA believes that using SRS to select the chemical name as currently listed on the TSCA Inventory will greatly reduce the number of incorrectly identified chemical substances and allow the data to be released more quickly to the public. See the discussion in Unit III.G.3.c. regarding identifying confidential chemical substances. Manufacturers (including importers) are allowed to supply, as part of a joint submission, an alternate chemical name, and in the case of importers, a trade name, in those instances where a supplier will not disclose to the submitter the specific chemical name of the imported TSCA Inventory chemical substance or a reactant used to manufacture the TSCA Inventory chemical substance. In these cases, the manufacturer (including importer) and the supplier may report the information required in this part in a joint submission. In order to clarify this requirement, EPA is amending 40 CFR part 711.15(b)(3)(i), to state that the importer must ask the supplier of the confidential chemical substance to directly provide EPA with the correct chemical identity, in a joint submission with the manufacturer. Similarly, in the event a manufacturer submitting a Form U cannot provide the whole chemical identity because the reportable chemical substance is manufactured using a reactant having an unknown specific chemical identity claimed as confidential by its supplier, the manufacturer must ask that the supplier directly provide to EPA the correct chemical identity of the confidential reactant in a joint submission. Nothing in 40 CFR 711.15(b)(3)(i) relieves a manufacturer (including an importer) of its obligation to report information that it actually knows or can reasonably ascertain. See Unit III.J.2., for additional information regarding joint submissions.

Detailed instructions regarding joint submissions are included in the Instructions document included in the docket (Ref. 7).

b. *Chemical identifying number.* As part of the chemical identity, submitters provide a chemical identifying number associated with the correct CA Index Name, as described in Unit III.G.3.a. EPA is requiring that submitters report only the CASRN as a chemical identifying number, except in the case of confidential chemical substances. In the case of confidential chemical substances, EPA is requiring that submitters report only the TSCA Accession Number as a chemical identifying number. EPA is removing the Premanufacture Notification (PMN) number as an allowed chemical identifying number because each TSCA Inventory chemical substance has either (or both) a CASRN or a TSCA Accession Number, which are likely to be already known to the submitter. Submitters who, in the past, have reported using the PMN number of a confidential substance can identify the TSCA Accession Number from SRS by searching on the PMN number. Those submitters who are not able to identify the TSCA Accession Number by searching SRS may contact EPA in writing, if necessary, to learn the TSCA Accession Number assigned when the Notice of Commencement (NOC) was submitted to the Agency. Specific information is included in the Instructions document (Ref.7).

c. *Chemical identity for chemical substances listed on the confidential portion of the TSCA Inventory.* In cases where a chemical substance is listed on the confidential portion of the TSCA Inventory, submitters are to report the chemical substance's TSCA Accession Number and generic name, which are listed on the non-confidential portion of the TSCA Inventory and are included in SRS. In order to continue to protect the confidentiality of the underlying specific chemical identification information (i.e., the

CASRN and specific chemical name), the submitter must claim the chemical identity as CBI and complete the upfront substantiation. Doing so will maintain a confidentiality claim for the underlying CASRN and specific chemical name on the confidential portion of the TSCA Inventory (the TSCA Accession Number and generic chemical name remain non-confidential). Failure to identify the chemical identity as CBI and complete the upfront substantiation will waive any CBI claim to the chemical identity and will result in the transfer of the chemical substance from the confidential portion of the TSCA Inventory to the non-confidential, publicly releasable, portion of the TSCA Inventory.

4. *Production volume.* Manufacturers (including importers) are required to report production volume information for each chemical substance for which they submit a CDR report. EPA has made a number of changes to the reporting of production volume and associated information.

a. *Report production volume for each of the years since the last principal reporting year.* In addition to the production volume for the principal reporting year, EPA is requiring the reporting of production volume for 2010 for the 2012 submission period and for each of the years since the last principal reporting year beginning with the 2016 submission period. More specifically, for the 2012 submission period, manufacturers (including importers) will be required to report the total annual volume (domestically manufactured and imported volumes in pounds) of each reportable chemical substance at each site during calendar year 2010. For submission periods subsequent to the 2012 submission period, manufacturers (including importers) will be required to report the total annual volume (domestically manufactured and imported volumes in pounds) of each reportable chemical substance at each site for each complete calendar year since the

last CDR principal reporting year. For example, for the 2016 submission period, manufacturers (including importers) of a reportable chemical substance will report the production volume of that chemical substance for each of the following calendar years: 2015, 2014, 2013, and 2012.

EPA had proposed that this requirement begin in full starting with the current submission period, which would have required submitters to report production volumes for 2006 through 2010 for the 2012 submission period. Several commenters supported the proposed change while others stated that the requirement would be overly burdensome, especially for the submission period immediately following promulgation of this rule. Some commenters recommended that EPA delay the implementation of the requirement until the next reporting cycle to allow companies sufficient time to prepare for the additional data collection effort. In response to the comments received, EPA believes its decision to defer this requirement until the next reporting cycle is warranted in light of other simultaneous changes to the CDR rule which increase reporting burden. The Agency also believes the delay will give companies adequate time to establish systems to collect and compile the required information.

For the principal reporting year, e.g., 2011, the domestic manufacture and the import production volume will continue to be reported separately on the same report. EPA review and analysis of the 2006 IUR data has revealed that some submitters are erroneously submitting multiple reports for the same chemical substance, at times reporting the information associated with domestic manufacturing and importing in different reports. Submitters should complete only one report for each chemical substance.

b. *Volume of chemical substance used on-site.* EPA is requiring that submitters report the volume of a manufactured (including imported) chemical substance used at the reporting site. The requirement to report the volume used on-site is replacing the requirement to indicate that the chemical substance is site-limited. Under this final rule, either domestically manufactured or imported chemical substances can be reported as used at the reporting site.

c. *Indicate whether imported chemical substances are physically at the reporting site.* EPA is adding a requirement to indicate whether an imported chemical substance is physically at the reporting site. Often, the site reporting an imported chemical substance never physically receives the chemical substance, but instead ships it directly to another location such as a warehouse, a processing or use site, or a customer's site.

d. *Report volume exported.* EPA is adding a requirement to report the production volume directly exported and not domestically processed or used. This will allow EPA to better identify the proportion of the production volume accounted for by the processing and use reporting, given that such downstream reporting is not required for directly exported chemical substances.

5. *Identify whether a chemical substance is to be recycled, remanufactured, reprocessed, or reused.* In the proposed rule, EPA sought comment on adding a checkbox indicating whether a manufactured chemical substance was recycled, remanufactured, reprocessed, reused, or reworked. In response to the comments received, EPA has determined that the term "reworked" may be interpreted and applied too broadly to provide the type of information that EPA needs to collect and has removed "reworked" from the list of recycling synonyms, but has chosen to otherwise finalize this reporting

requirement as proposed. Consequently, EPA is adding a requirement to indicate whether a manufactured chemical substance, such as a byproduct, is to be recycled, remanufactured, reprocessed, or reused. Submitters should indicate whether their manufactured chemical substance, which otherwise would be disposed of as a waste, is being removed from the waste stream and has a commercial purpose (i.e., it is being recycled, remanufactured, reprocessed, or reused). Indicating that a manufactured chemical substance, such as a byproduct, is to be recycled, remanufactured, reprocessed, or reused does not affect the reporting requirements associated with any chemical substance manufactured from the byproduct. See Unit IV.2., for detailed information on byproduct reporting.

6. *Concentration ranges.* EPA is eliminating gaps in the ranges used to report concentration in 40 CFR 711.15(b)(3) and (b)(4). The ranges are now:

- Less than 1% by weight.
- At least 1% but less than 30% by weight.
- At least 30% but less than 60% by weight.
- At least 60% but less than 90% by weight.
- At least 90% by weight.

7. *Industrial processing and use information reporting.* EPA is revising the list of industrial function categories and replacing the NAICS codes with industrial sector categories, as described in Unit III.G.7.a. and b.

a. *Industrial function categories.* EPA is revising the list of industrial function categories by combining categories that lead to common exposure scenarios and adding categories where the Agency believes the existing categories do not adequately describe

potential uses. EPA worked with Environment Canada and Health Canada to develop the set of categories, which will be used by both the United States and Canada for inventory reporting (Ref. 11).

EPA is adding eight new industrial function categories and removing six existing categories from the previous list; the total number of industrial function categories has increased to 35. Also, EPA is renaming several of the industrial function categories to provide a more informative description of the function of chemical substances that should be reported in that category. Lastly, EPA is requiring that if a submitter selects the category “Other,” the submitter must provide its own description of the industrial function of the chemical substance. EPA is using the industrial function categories listed in Table 2 of this unit:

Table 2.--Codes for Reporting Industrial Function Categories

Code	Category
U001	Abrasives
U002	Adhesives and sealant chemicals
U003	Adsorbents and absorbents
U004	Agricultural chemicals (non-pesticidal)
U005	Anti-adhesive agents
U006	Bleaching agents
U007	Corrosion inhibitors and anti-scaling agents
U008	Dyes
U009	Fillers
U010	Finishing agents
U011	Flame retardants

U012	Fuels and fuel additives
U013	Functional fluids (closed systems)
U014	Functional fluids (open systems)
U015	Intermediates
U016	Ion exchange agents
U017	Lubricants and lubricant additives
U018	Odor agents
U019	Oxidizing/reducing agents
U020	Photosensitive chemicals
U021	Pigments
U022	Plasticizers
U023	Plating agents and surface treating agents
U024	Process regulators
U025	Processing aids, specific to petroleum production
U026	Processing aids, not otherwise listed
U027	Propellants and blowing agents
U028	Solids separation agents
U029	Solvents (for cleaning or degreasing)
U030	Solvents (which become part of product formulation or mixture)
U031	Surface active agents
U032	Viscosity adjustors
U033	Laboratory chemicals
U034	Paint additives and coating additives not described by other categories
U999	Other (specify)

b. *IS codes*. EPA is replacing the 5-digit NAICS codes with 48 IS codes (Ref. 16). The sectors were adapted from the European Union’s (EU’s) “Guidance on Information Requirements and Chemical Safety Assessment.” The IS codes divide the entire range of NAICS codes into sectors so that there is a sector corresponding to any NAICS code (see the Instructions document, Ref. 7). The use of the sectors will reduce the number of unique combinations, thereby increasing the usability of the data, and also reducing the CDR reporting burden.

EPA is using the 48 sectors listed in Table 3 of this unit:

Table 3.--Industrial Sectors

Code	Sector Description
IS1	Agriculture, Forestry, Fishing and Hunting
IS2	Oil and Gas Drilling, Extraction, and support activities
IS3	Mining (except Oil and Gas) and support activities
IS4	Utilities
IS5	Construction
IS6	Food, beverage, and tobacco product manufacturing
IS7	Textiles, apparel, and leather manufacturing
IS8	Wood Product Manufacturing
IS9	Paper Manufacturing
IS10	Printing and Related Support Activities
IS11	Petroleum Refineries
IS12	Asphalt Paving, Roofing, and Coating Materials Manufacturing
IS13	Petroleum Lubricating Oil and Grease Manufacturing
IS14	All other Petroleum and Coal Products Manufacturing

IS15	Petrochemical Manufacturing
IS16	Industrial Gas Manufacturing
IS17	Synthetic Dye and Pigment Manufacturing
IS18	Carbon Black Manufacturing
IS19	All Other Basic Inorganic Chemical Manufacturing
IS20	Cyclic Crude and Intermediate Manufacturing
IS21	All Other Basic Organic Chemical Manufacturing
IS22	Plastics Material and Resin Manufacturing
IS23	Synthetic Rubber Manufacturing
IS24	Organic Fiber Manufacturing
IS25	Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing
IS26	Pharmaceutical and Medicine Manufacturing
IS27	Paint and Coating Manufacturing
IS28	Adhesive Manufacturing
IS29	Soap, Cleaning Compound, and Toilet Preparation Manufacturing
IS30	Printing Ink Manufacturing
IS31	Explosives Manufacturing
IS32	Custom Compounding of Purchased Resins
IS33	Photographic Film, Paper, Plate, and Chemical Manufacturing
IS34	All Other Chemical Product and Preparation Manufacturing
IS35	Plastics Product Manufacturing
IS36	Rubber Product Manufacturing
IS37	Non-metallic Mineral Product Manufacturing (includes clay, glass, cement, concrete, lime, gypsum, and other non-metallic mineral product manufacturing)
IS38	Primary Metal Manufacturing

IS39	Fabricated Metal Product Manufacturing
IS40	Machinery Manufacturing
IS41	Computer and Electronic Product Manufacturing
IS42	Electrical Equipment, Appliance, and Component Manufacturing
IS43	Transportation Equipment Manufacturing
IS44	Furniture and Related Product Manufacturing
IS45	Miscellaneous Manufacturing
IS46	Wholesale and Retail Trade
IS47	Services
IS48	Other (requires additional information)

When the category reported for the IS code is “Other,” the submitter is required to provide a written description of the use of the chemical substance, which may include the NAICS code.

8. *Consumer and commercial use reporting.* EPA is making four changes to the consumer and commercial information required to be reported:

- Revising and expanding the list of consumer and commercial product categories.
- Requiring the provision of a description when the product category “Other” is reported.
- Identifying whether the use is a consumer or a commercial use, or both.
- Reporting the number of commercial workers reasonably likely to be exposed while using the reported chemical substance.

Reporting associated with children’s use, the maximum concentration, and the percent production volume remains unchanged.

a. *Consumer and commercial product categories.* EPA is revising the list of consumer and commercial product categories by combining categories that lead to common exposure scenarios and adding categories that were not adequately described in the initial set of categories. EPA worked with Environment Canada and Health Canada to develop the categories. Harmonized categories will facilitate consistent reporting of chemical substance use information by industry in the United States and Canada (Ref. 11).

The list includes 33 product categories, including “Other.” Examples of new categories which have been added include explosive materials, building/construction products not covered elsewhere, and air care products. The glass and ceramic products category had relatively few 2006 IUR submissions and overlaps with the new categories, and so has been eliminated. Also, several of the consumer and commercial product categories have been renamed to better describe the products that should be reported in those categories. In addition to revising the overall product categories, narrower definitions and expanded lists of examples of products in which the chemical substance would be used will be added to each category descriptor. The examples were selected to include items that could have fit into other categories in order to address the overlap inherent in any product category list. The product categories were then placed into several broader groupings, e.g., “Chemicals with Agriculture and Outdoor Uses” based on the similarities of products. EPA believes that the user will find the current groupings easier to use than the alphabetical listing used for the 2006 IUR. EPA is also requiring that if a submitter chooses the product category “Other,” the submitter must include a text description for the consumer and commercial product containing the chemical substance.

EPA is using the consumer and commercial product categories listed in Table 4 of this unit:

Table 4.--Codes for Reporting Consumer and Commercial Product Categories

Code	Category
Chemical Substances in Furnishing, Cleaning, Treatment Care Products	
C101	Floor Coverings
C102	Foam Seating and Bedding Products
C103	Furniture and Furnishings not covered elsewhere
C104	Fabric, Textile, and Leather Products not covered elsewhere
C105	Cleaning and Furnishing Care Products
C106	Laundry and Dishwashing Products
C107	Water Treatment Products
C108	Personal Care Products
C109	Air Care Products
C110	Apparel and Footwear Care Products
Chemical Substances in Construction, Paint, Electrical, and Metal Products	
C201	Adhesives and Sealants
C202	Paints and Coatings
C203	Building/Construction Materials -- Wood and Engineered Wood Products
C204	Building/Construction Materials not covered elsewhere
C205	Electrical and Electronic Products
C206	Metal Products not covered elsewhere
C207	Batteries
Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products	
C301	Food Packaging

C302	Paper Products
C303	Plastic and Rubber Products not covered elsewhere
C304	Toys, Playground, and Sporting Equipment
C305	Arts, Crafts, and Hobby Materials
C306	Ink, Toner, and Colorant Products
C307	Photographic Supplies, Film, and Photochemicals
Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products	
C401	Automotive Care Products
C402	Lubricants and Greases
C403	Anti-Freeze and De-icing Products
C404	Fuels and Related Products
C405	Explosive Materials
C406	Agricultural Products (non-pesticidal)
C407	Lawn and Garden Care Products
Chemical Substances in Products not Described by Other Codes	
C980	Non-TSCA Use
C909	Other (specify)

b. *Designation of consumer or commercial use.* EPA is requiring submitters to designate, via a checkbox, whether the indicated product category is a consumer or a commercial use, or both.

c. *Number of commercial workers reasonably likely to be exposed.* EPA is requiring that submitters report the total number of commercial workers, including those at sites not under the submitter's control, that are reasonably likely to be exposed while using the reportable chemical substance, with respect to each commercial use. The

approximate number of workers should be reported using the same definitions and ranges used for manufacturing and industrial processing and use workers required by 40 CFR 711.15(b)(3)(vii) and (b)(4)(i)(F), respectively. The ranges are:

- Fewer than 10 workers.
- At least 10 but fewer than 25 workers.
- At least 25 but fewer than 50 workers.
- At least 50 but fewer than 100 workers.
- At least 100 but fewer than 500 workers.
- At least 500 but fewer than 1,000 workers.
- At least 1,000 but fewer than 10,000 workers.
- At least 10,000 workers.

H. What Changes Have Been Made to the Standard for the Reporting of Processing and Use Information?

In order to collect more complete information regarding industrial processing and use, and commercial and consumer use of chemical substances, EPA is, in 40 CFR 711.15(b)(4), replacing the “readily obtainable” reporting standard used for reporting under 40 CFR 710.52(c)(4) with the “known to or reasonably ascertainable by” reporting standard set forth under TSCA section 8(a)(2). This is the same standard that applied to the reporting of information described in the regulations at 40 CFR 710.52(c)(1), (c)(2), and (c)(3) for the 2006 IUR submission, and this standard continues to apply to the reporting of such information under 40 CFR 711.15(b)(1), (b)(2), and (b)(3). This standard covers 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.

Under the standard, a submitter would therefore prepare its report about the processing and use of a chemical substance it manufactures (including imports), without confining its inquiry solely to what is known to managerial and supervisory employees, but would also be expected to review information which the manufacturer (including importer) may have in their possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform. The standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

“Known to or reasonably ascertainable” information includes, but is not limited to, information that may be possessed by employees or other agents of the company reporting under the CDR rule, including persons involved in the research, development, manufacturing, or marketing of a chemical substance and includes knowledge gained through discussions, symposia, and technical publications. Examples of types of information that are considered to be in a person’s possession or control, or that a reasonable person similarly situated might be expected to possess, control, or know, include files maintained by the submitter, such as marketing studies, sales reports, or customer surveys; information contained in standard references, such as MSDSs, that contain use information or concentrations of chemicals in mixtures; and information from the CASRN and from the D&B number.

The following hypothetical examples illustrate the anticipated application of the “known to or reasonably ascertainable standard,” in the specific context of the collection of processing and use data under the CDR. Because the standard applies on a case-by-case basis, however, these examples cannot substitute for a complete analysis of a submitter’s particular circumstances:

Company XYZ discovers that it has no knowledge of how a particular reportable chemical substance (chemical substance #1) is processed or used by its customers. Company XYZ usually maintains marketing data documenting customers’ use of its chemicals, in line with the reasonable business practices typical of comparable manufacturers, but it irrevocably lost these data for chemical substance #1 due to an inadvertent computer malfunction. Company XYZ has many customers, but it expects that it could substantially reconstruct this missing information by briefly contacting its largest customer and asking that customer how chemical substance #1 is generally used. Company XYZ contacts this customer, reports on the basis of the processing and use data that the customer was willing to provide. Company XYZ has likely fulfilled its duties under the reporting standard. Company XYZ would not have fulfilled its duties under the reporting standard if it had not endeavored to supplement the information it already knew.

Company XYZ has never maintained information on how a particular reportable chemical substance (chemical substance #2) is processed or used by its customers. However, it is typical for comparable manufacturers to collect such information as part of their reasonable business practices. Company XYZ has many customers but it expects that it could substantially fill this data gap by reviewing the public website of its largest

customer. Company XYZ reviews this website, and reports on the basis of the information contained in the website. Company XYZ has likely fulfilled its duties under the reporting standard. Company XYZ would not have fulfilled its duties under the reporting standard if it had not endeavored to supplement the information it already knew.

Company ABC maintains seasonal marketing data on changes in use patterns for a particular chemical substance (chemical substance #3). Comparable manufacturers typically only maintain such data on an annual basis, in line with reasonable business practices. Company ABC irrevocably loses its summer marketing data for Substance #3, due to an inadvertent computer malfunction. Company ABC expects that it could substantially reconstruct the missing summer marketing data by contacting its largest customer and asking the customer what it used or processed chemical substance #3 for in the past summer. Nevertheless, instead of attempting to reconstruct the summer data in this manner, Company ABC reports on the basis of the processing and use data that it already knows (regarding the winter, spring, and fall of the year). Company ABC has likely fulfilled its duties under the reporting standard. Company ABC would not have fulfilled its duties under the reporting standard if it designated the information as “not known or reasonably ascertainable” simply because one of the seasonal marketing reports was missing.

Company ABC has never maintained information on how a particular reportable chemical substance (chemical substance #4) is processed or used by its customers. However, it is typical for comparable manufacturers to collect such information as part of their reasonable business practices. Company ABC has one major customer and ten

minor customers. Company ABC asks its major customer to supply information about how chemical substance #4 is processed and used, but that customer is unwilling to supply this information. Company ABC reasonably expects that the only remaining way to substantially fill this data gap would be to send a survey to its ten minor customers. Company ABC reports that the information is “not known or reasonably ascertainable” to it. Company ABC has likely fulfilled its duties under the reporting standard.

EPA would like furthermore to clarify that submitters are not required to conduct a new or additional customer survey (i.e., to pose a comprehensive set of identical questions to multiple customers) under this standard. If particular information cannot be derived or reasonably estimated from the information available to the company without conducting further customer surveys, it is not “known to or reasonably ascertainable” to the submitter for purposes of the CDR. However, to the extent that customer surveys are already in the submitter’s possession or control, and to the extent that reasonable efforts to analyze or derive information from already-available customer surveys may inform processing and use information that is reported, the information is generally “known to or reasonably ascertainable.” See Unit V.E.1., and the Responses to Comments document (Ref. 12) for further discussion. EPA’s reporting tool permits submitters to enter or select “NKRA” on Form U to address circumstances where the information is not known to or reasonably ascertainable by the submitter.

I. What Changes Have Been Made to Requirements for Making CBI Claims?

EPA is making several changes to the requirements for claiming information as confidential. Submitters may claim certain information reported under the CDR as CBI in accordance with 40 CFR part 2 and CDR rules at 40 CFR 711.30. Claims of

confidentiality may be made for chemical identity, site identity, and processing and use information, and submitters must substantiate these claims at the time information is submitted to EPA. EPA's procedures for handling information claimed as confidential 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 parameters of TSCA section 14. EPA cautions submitters that they may be subject to criminal penalties under 18 U.S.C. 1001 if they knowingly and willfully make a false statement in connection with the assertion of a CBI claim. CBI claims should be limited to only those data elements the release of which would likely cause substantial harm to the business' competitive position. Interested persons are reminded that with regard to chemical substance use information, EPA is interested in aggregated, general uses, not detailed uses associated with specific customers.

To claim information as confidential, a submitter must indicate its claim by both checking the appropriate box and signing the certification statement on the reporting form, and may also be required (depending on the data element) to provide substantiation of the claim at the time it is made. A submitter must indicate its claims at the time the information is submitted. If a submitter fails to follow these procedures, EPA may release the information to the public without further notice to the submitter. By signing the certification statement the submitter attests to the secrecy and value of the information for which confidentiality claims have been asserted.

1. *Chemical identity CBI claims.* There is no substantive change to submitters' ability to make confidentiality claims for chemical identity in the CDR. As in the past, a submitter may assert a claim of confidentiality for the identity of the reported chemical

substance only when the chemical substance is listed on the confidential portion of the TSCA Inventory. Submitters who assert a confidentiality claim for chemical identity must also provide substantiation for the claim at time of filing. See 40 CFR 711.30(b).

However, in response to comments, this final rule includes some changes to the process that must be used to make this type of CBI claim. The proposed rule, at 40 CFR 711.15(b)(3)(i), provided that “[a] submitter under this part may use an EPA-designated TSCA Accession Number for a confidential chemical substance in lieu of a CASRN when a CASRN is not known to or reasonably ascertainable by the submitter.” In the proposed rule, EPA also noted that up to 5% of the reports submitted under the 2006 IUR contained chemical identity problems. EPA therefore proposed to require that submitters report using the CA Index Name currently used to list the chemical substance on the TSCA inventory. EPA further indicated that it would include CASRNs and CA Index Names into the e-CDRweb tool, to the extent possible without jeopardizing confidentiality claims. EPA believes that selecting chemical identity from a pre-populated list, rather than keying in the chemical identity information, will significantly improve the accuracy and consistency of submitted reports.

EPA received several comments from industry groups requesting that the e-CDRweb tool include security safeguards to adequately protect CBI. In light of the security concerns expressed in public comments, EPA has decided not to include CASRNs and CA Index Names for chemical substances on the confidential portion of the TSCA Inventory into the portions of the e-CDRweb tool that will be publicly accessible. However, EPA still believes it is important to require that all chemical identities be selected from a pre-populated list, to avoid repeating the chemical identity problems

experienced with the 2006 IUR. Therefore, 40 CFR 711.15(a)(3)(i) has been revised in this final rule to require that submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory use the chemical substance's TSCA Accession Number and generic name. Requiring the use of TSCA Accession Numbers and generic names will allow EPA to adequately protect confidential CASRNs and CA Index Names (by omitting them from the pre-populated selection list) while still obtaining the improvements in reporting accuracy it sought in the proposed rule.

In SRS, a submitter can readily find a cross-reference list that displays the TSCA Accession Number, generic chemical name, and the PMN case number (or for an initial TSCA Inventory chemical substance, the TSCA Inventory reporting form number) for any confidential chemical substance listed on the TSCA Inventory. Submitters who wish to retain the CBI claim for the chemical substance identified by the TSCA Accession Number must assert and substantiate the claim at time of filing. Submitters who do not wish to retain the CBI claim for the chemical substance identity, and who wish the chemical substance to be listed on the public portion of the TSCA Inventory, should not assert a CBI claim or provide substantiation. Submitters who fail to follow the required procedures for asserting CBI claims for chemical identity will waive the claims, and EPA may release the information without further notice to the submitter. See the regulatory text at 40 CFR 711.30(e).

2. *Upfront substantiation for processing and use information CBI claims.* Under the CDR, a submitter may assert a claim of confidentiality for data associated with the processing and use of its chemical substance if the submitter has reason to believe that release of the information would reveal trade secrets, or confidential commercial or

financial information, as provided by TSCA section 14 and 40 CFR part 2. Under this final rule, EPA is requiring upfront substantiation for CBI claims for processing and use information.

In order to submit a claim of confidentiality for processing and use information data elements, the submitter is required (in addition to signing the certification statement) to both check the appropriate box on the reporting form and substantiate the claim in writing, within the reporting tool, by answering certain questions provided in 40 CFR 711.30(d). EPA revised the substantiation question at 40 CFR 711.30(d)(1)(ii), respecting competitive harm, to include harmful effect “to your customer’s competitive position.” Where a submitter fails to submit substantiation of the processing and use CBI claim in accordance with the applicable rules (i.e., the submitter does not provide an answer to all the required questions associated with the claim on the Form U it submits via e-CDRweb), EPA will consider the information not subject to a confidentiality claim and may make the information available to the public without further notice to the submitter.

3. Prohibition of confidentiality claims for data elements identified as “not known or reasonably ascertainable.” EPA is prohibiting claims of confidentiality pertaining to the designation that information is “not known or reasonably ascertainable.” As described in Unit II.A., for the 2012 and future CDR collections, submitters will be required to report processing and use information to the extent that it is known to or reasonably ascertainable by them.

For the 2006 IUR collection, EPA observed that, on occasion, processing and use information was claimed as confidential when a submitter determined that the information was not readily obtainable. Section 14 of TSCA limits the disclosure of

information entitled to confidential treatment under exemption 4 of the Freedom of Information Act (FOIA). EPA has considered the NKRA designation and its relationship to a potential CBI or trade secret claim. Given that a NKRA assertion is an assertion that no information is available, the Agency does not believe that the designation conveys trade secret or confidential commercial or financial information.

J. What Changes Specifically Affect Importers?

1. *Importer site address.* Submitters report CDR data on chemical substances that they manufacture domestically and that they import into the United States. Previously, the regulations defining the site for importer reporting were found in both the definition for site in 40 CFR 710.3 and in paragraph 40 CFR 710.48(b). EPA is eliminating unnecessary duplication in the CDR regulation by moving the additional information regarding the importer site from 40 CFR 710.48(b) into a revised definition for site at 40 CFR 711.3, as described in Unit III.C.2., and eliminating 40 CFR 710.48(b).

In addition, EPA has observed that submitters occasionally use a foreign address as the site address for the importer. EPA now is requiring that submitters report a U.S. site address, by modifying the definition for site to state specifically that the site must be a U.S. site. The U.S. address of an agent acting on behalf of the importer, and authorized to accept service of process for the importer, may be reported as the importer's site address if the operating unit that is directly responsible for importing the chemical substance and that controls the import transaction has no U.S. address. The Agency expects that all importers will have a U.S. site, as defined in the 40 CFR 711.3 definition for *site*, because, under Customs regulations at 19 CFR 141.18, a non-resident corporation is not permitted to enter merchandise for consumption unless it has a resident

agent in the State where the port of entry is located, who is authorized to accept service of process against the corporation.

2. *Joint submissions.* For purposes of CDR, submitters are allowed to report the CDR information jointly with the foreign supplier of a reportable chemical substance whose chemical identity is unknown to the importer. Previously, joint submissions could not be made electronically. EPA is now requiring that submitters use CDX and e-CDRweb for preparation and submission of joint submissions. See 40 CFR 711.15(b)(3)(i)(C). Therefore, the authorized officials of the jointly submitting companies will need to register with CDX in order to submit a joint report to EPA.

Importers may not know the specific chemical identity of a chemical substance because the foreign supplier chooses to keep it confidential. In such a situation, the importer must use e-CDRweb to ask the foreign supplier to submit the chemical identity information directly to EPA through a joint report. To submit a joint report, the importer completes the majority of the required information, and supplies a trade name or other designation to identify the chemical substance, and provides contact information for the foreign supplier. The importer then uses e-CDRweb to contact the foreign supplier and request that the foreign supplier report the specific chemical identity information directly to EPA. The importer must submit a copy of such request to EPA, along with the rest of its CDR submission for the chemical substance. As a general matter, EPA expects that importers will supply the information described at 40 CFR 711.15(b)(3)(i)(A), rather than an “NKRA” designation, when importers do not know the confidential chemical identity of a chemical substance they import. EPA believes that an NKRA designation would generally only be appropriate in the unlikely event that an importer did not know, and

could not reasonably ascertain, the information needed to link its submission with a secondary report from the supplier.

In an acceptable joint submission, the secondary submitter supplies the chemical identity, as well as its technical contact and company information, and provides the primary submitter's site information. EPA will not accept joint submissions that are not submitted electronically using e-CDRweb and CDX. All information will be saved by the reporting tool and both submissions will be matched based upon company and chemical substance information. Once the forms are linked, EPA will process the joint submission as one report for the reported chemical substance. See the Instruction document (Ref. 7), for detailed instructions on submitting a joint report.

IV. What Clarifications Have Been Made to Reporting Requirements?

1. *Clarification of the relationship between company name and site identity CBI claims.* Under the CDR, submitters are able to separately claim as CBI the company name and site identity associated with a chemical substance for which they are reporting under the CDR. The submitter is required to provide an upfront substantiation for CBI claims for the site identity. EPA believes there is some confusion as to what is considered confidential when such claims are made, and is taking this opportunity to provide clarification.

The CBI claim protects the link between the company and/or site identity and the particular chemical substance. If the company or site identity associated with a particular chemical substance is not claimed as CBI, EPA may make that information available to the public without further notice to the submitter. EPA will not impute the existence of a

CBI claim for company identity or for site identity from a CBI claim associated with a different chemical substance.

Company and site identity CBI claims are separate claims, and in some cases one type of claim may be justified while the other is not. Therefore, a submitter is permitted to assert its CBI claim for the company identity, the site identity, or both the company and site identity. Such claims must be made for each chemical substance for which such claims are being made. Because the circumstances for each chemical substance can vary, the CDR rule does not allow for blanket claims covering all chemical substances in a site's CDR report.

Likewise, the submitter must provide separately the required upfront substantiation for the site identity CBI claims associated with each chemical substance. For instance, if the submitter is reporting for five chemical substances and wishes to claim its site information confidential for three of the five chemical substances, it must assert the claim and provide separate upfront substantiation three times, once for each of the three chemical substances.

EPA has also observed that submitters sometimes claim only their company identity, and not their site identity, as confidential. If the site identity for a particular chemical substance is not claimed as CBI, or is claimed but not substantiated pursuant to 40 CFR 711.30(c), EPA may make that information available to the public without further notice to the submitter. EPA will not impute the existence of a CBI claim for site identity from a CBI claim for company identity, even if the company name appears within the site identity information. To help ensure that submitters consider this issue, the e-CDRweb reporting tool provides a warning whenever the company identity is claimed

as CBI for a particular chemical substance and the site identity is not also claimed as CBI for that chemical substance.

2. *Explanation of byproduct reporting.* During the 2006 submission period, EPA received questions about the requirements for reporting byproducts. The questions included whether byproduct manufacturers (including importers) were required to report the byproducts under the IUR rule. Based on those and subsequent inquiries, and from the public comments from the proposed rule, it is apparent that scope of the CDR obligation to report byproducts is not well understood by industry. The scope of byproduct reporting has become a particularly pertinent issue because (by the terms of the 2003 IUR Amendments) inorganic chemical substances are now no longer exempt from reporting under CDR, including (beginning with the 2012 CDR) the information collection requirements for processing and use information. Inorganic chemical substances are often recycled, which may trigger the need to report a byproduct substance that is recycled. In an effort to further clarify reporting obligations, EPA is providing additional information on byproduct reporting, including circumstances under which reporting is not required, in two guidance documents included in the docket for this final rule (Refs. 7 and 16) and on EPA's website at <http://www.epa.gov/iur>. For purposes of CDR, a byproduct is a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture (40 CFR 704.3). Thus, for example, when a chemical substance or mixture is used for the purpose of manufacturing an article, and that manufacture results in the production of a different chemical substance, that different chemical substance is a byproduct for purposes of the CDR. Chemical substances that are byproducts of the manufacture,

processing, use, or disposal of another chemical substance or mixture, like any other manufactured chemical substances, are subject to CDR reporting if they are listed on the TSCA Inventory, are not otherwise excluded from reporting, and their manufacturer is not specifically exempted from CDR reporting requirements.

The 40 CFR 704.3 definition of *manufacture for commercial purposes* states that “[m]anufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.” Thus, byproducts of the manufacture, processing, use, or disposal of another chemical substance or mixture for a commercial purpose are themselves both “manufactured” and “manufactured for commercial purposes.” Also, considering the overall context of this definition, EPA interprets “chemical product” broadly to include any product of the manufacturing, processing, use, or disposal of another chemical substance or mixture, other than a byproduct.

Byproducts that are manufactured (including imported) in volumes of 25,000 lb or more at a single site are potentially subject to CDR requirements. However, 40 CFR 711.10(c) excludes from reporting those chemical substances meeting the requirements of 40 CFR 720.30(g) or (h). Manufacturers (including importers) of byproducts are not required to report the manufacture (including import) of a byproduct if the byproduct is

not used for commercial purposes. See 40 CFR 720.30(h)(2). Thus, even where a byproduct is manufactured (including imported) for a commercial purpose, if the byproduct is not subsequently put to use for another commercial purpose, the byproduct is excluded from CDR reporting. Furthermore, if the byproduct's "only commercial purpose is for use by public or private organizations that: (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes," 40 CFR 720.30(g), that byproduct is also excluded from CDR reporting. This exclusion applies only to the byproduct; it does not apply to the component chemical substances extracted from the byproduct. The Instructions document (Ref. 7) includes a decision tree to assist a byproduct manufacturer (including importer) in its determination of the need to report its byproduct chemicals.

Some manufacturers (including importers) of byproducts have expressed a belief that a chemical substance that is regulated by another EPA program, such as under the Resource Conservation and Recovery Act (RCRA), or that is exempt from certain requirements by the other program based on certain treatments or disposals, should not be required to be reported for CDR purposes. However, under this final rule, when such chemical substances have a commercial purpose not exempted by 40 CFR 720.30(g), the manufacturer (including importer) of such a chemical substance may have CDR reporting obligations, and is not relieved of those obligations based on exemptions under other laws.

Although the need to report for byproduct chemical substances is not a new requirement, EPA recognizes that there were many comments and concerns raised about byproduct chemical substances, as stated earlier in this unit, and that there may be

byproduct manufacturers that remain unsure of their reporting obligations under the CDR. In particular, the Agency recognizes that this may be an issue for those byproduct manufacturers who recycle byproducts by sending them off-site to a recycler. The Agency is committed to helping byproduct manufacturers report according to the CDR requirements and views the 2012 reporting cycle as an opportunity for the Agency and byproduct manufacturers to work together. Among other things, the Agency will use this opportunity to determine whether additional guidance tailored to these manufacturers is needed. In addition, EPA intends to provide training specific to byproduct reporting and to make available Agency personnel to answer questions on an individual basis.

EPA also intends to continue to work with industry and the interested public. EPA encourages recycling. The Agency intends to examine the collected information related to byproducts, recognizing the importance of recycling, to identify whether there are segments of byproduct manufacturing for which EPA can determine that there is no need for the CDR information for the 2016 or other future reporting cycles.

V. Public Comments

EPA carefully considered the comments it received on the proposed IUR modifications. Major comments are discussed in this unit. Additional comment summaries and more detailed responses, including responses to most of the additional issues that EPA requested comment on, are contained in the Responses to Comments document (Ref. 12).

As part of this action, EPA is changing the identification of the regulation from IUR to CDR. Elsewhere in this document, EPA has retained the use of the term “IUR” to reflect historical terminology, and has used the term “CDR” to describe the revised

reporting requirements and future submission periods. However, in order to enhance understanding of the responses to the public comments, EPA is retaining the use of the IUR acronym for this unit, even where referring to revised reporting requirements and future submission periods. The reader should recognize that where IUR is used to refer to the 40 CFR part 711 regulations or to future IUR submission periods, IUR and CDR are synonymous.

A. General Comments

1. *Justification for proposed modifications.* Several commenters supported many of EPA's proposed reporting changes, stating that the changes will facilitate EPA's ability to track chemical substances used and made in the United States, which would strengthen EPA's ability to identify chemical substances for further assessment. They also noted that the IUR data not only supports activities under EPA authorities, but is also used by other Federal agencies, the States, and other interested stakeholders to identify potential chemical substances of concern. Other commenters expressed the view that EPA has not provided adequate justification supporting the Agency's need for the IUR data and has not sufficiently tailored the requested information to meet EPA's goals. One commenter did not agree that the modifications will increase the "usability of collected information" or "focus reporting" on what is "most needed" by EPA. Another commenter mentioned that the Agency does not explain how the existing IUR fails to meet these goals or why an IUR expansion is needed to carry out its Congressionally mandated TSCA duties. Additionally, commenters suggested that EPA should clearly indicate how the IUR data will be utilized in programs that systematically review hazard and exposure of existing chemicals.

EPA has an obligation under TSCA to protect human health and the environment from unreasonable risks associated with chemical substances under its jurisdiction. EPA is amending the IUR rule to improve and enhance data reporting requirements under IUR reporting beyond that required during the 2006 submission period. There were problems associated with many 2006 IUR data submissions that severely limited EPA's ability to screen chemical substances for exposure and risks and to make data available to the public. These problems included the fact that many submissions were incomplete or improperly completed, contained invalid chemical identities, and/or inappropriately or incorrectly claimed certain data elements as CBI. EPA anticipates that this final rule will

- a. Ensure the required information is properly reported and that the information in the Agency's database reflects the information provided in the IUR reports.
- b. Increase the usability of the collected information.
- c. Increase the availability of information for the public.
- d. Focus reporting on information that is most needed by the Agency.

Additionally, EPA believes that the modifications in this final rule will supply manufacturing, and processing and use information the Agency did not previously possess and should be accurate and reliable enough to develop screening level assessments.

Data collected under the IUR will be used in a wide variety of programs fundamental to fulfilling the Agency's TSCA statutory mandate. EPA believes that the IUR data is the most basic data set that will give EPA and the public an understanding of the volume of chemical substances produced or imported into the United States, how the chemical substances are or may be used, and the types of exposures (occupational,

consumer, environmental, etc.) potentially associated with the chemical substances. Many chemical substances are exempted from reporting under the IUR rule, which further tailors IUR requirements to EPA's information needs. Data about production volume, exposures, and/or environmental releases are required to make some of the findings necessary to require testing under TSCA section 4, and helps EPA to prioritize chemical substances for further data gathering or risk management action. For example, data supplied by the IUR have supported a series of test rules in the HPV Challenge Program, which were implemented to generate health and environmental effects data on HPV chemical substances for risk assessment purposes. The IUR supported these test rules by providing production volume and exposure information needed to make the findings for these test rules. Without the IUR information, EPA might not have been able to make these findings. The Agency anticipates that the data collected under the 2012 IUR will better support the development of test rules.

The Agency's Existing Chemicals Program will use the IUR data to assess whether the Agency needs additional data about the hazards or exposures to a particular chemical substance under TSCA sections 4 or 8, and may use IUR data to inform risk management actions such as those identified in TSCA sections 5 and 6. EPA's extensive use of the 2006 IUR data in the Agency's Existing Chemicals Program is consistent with how EPA envisioned the data would be used when the 2003 IUR Amendments were promulgated. EPA used the 2006 IUR data together with other available information in developing Action Plans on chemical substances beginning in 2009, and noted the limitations inherent in those data. Any future program is expected to be similar in analytical approach regarding the use of screening-level hazard and screening-level

exposure data to develop risk prioritizations. EPA's future Existing Chemicals Program will build on the experience of this past program, and the modified IUR data collected during the 2012 and future submission periods will enable the Agency to further enhance its program. More detailed discussions are in the Responses to Comments document (Ref. 12).

2. *Transitioning to 2012.* Commenters stated the new requirements are overly burdensome and unrealistic considering the time constraints. Commenters supported delaying the submission period in a variety of ways, including:

a. Extending by several months and delaying the implementation of changes until the next submission period,

b. Delaying the submission period until 9 to 12 months following the promulgation of the final rule, or

c. Moving the submission period to 2012 and changing the principal reporting year to 2011.

In light of these comments, to provide sufficient time for companies to comply with the amended reporting requirements, and to finalize the proposed modifications, EPA promulgated a final rule (Ref. 6) to suspend the 2011 submission period. In this final rule, EPA supersedes the suspension of the submission period by establishing a new sequence of submission period, beginning with one from February 1, 2012, through June 30, 2012. EPA believes that the timing of the 2012 submission period provides companies sufficient time to collect and submit the required data, and that steps taken by the Agency have and will provide the opportunity for companies to gain an understanding of the submission process and to prepare their internal electronic systems as needed. For

example, EPA was asked by several companies and trade organizations to provide an overview of the reporting tool. Acknowledging that companies were concerned about the time needed to develop their internal databases to collect the required information, on November 30, 2010, the Agency held an informational workshop and webinar to help companies develop a better understanding of the CDX registration process and the e-CDRweb electronic reporting tool. A recording of the workshop and a summary of the questions and answers is available on the IUR website (<http://www.epa.gov/iur>). EPA used stakeholders' comments from the workshop to help ensure the tool would address the needs of the submitters. In addition, the Agency plans to provide an opportunity, prior to finalization of the e-CDRweb, for stakeholders to test a pre-release version of the tool. EPA plans to conduct a training webinar shortly after the publication of this final rule to provide detailed instructions on the reporting requirements and on using e-CDRweb to complete and submit Form U. Finally, to the extent that the timing of the next submission period actually presents a substantial obstacle to the submission of any particular data element, notwithstanding EPA's efforts to familiarize submitters with the draft and final reporting tool, and EPA's post-promulgation efforts to familiarize submitters with the reporting requirements, the IUR reporting standard of "known to or reasonably ascertainable" addresses such circumstances without the need for a delay in implementation (see Unit V.E.1.).

One commenter suggested that EPA continue under the old IUR rule for this submission period. The Agency does not agree that it should continue under the IUR rule in effect for the 2006 submission period; however, the Agency recognizes that additional time may be necessary for many submitters to become familiar with the updated IUR

reporting requirements and develop processes for collecting the information. Therefore, the Agency will be phasing in certain requirements so that the scope of exposure-related information to be collected will be increased for the 2012 IUR data collection and then further increased for the 2016 data collection and subsequent reporting years. As mentioned by one commenter, the “IUR rule is one of the very few means by which the federal government can obtain and provide public access to robust information on the identity, production, processing and use of” chemical substances (Ref. 17). In order to fulfill the EPA Administrator’s goal of enhancing EPA’s TSCA chemical management program, EPA needs to begin collecting some of the new and updated information in the 2012 submission period. As described on EPA’s website (<http://www.epa.gov/opptintr/existingchemicals/pubs/enhanchems.html>), EPA’s comprehensive approach to enhancing the Agency’s current chemicals management program includes obtaining information needed to understand chemical substance risks and increasing transparency and public access to information about chemical substances. The changes to the IUR are specifically identified as a key component for these aspects of the enhanced program, including required electronic reporting and the expanded manufacturing, processing and use information. For example, the expansion of reporting processing and use information for all chemical substances addresses the identified lack or insufficiency of such information for most chemical substances – including HPV chemical substances. EPA’s efforts to understand and prioritize chemical substances based on risk, using the 2006 IUR data, were instrumental in identifying the needed changes to the IUR requirements. These included:

- EPA's Risk-Based Prioritization (RBP) process was developed to take the hazard data assembled for HPV chemical substances under EPA's HPV Challenge Program to conduct screening-level hazard assessments and use the 2006 IUR data to develop screening-level exposure assessments, with the goal of using the two types of assessments to develop screening-level risk prioritizations for the HPV chemical substances with fairly complete Screening Information Data Sets (SIDS). EPA quickly discovered that while the hazard data allowed EPA to make a screening-level conclusion about hazard, the 2006 IUR data rarely provided sufficient information for EPA to reach a screening-level conclusion about exposure.

- EPA discovered with the 2006 IUR that a larger than expected portion of HPV chemical substance manufacturers produced below the 300,000 lb threshold at individual sites, resulting in many submitters not being required to provide processing and use information for those volumes. In some cases, all of the reporters fell below the threshold.

- For MPV chemical substances, with national production volumes between 25,000 and one million lb, even fewer individual sites reported production volumes over the 300,000 lb threshold. Although EPA desired to include these chemical substances in its risk-based prioritization process, the screening-level exposure information was not available.

- For those chemical substances for which EPA had some processing and use data, the Agency had difficulty evaluating exposure for commercial workers and consumers because the 2006 IUR data did not differentiate between these populations. The separation of these populations for future IUR collections, and including other

information such as that related to children's use of the chemical substances, will help EPA better identify potential risks to more targeted populations.

These examples illustrate several obstacles EPA encountered in understanding chemical substance risks, which stemmed from the scope of the 2006 IUR data collection. They also illustrate how the revised IUR data collection will increase the Agency's ability to understand exposure concerns so that EPA will be better able to identify steps needed to manage risks associated with chemical substances. Not only will the revised IUR data collection provide information that would have been helpful for past programs, it is directly applicable to the Agency's current and future programs. EPA will be able to use the 2012 IUR data to identify additional chemical substances for its Chemical Action Plan program, will also be able to identify if any of the current Action Plans may need to be revised, and will be able to develop other aspects of the enhanced existing chemical substance management program that are associated with understanding chemical substance risk.

In addition, requiring the use of electronic reporting will ensure that data are available in a timely manner and will reduce data entry errors, thereby increasing the usability and reliability of the data for EPA and other Federal agencies. It will also help to fulfill the EPA Administrator's commitment to increase public access to information on chemical substances.

3. *EPA's use of IUR data.* The Agency received comments related to how IUR data can best be used to assist in assessing, prioritizing, and taking action on chemical substances that pose unreasonable risks. Commenters stated that the current IUR was sufficient for EPA to use as a screening tool for the prioritization of chemical substances

in commerce, and that EPA should use the Agency's wide variety of regulatory tools and authorities to collect more detailed information. Commenters also expressed interest in providing input on using the IUR and the Agency's prioritization process.

EPA disagrees that the current IUR is sufficient for its purposes. Between August 2007 and mid-2009, EPA developed screening-level hazard, exposure, and risk characterizations for some chemical substances produced or imported in quantities of 25,000 lb or greater a year. Based on those characterizations, EPA developed either a RBP or a hazard-based prioritization (HBP) for individual chemical substances or a group of chemical substances that were similar in some way, e.g., structure, properties, toxicity. Those prioritizations did not constitute definitive determinations regarding hazard, risk, or the sufficiency of available information for any regulatory purpose, but were rather initial evaluations of data and understanding currently available to EPA. EPA's experience using the IUR information to develop the prioritizations was that the 2006 IUR data were not sufficient to provide the needed exposure-related information. When EPA was developing RBPs for its HPV chemical substances, it needed both hazard and exposure screening-level information. Lacking sufficient exposure information, EPA found it necessary in many cases to make assumptions about exposure and the resulting prioritization decision was primarily hazard-based, as opposed to risk-based, as evidenced by statements in many of the RBP as well as HBP documents that EPA developed (available on-line at http://iaspub.epa.gov/opptppv/existchem_hpv_prioritizations.INDEX_HTML) that further information on exposure was needed to confirm the prioritization. Thus the exposure information provided in the 2006 IUR reporting did not provide EPA with sufficient

information to prioritize chemical substances for which it generally possessed a base set of hazard data. Therefore, for some of the RBPs the next steps indicated that additional exposure information would be necessary to validate the prioritizations before determining whether any further action was needed. In developing these characterizations, EPA identified areas where the IUR data collection should be improved and enhanced. These improvements, which are reflected in the modifications to the reporting requirements in the current rule, will allow EPA to better prioritize chemical substances for further assessment as well as make appropriate risk management decisions for follow-up action on chemical substances that may pose potential risks to human health or the environment.

EPA is considering using other regulatory tools and authorities to collect more in-depth information, but believes the IUR is the correct mechanism for the data collection finalized in this document. EPA also is considering ways to obtain public input on its use of the IUR data and its chemical substance prioritization process, as suggested by the commenters.

4. *Canada's prioritization approach.* Some commenters recommended that EPA adopt Canada's prioritization approach. EPA assumes that the commenters were referring to the Domestic Substances List (DSL) Categorization that Canada completed in 2006. The DSL Categorization was a statutorily mandated risk-based prioritization which required review of both hazard and exposure information for 23,000 chemical substances in a very short period of time. Health Canada was required to identify chemical substances presenting human health hazards as well as the greatest potential for exposure to Canadians. Even though categorization was a legally mandated process with a deadline

for consideration of all chemical substances on the DSL, Health Canada felt that production volume alone was not a sufficient surrogate for exposure. In order to move beyond production volume, Health Canada sought additional information, including some of the types of data that EPA is requiring for the 2012 reporting period (Ref. 18). Based on its review of hazard and IUR data collected on HPV and MPV chemical substances, EPA also believes that using large production volume as the sole surrogate for exposure is not sufficient to identify chemical substances of highest concern. Some of the risk-based prioritizations of HPV chemical substances resulted in low priority decisions for the HPV chemical substances that were low hazard, used in closed systems and consumed as intermediates. On the other hand, some of the MPV chemical substances were identified as potentially high or medium priority, because they had high or medium hazard and would present high or medium risk concerns if they had widespread exposure or dispersive uses. The only way for the Agency to move from prioritizations based primarily on hazard to truly risk-based prioritization is for it to receive regularly updated information on exposure and use for chemical substances being made and used in the United States. The chemical substance manufacturing industry has indicated in several ways, including in comments on the proposed rule, that it supports risk-based as opposed to hazard-based prioritization. A commenter also noted that industry strongly supports risk-based decisions and for that reason needs to provide robust production, processing, and use data.

B. Comments on Electronic Reporting

EPA received various comments on the proposed requirement to use the reporting tool, e-CDRweb, to submit all IUR submissions. In general, comments were submitted on

the reporting tool phasing-in electronic reporting registering with CDX, and electronic signatures. See section B. in the Responses to Comments document (Ref. 12) for further discussion on electronic reporting.

1. *Comments on the reporting tool and phasing-in electronic reporting.* In general, commenters supported electronic reporting. Some commenters suggested that the Agency develop a phased-in process for electronic reporting, in order to provide more time for companies to become familiar with the new format and to develop their own data systems. Some commenters wanted to be able to upload data via an XML file into the web-based tool. The requirement to use electronic submissions over the Internet was a concern for some commenters. EPA, based on its experience collecting and managing the 2006 IUR reports, has concluded that mandatory electronic reporting is a critical next step for collection of the 2012 data. Optional electronic reporting for the 2006 IUR provided the Agency with experience relating to both industry and Agency needs, and the Agency has applied this experience in the course of developing of the 2012 electronic reporting tool (e-CDRweb). For example, the use of a web-based tool for the 2012 IUR will eliminate many of the software compatibility and firewall setting issues that were encountered during the 2006 submission period. In addition, e-CDRweb utilizes other Agency systems, such as SRS, enabling the submitter to readily select the chemical identity in the correct format, thereby eliminating problems relating to the previous need to type or write in the chemical name. With these enhancements, EPA believes the use of e-CDRweb will substantially reduce error rates and burden; consequently, EPA does not believe it is necessary to have another optional electronic reporting period.

In addition, the Agency's CDX service is increasingly being used by a variety of programs, as the Agency moves toward comprehensive electronic reporting. EPA is continually looking for ways to improve CDX, to better address submitter and Agency needs. For example, EPA has developed an eTSCA registration for CDX which, when fully implemented, will eliminate the need to register separately to use the e-CDRweb and ePMN systems. ePMN registrations using the current eTSCA will be acceptable e-CDRweb registrations.

The Agency believes that commenters' concerns regarding mandatory use of the new electronic reporting tool reflect a lack of understanding of the tool's capabilities and enhancements. The reporting tool provides the ability to submit data in an XML format and includes enhancements to CDX that are designed to allow for multi-user capabilities and otherwise facilitate electronic reporting. EPA has provided training opportunities and guidance materials to facilitate electronic reporting, as well as testing opportunities, to alleviate particular commenters' concerns. For example, the Agency held an informational workshop and webinar on November 30, 2010. The workshop was designed to help companies develop a better understanding of the CDX registration process and the e-CDRweb electronic reporting tool. The workshop, which was recorded live as a webinar, was posted to the IUR website at <http://www.epa.gov/iur> along with accompanying slides, a question and answer document, and a draft XML schema. In addition, EPA plans to invite several companies to test e-CDRweb to identify areas needing improvements. The comments and concerns of industry representatives will be taken into consideration as EPA further develops the reporting tool. EPA also intends to hold further training and outreach sessions at which industry representatives may express

remaining questions and concerns regarding the operation of the e-CDRweb tool, which EPA will address. Additionally, EPA has published a revised Instructions document (Ref. 7) explaining the reporting requirements and how to complete Form U using the reporting tool.

Electronic reporting was first offered as an option for the 2006 IUR. As explained in the preamble to the proposed rule and the Responses to Comments document, there were many problems, errors, and delays associated with paper submissions of the 2006 IUR data, which make the continued use of paper reporting highly inefficient and therefore undesirable. In light of the substantial disadvantages associated with allowing paper submissions, and the reporting tool improvements and training opportunities outlined in this unit (and explained in greater detail in the proposed rule and the Responses to Comments document), EPA does not believe it is reasonable to phase in electronic reporting over another reporting period and is confident that submitters will be able to successfully use the e-CDRweb tool to electronically report under the CDR rule in 2012.

2. Comments on registering with CDX and providing electronic signatures.

Commenters thought the modified ESA Form, in particular the need for multiple notarized signatures, was burdensome and unnecessary. Commenters stated that there should be more than one individual with an electronic signature and that multiple persons may need to be able to input and submit IUR data for a company's U.S. sites. The commenters noted that the actual preparer/drafter would rarely be the signatory. Another respondent noted that companies should be allowed, but not required, to have the same authorized official for the PMN and IUR submission.

EPA understands and is cognizant of the concerns presented by industry regarding the revised ESA Form. An ESA Form is required for CDX registration and is necessary to submit electronic data to EPA. Regarding the prior need for multiple notarized signatures, EPA has determined that requiring a notarized signature as part of the ESA Form is no longer necessary. EPA is also exploring an approach to eliminate the need for an individual to register multiple times with CDX to submit to various TSCA programs. As with PMN electronic submissions, multiple people from the same site or company are able to register with CDX and participate in completing the site's Form U. Although one individual will be designated as an authorized official who will sign and submit the completed Form U, the e-CDRweb tool allows for more than one individual to edit a submission. Ultimately, EPA's goal is to provide one ESA Form across all TSCA programs and is exploring the reuse of electronic signatures issued under the New Chemicals Program, as well as other EPA programs.

C. Comments on Reporting Thresholds

1. *Method for determining whether you must report.* EPA proposed to modify the method used to determine whether a person is subject to IUR reporting. The new method requires persons to report under the IUR if they manufactured (including imported) 25,000 lb or more of a chemical substance at any single site in any calendar year since the last principal reporting year. This method becomes effective after the 2012 submission period. (Note: There is also a lowered production volume threshold for certain chemical substances, effective after the 2012 submission period. See 40 CFR 711.8(b).) Several commenters believed the change is appropriate and should be implemented for the submission period following the upcoming submission period (i.e., in the submission

period following the 2011 submission period described in the proposed rule). They noted that the new requirement is essential to effectively capture the substantial year-to-year fluctuation in production/import volumes that was missed in past IUR reporting cycles, thereby skewing the picture of how many and which chemical substances are actually in commerce at a given time and what levels of production or import. One commenter went further to say that the modification would eliminate gaps and uncertainties in the information collected under the current IUR that result from infrequent collections and reporting of data. Another said that this will keep manufacturers from disguising their actual output by producing certain specialty chemical substances only in years that are not currently subject to IUR reporting. Two commenters supported the change but opposed the proposal to delay implementation until after the 2011 submission period described in the proposed rule, because it would further delay the ability to obtain accurate annual production information.

In contrast, others had mixed opinions or did not think the change was needed. Some commenters felt that unless the value of collecting and analyzing historical data could be clearly demonstrated such that the resource for the Agency and regulatory community can be justified, EPA should retain the mechanism whereby the need to report is based on consideration of a single reporting year. Some commenters stated that EPA had not shown special utility for the information generated. Another commenter believes that there is no significant incremental benefit to require reporting from companies that produce or import less than 25,000 lb of a reportable chemical substance for 4 out of 5 years. The Agency realizes that the new multi-year consideration of production volume will increase reporting burden on industry, but believes that there is sufficient evidence

that wide fluctuations in production volumes from year to year indicate the past IUR reporting was not accurately characterizing the chemical production. As EPA noted in the proposed rule, production volumes of chemical substances vacillating above and below reporting thresholds in different IUR reporting periods resulted in a change of approximately 30% in the composition of the chemical substances being reported from one IUR reporting period to the next. For example, EPA prepared a prioritization document for the butenedioic acid dialkyl esters cluster, which consists of 10 butenedioic acid dialkyl esters, seven of which were MPVs and three HPVs in 2006 (Ref. 19). Three of the chemical substances have had fluctuating production volumes above and below one million lb. In 1990 and 1994 when the HPV Challenge Program was being developed, the chemical substances identified by CASRNs 68921-51-7, 141-05-9, and 624-48-6 had production volumes below one million lb and so were not included in the HPV Challenge Program for completion of SIDS datasets. In 1998 and 2006, CASRN 68921-51-7's production volumes have been above one million lb, making it an HPV in those years. In 2002, CASRNs 141-05-9 and 624-48-6 had production volumes above one million lb. In part because of their fluctuating production volumes, neither SIDS datasets nor consistent exposure and use information were available for these chemical substances and so they were included in a cluster for an HBP as opposed to an RBP. One commenter also submitted an analysis of the degree of fluctuation of chemical substances and production volumes in the 2002 and 2006 IUR reporting years. This analysis found that about 32% of the organic chemical substances reported in 2002, including 400 HPVs, were not reported for 2006 and that about 26% of the chemical substances reported in 2006, including more than 200 organic HPVs, were not reported in 2002.

In addition, in comments submitted to the Agency in response to other programs, industry representatives expressed concern that short reporting determination periods would drastically misrepresent the chemical substances that currently are in commerce. They stated they manufactured or imported some chemical substances only occasionally, and that these chemical substances would not be captured if the reporting covered too short a period. The proposed rule provides a more detailed discussion of these comments (Ref. 1).

EPA believes that most sites will be able to gather production volume information without a substantial effort. In many instances, production volumes for recent past years are tracked under standard business practices. For example, EPA believes it is standard business practice for a company to furnish records of recent operations in the case of a proposed sale or merger, and that companies therefore typically retain such records so as to be prepared for such eventualities. EPA also notes that in the case that prior years' production volume information is not known to or reasonably ascertainable by the submitter (EPA expects that such cases would be extremely rare), those data would not be subject to reporting under the IUR and therefore would not trigger an obligation to report. Furthermore, persons who have submitted a PMN to the Agency's New Chemicals Program are required to maintain records of production volume for the first 3 years of production or import and in certain circumstances, including but not limited to the names and addresses of any person to whom the chemical substance is distributed. They must be maintained for 5 years from the date of commencement of manufacture or import (See 40 CFR 720.78). EPA expects that many companies would also track production volumes for planning, marketing, and sales projection purposes. Several types

of TSCA actions, such as TSCA section 5(a)(2) SNURs and TSCA section 5(e) orders also require that production volume records be kept for 5 years for certain chemical substances, and several commenters indicated that they archived these records.

2. Elimination of the 300,000 lb threshold. The Agency received a substantial number of comments on the proposed elimination of the 300,000 lb threshold for reporting processing and use information. Comments submitted on various topics are described in this unit.

a. Increased numbers of covered chemical substances. Commenters asserted that the inclusion of inorganic chemical substances, coupled with the threshold change for processing and use information, will result in a substantial increase in the amount of data being submitted to the Agency. Commenters felt that EPA staff will need significant time to compile, review, and analyze the data submitted. One commenter suggested the Agency use a phased-in approach to adequately collect and process the increased information.

In response to these comments and comments received during interagency review, EPA decided to phase in the eventual elimination of the 300,000 lb threshold as a separate reporting threshold. For the 2012 submission period, all submitters of non-excluded chemical substances are required to report processing and use information if they manufactured (including imported) 100,000 lb or more of a chemical substance in 2011. For subsequent submission periods, the reporting threshold for processing and use information will be the same as for other types of information: 25, 000 lb (or 2,500 lb for chemicals subject to 40 CFR 711.8(b)). Thus, there will be no separate threshold for the reporting of production and use information after 2012 -- the applicable reporting

threshold will be the same as for other types of information. EPA believes this is a reasonable approach because it provides new submitters with an opportunity to become familiar with the reporting requirements, and provides much needed processing and use information on additional chemical substances. Future full reporting of exposure-related information will provide EPA and others with needed additional information for those chemical substances with production volumes of 25,000 lb or more at a site. While it is true that the amount of data in the IUR reports is expected to increase substantially in the 2012 and subsequent submission periods, EPA is better prepared now than it was for the 2006 IUR to compile, review, and analyze the anticipated increase of data. With the new e-CDRweb electronic tool, large amounts of data will be able to be submitted with less difficulty on the part of the submitter, and will be more readily organized, analyzed, and made available to the public by the Agency. In addition, the use of SRS for identifying chemical substances and validation process built into the e-CDRweb tool will eliminate most or all of the problems EPA had with missing information (which necessitated phone calls and e-mails to submitters), and manual entry of data, which was time-consuming and resulted in many mistakes. Given the requirement for mandatory electronic submissions and the corresponding improvements to the e-CDRweb tool, the Agency is confident that the increase in data submissions will be easily managed for the 2012 submission period and the next, and both EPA and the public will quickly have a useable set of exposure-related IUR data.

b. *Reporting burden.* Numerous commenters were concerned about the increased reporting burden, particularly for smaller companies, and the complexity of Form U, Part III. One commenter stated that EPA should assess the benefits of the additional reporting

requirements to establish a cost justification of the proposal. Other commenters were concerned that the lowered threshold would increase the number of imported mixtures and that it would be difficult to calculate and aggregate across products for lower volume chemical substances.

EPA analyzed the potential impacts of this requirement to all submitters, including potential burden to small businesses, in the Economic Analysis (Ref. 14). EPA recognizes that reducing the reporting threshold for processing and use information increases the reporting burden; however, phasing in the lower threshold reduces the burden for this reporting cycle and the cost to industry will decrease in all future reporting cycles. EPA disagrees with comments suggesting that the requirement may have a disproportionate effect on smaller companies (commenters suggested that smaller companies are more likely to manufacture below the 300,000 lb threshold that is eventually being eliminated). The quantity of a chemical substance that is manufactured (including imported) at a site is not necessarily dependent on the number of employees, which is the criteria by which a company is considered to be small. For example, a highly automated facility could produce large volumes of a chemical substance with a relatively small number of employees. Additionally, as noted in the Economic Analysis (Ref. 14), the Agency determined that because the small businesses affected by this final rule actually have average sales of more than \$11 million, and because any potentially affected companies with sales of \$0.81 million or less (the level at which the cost-to-sales ratio of the final rule would exceed 1%) would generally be exempt from reporting obligations under the IUR, small entities will not be significantly affected by this final rule.

EPA recognizes that, with the reduction and eventual elimination of the 300,000 lb threshold, importers may face an increase in burden to identify more component chemical substances contained within more imported mixtures. However, EPA believes that due to the deferral of the threshold reduction until the 2012 submission period (which involves reporting on the processing and use of imports occurring in 2011) and the deferral of the threshold elimination until the 2016 submission period (which includes reporting on the processing and use of imports occurring in 2015), importers will have had sufficient time to conduct an inquiry as to the specific chemical substances they import in mixtures. Furthermore, the inquiry need only be as extensive as a reasonable person, similarly situated, might be expected to perform.

EPA has several reasons to expect that importers have a reasonable awareness of the component chemical substances contained within imported mixtures. Importers have long been responsible for certifying that their imported chemical substances, including those chemical substances present as part of mixtures, are in compliance with TSCA (See 19 CFR 12.119). Furthermore, importers have long been required to provide chemical-specific information as to the constituents of imported mixtures under the IUR (see the definition of *importer* at 40 CFR 704.3 and the note at 40 CFR 710.4(c)(2)) and under the PMN program (40 CFR 720.30(b)). Furthermore, importers are often required to report chemical-specific information regarding imported mixtures under other EPA-administered statutes, such as the Emergency Planning and Community Right-To-Know Act (EPCRA) and RCRA. While reporting under the IUR differs in many significant respects from reporting under the EPCRA and RCRA programs, in all cases the importer is required to know the identity of the chemical substances they import. EPA notes that

one commenter described, in detail, its practice of accounting for component chemical substances in imported mixtures. The commenter stated that “[w]ith the advent of the [Registration, Evaluation, Authorisation and Restriction of Chemicals] REACH we recently implemented an application that is capable of tracking volumes of individual substances in mixtures and summing them up over a period of time. The system automatically looks at the current formulation of any product that is crossing a border and adds the volume of each component to the cumulative total for that substance” (Ref. 20). Finally, EPA notes that a chemical substance that is imported solely in small quantities for research and development, as an impurity, as part of an article, or in certain other forms, see 40 CFR 720.30(g) and (h), is not subject to the IUR reporting requirements. See 40 CFR 711.10.

c. Justification for data. Several commenters strongly supported EPA’s proposed change, stating that the information is essential for the completion of prioritizations for IUR reportable chemical substances; is critical for evaluating the potential for release of and exposure to chemical substances in commerce; and that the information requested is basic, screening-level data that should be required for all reported chemical substances. Additional commenters generally supported the change, but wanted it to take effect after the 2011 reporting cycle. Other commenters had concerns about the value of the information that is reported in Part III of Form U. One commenter stated that EPA has not made public documentation of the past use of this information to address screening and prioritization of chemical substances. Another commenter believes that EPA should provide more specificity on its needs and explain why other, more tailored, options do not provide the necessary data. EPA’s information needs have changed since the last major

amendment of the IUR rule in 2003. Production volume changes from year to year, so chemical substances can easily fluctuate above and below a relatively high reporting threshold, such as the previous 300,000 lb threshold for reporting processing and use, making it difficult for EPA to collect regular exposure information on many chemical substances. Requiring the reporting of processing and use information on an expanded list of chemical substances will assist the Agency and others in screening potential exposures and risks resulting from industrial chemical substance operations and commercial and consumer uses of chemical substances. The information will also help to provide an accurate and readily available source of, as noted in Unit V.A.1., basic exposure-related information for a subset of chemical substances listed on the TSCA Inventory. Furthermore, collection of this data is consistent with the EPA Administrator's strong commitment to provide the public with more information on a greater number of chemical substances.

As EPA discusses in this unit and elsewhere, the 2006 IUR information did not provide sufficient useable exposure-related data for EPA's screening level assessments. If EPA delayed reducing the processing and use reporting threshold until the 2016 submission period, EPA would have to wait several more years before more useful exposure-related information is received for chemical substances for which EPA has already determined are currently in need of such information. With the phased-in approach, EPA will be able to collect much needed processing and use information on additional chemical substances during the 2012 submission period. Requiring full reporting for all chemical substances in subsequent reporting cycles (i.e., eliminating the separate, higher, threshold for production and use information) provides EPA with the

exposure-related information needed to continue efforts begun with the 2012 data. For example, the data reported in 2006 did not provide an adequate amount of exposure-related information, especially for HPV chemical substances. When attempting to use the 2006 IUR data for its screening level exposure assessments, EPA found that numerous chemical substances previously identified as HPVs were reported in amounts classifying them as MPV chemical substances, below the 300,000 lb cut off, and thus processing and use information was not provided for chemical substances for which EPA had a relatively complete hazard data set from the HPV Challenge Program. For example, an RBP was prepared for the chlorobenzenes category, which consisted of four chlorobenzenes sponsored under the HPV Challenge Program (Ref. 21). Only one of the four chemical substances, 1,3-dichlorobenzene (CASRN 541-73-1), was considered high priority; however, because it was an MPV chemical substance in 2006, no exposure and use data was available from the IUR reporting, so the high priority determination was based on high human health hazard and assumptions made about exposure.

The 2006 IUR data did not provide sufficient information on MPV chemical substances for use by the Agency's Existing Chemicals Program. Screening chemical substance risks generally requires a combination of both hazard and exposure information. Because most MPV chemical substances were produced below the 300,000 lb reporting threshold, EPA did not have exposure information available from the 2006 IUR and therefore, developed hazard based prioritizations which were supported by a screening level hazard characterization and consideration of very limited exposure and use data. The lack of information on exposure and use was especially problematic in those instances where the screening level hazard characterization identified either a

medium or high hazard. Basic hazard data is easier to find in existing databases; however, specific exposure data is needed to make a priority determination risk-based. EPA believes that the lowering of the reporting threshold will provide more exposure-related information on a greater number of MPV chemical substances. EPA disagrees with the comment that it has not made public documentation of the past use of processing and use information to address screening and prioritization of chemical substances. As discussed in Unit V.A.3., EPA used 2006 IUR data starting in 2007 in its development of RBPs and HBPs which it has made available on its website. More recently, the Existing Chemicals Program used the IUR database when developing the Chemical Action Plans. For some Action Plan chemical substances, the 2006 IUR data were not sufficiently complete to be useful. An example is the Action Plan for Dyes Derived from Benzidine and Its Congeners, where the chemical substances of concern are known or reasonably anticipated human carcinogens; however, those listed were produced in amounts below the 300,000 lb threshold and so little exposure data was reported. Based on IUR data from prior reporting periods, some of the other dyes had been reported in the 10,000 to 25,000 lb range, but there was no 2006 IUR data available to determine whether these chemical substances were still being used in amounts beyond the small amounts used as analytical reagents. The Action Plans are available on EPA's website at <http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html>. By lowering the reporting threshold for processing and use information to 25,000 lb in 2016, EPA is increasing consistency for the IUR with reporting requirements of the TRI program. Under the TRI program, chemical substances that are not chemical substances of special concern listed at 40 CFR 372.28 (e.g., mercury, lead) are required to be reported if they

are manufactured or processed in volumes of 25,000 lb or more annually or otherwise used in volumes of 10,000 lb or more annually. Though the chemical substances on the TRI list of toxic chemicals may be different from those reported under the IUR, an analysis showed that over 80% of the sites that reported under the 2006 IUR also reported under TRI in 2006. Given that there is some overlap in the companies that report and the information collected on activities and uses of chemical substances under both programs, EPA believes that many companies are already accustomed to reporting on lower volume chemical substances.

d. Lack of data for chemical substances. Several commenters noted that the 2010 reporting year will be over by the time the rule is finalized, and companies would not have had the opportunity to establish systems for collecting the information for chemical substances in the 25,000 to 300,000 lb range. Other commenters asserted that EPA was seeking data that are limited or unavailable because manufacturers do not know how their downstream customers use their chemical substances. Another commenter asserted that the lowered threshold will not enhance the quality or integrity of the resulting IUR data due to uncertainties in making estimates. EPA recognizes that submitters may not always have detailed information about how the chemical substance(s) they manufacture (including import) are used. As a result, submitters will be required only to report this information to the extent that it is known or can be reasonably ascertained. Based on its experience with the New Chemicals Program, discussions with industry about voluntary risk management programs, and industry's various self-regulation initiatives, the Agency believes that most submitters have at least some basic information about downstream uses, such as the information that is required by the IUR rule. EPA does not anticipate

that the quality of the data collected in 2012 will significantly decrease due to the timing of the amendment to the reporting threshold. As mentioned earlier, EPA published a final rule (Ref. 6) to suspend the 2011 submission period to provide sufficient time for companies to comply with the updated IUR reporting requirements. This final rule was published in advance of the 2012 submission period, which is February 1, 2012, to June 30, 2012. For these reasons, companies should have the opportunity to establish systems for collecting the information on their reportable chemical substances. Furthermore, many of the reporting elements are the same as in past IUR reporting periods, and EPA notes that this final rule affords sufficient flexibility to account for those circumstances in which information is truly unknown and not reasonably ascertainable. The Agency believes that the data will be of sufficient reliability for use by the Agency and others for purposes such as screening-level risk assessments and prioritization.

3. *Eliminate 25,000 lb threshold for specific regulated chemical substances.* EPA proposed to eliminate the 25,000 lb reporting threshold for chemical substances subject to particular TSCA rules and/or orders and to require manufacturers (including importers) of such chemical substances to report under the IUR, regardless of the production volume. Comments submitted on various topics are described in this unit.

a. *Burden.* One commenter stated that companies not expecting this significant change will be unprepared to gather required information. Several commenters expressed the view that the requirement will increase the burden upon industry without any real benefit to the environment and will create a situation where manufacturers (including importers) are responsible for knowing all byproducts of their process, no matter how small. Others felt that enacting this requirement without a *de minimis* concentration

threshold would add an unnecessary additional layer of complexity to IUR analysis and would result in each reporting entity responsible for a far greater number of Form U submittals.

The Agency believes it is likely that recordkeeping practices were already in place for a company to track the volumes of the chemical substances it is manufacturing (including importing). In response to commenters, EPA decided to take two steps to limit the burden increase associated with IUR reporting for the specific regulated chemical substances. As a result, EPA is reducing the reporting threshold for these chemical substances to 2,500 lb, instead of entirely eliminating the reporting threshold. In addition, EPA is phasing in this change to the IUR; it will not affect IUR submissions until the 2016 submission period (i.e., it applies to the submission in 2016, of records of production occurring between 2012 and 2015). EPA believes this should help to reduce the reporting burden for submitters because it provides sufficient time for companies to put in place recordkeeping procedures to collect and report the required data for situations where the recordkeeping procedures do not already exist. The burden of reporting will also be greatly diminished by the use of the reporting tool. The Economic Analysis contains EPA's analysis of the burden associated with this reporting (Ref. 14).

EPA disagrees that the increased burden will not yield any real benefits. Chemical substances that are the subject of particular TSCA rules and/or orders are of demonstrated high interest to the Agency. Receipt of up-to-date exposure and use information on these chemical substances, produced at 2,500 lb or more, will help EPA as it develops risk management strategies for those chemical substances subject to proposed rules. Additionally, EPA will use the 2016 IUR data as it monitors chemical substance

production and compliance with the rules. The new requirement will also contribute to the EPA Administrator's commitment to increase the availability of chemical substance information to the public.

b. *Imports and mixtures.* Commenters thought this requirement will be difficult to meet in practice, particularly for imported chemical substances or mixtures. One commenter felt the requirement would create a needle-in-a-haystack situation in which a company would need to examine all chemical substances and/or mixtures imported, regardless of the concentration of the chemical substance or volume of the import. Other commenters believed that importers would have great difficulty knowing that low-concentration ingredients are present in formulated mixtures, especially when they are not subject to inclusion on a label or Material Safety Data Sheets (MSDS). EPA recognizes that eliminating the 25,000 lb reporting threshold may, in some instances, make it more difficult for importers to determine the production information for component chemical substances in imported products. Consequently, the reporting threshold will be 2,500 lb, instead of zero, and will be phased in to begin with the 2016 IUR. The IUR also includes a number of exemptions that address the "needle-in-a-haystack" concern expressed by the commenter. IUR reporting is not required for a chemical substance that is imported solely in small quantities for research and development, as an impurity, as part of an article, or in certain other forms. See 40 CFR 711.10, 40 CFR 720.30(g) and (h). Furthermore, companies should be accustomed to reporting chemical-specific information to EPA because the Agency has always sought information on individual chemical substances in mixtures under the IUR and other TSCA regulations. For example, TSCA section 13 requires chemical importers to certify

that the chemical substance or mixture it is importing is not being imported in violation of TSCA; an importer must, therefore, have knowledge of the regulatory status of the chemical substances it is importing. If an importer does not know, or can't reasonably ascertain that a particular chemical substance is present in a mixture, it is not required to report the chemical substance. If an MSDS makes no mention of the presence of an ingredient, and the importer does not otherwise know that the ingredient is present, EPA would generally agree that the importer does not know, and cannot reasonably ascertain that it is importing that ingredient. Therefore, no IUR report for that ingredient would be required. In addition, manufacturers (including importers) are not required to report impurities.

If an importer does not know and cannot reasonably ascertain that a particular chemical substance is present in an imported mixture, it is not required to report the chemical substance under the IUR. Importers of mixtures with constituents of proprietary or otherwise unknown chemical identity should ask the supplier for the chemical identity to help determine whether an IUR report must be completed. If an importer knows that it is importing a particular chemical substance above the relevant threshold, but does not know the chemical identity because the supplier is unwilling to share the chemical identity with the importer, it is sufficient for the importer to follow the procedures in 40 CFR 711.15(b)(3)(i)(A), requesting that the foreign supplier provide the chemical identity directly to EPA in a joint submission.

The IUR reporting related to mixtures and UVCB chemical substances (chemical substances that are of Unknown or Variable composition, Complex reaction products, or Biological materials) requires careful consideration by submitters. Whenever a submitter

has manufactured or imported a combination of several chemical substances, the submitter must first determine whether for TSCA purposes it is a mixture or a single UVCB chemical substance. A mixture is any combination of chemical substances that meets the statutory definition of “mixture” at TSCA section 3(8). Mixtures are not reported to IUR – rather the mixture's component chemical substances, the chemical substances that make it up, are potentially subject to reporting, as described in this unit. A UVCB chemical substance is an indefinite combination of chemical substances, that does not meet the statutory definition of “mixture” at TSCA section 3(8), whose number and individual identities and/or composition are not precisely or completely known. A UVCB combination of chemical substances is subject to reporting under IUR and is considered a single chemical substance. Generally, the determination of whether a combination of chemical substances is a mixture or a UVCB chemical substance is made by the time that chemical substance has been commercialized and, as such, would be clear early in the IUR process. The following discussion is presented with this generality in mind.

- If you imported a mixture, you will need to report the individual chemical components of the mixture to the extent that your total volume for the individual chemical substance triggers reporting (i.e., generally to the extent that such volume reaches the 25,000 lb threshold).
- If you domestically manufactured a mixture, you will need to determine whether any chemical substances were formed from a chemical reaction that occurred as part of manufacturing the mixture. If a chemical reaction has occurred, a chemical substance formed from the chemical reaction may be subject to reporting, based on its production volume or the applicability of other exemptions. If a chemical reaction has not occurred,

you have not manufactured any reportable chemical substances in the production of the mixture. In such a case, the production of the mixture has not triggered any IUR reporting requirement.

- Domestic manufacturers and importers should also consider whether the combination of chemicals they have domestically manufactured or imported (respectively) should be chemically identified for TSCA purposes as a single UVCB chemical substance instead of a mixture.

EPA has developed two inventory nomenclature guidance documents related to the mixture-UVCB determination titled:

- i. “Toxic Substances Control Act Inventory Representation For Chemical Substances Of Unknown Or Variable Composition, Complex Reaction Products And Biological Materials: UVCB Substances” available on-line at <http://www.epa.gov/oppt/newchems/pubs/uvcb.txt>.

- ii. “Toxic Substances Control Act Inventory Representation For Combinations Of Two Or More Substances: Complex Reaction Products” available on-line at <http://www.epa.gov/oppt/newchems/pubs/rxnprods.txt>.

- c. *List of subject chemical substances.* Commenters suggested that EPA provide an up-to-date list of the chemical substances impacted at the beginning of the information collection year to ensure more accurate and complete reporting. EPA provides just such a list. It is titled “Chemical Substances that are the Subject of Certain TSCA Orders, Proposed or Final TSCA Rules, or Relief Granted under Civil Actions.” It can be found in Appendix B of the Instructions document (Ref. 7). The pertinent chemicals are listed both by CASRNs (for non-confidential chemical substances) or by TSCA Accession

Numbers (for confidential substances) that are the subject of a rule. The Instructions document, which was updated for the 2012 IUR reporting, is available in the docket for this final rule and on EPA's IUR website at <http://www.epa.gov/iur>. This list is intended to be a helpful information resource, but it is not legally determinative of the status of any particular chemical substance.

d. *Reporting for chemical substances subject to a proposed rule.* Some commenters supported EPA's suggestion to eliminate the 25,000 lb threshold for certain chemical substances that are the subject of a rule proposed under TSCA section 5(a)(2), 5(b)(4), or 6. Another commenter believed it was inappropriate to impose expanded reporting requirements on chemical substances subject to proposed rules which might not be finalized. The Agency generally agrees with the commenters who stated that if chemical substances that would typically be exempted from reporting are subject of a rule proposed under TSCA section 5(a)(2), 5(b)(4) or 6, the chemical substances should be reported despite the lower volumes produced. However, as discussed in Unit III.E.3., EPA has decided to reduce the reporting threshold for these chemical substances to 2,500 lb, instead of entirely eliminating the reporting threshold. In addition, EPA is phasing in this change to the IUR; it will not affect IUR submissions until the 2016 submission period.

The Agency disagrees with the commenter who argued that the change to the 25,000 lb reporting threshold (at 40 CFR 711.8(b), promulgated under TSCA section 8(a)) should not be triggered by the mere issuance of a proposed rule for a chemical. The latter commenter suggested that it would be inappropriate to collect more detailed information on such a chemical substance until the proposed rule had been fully vetted

and analyzed, noting that finalization can often take a number of years. However, EPA believes that the issuance of one of the proposed rules described in this unit represents an appropriate circumstance to trigger enhanced information collection under the IUR. EPA issues a proposed rule under TSCA section 5, or 6 only after making proposed findings under TSCA section 6 that a chemical substance or some specified use of a chemical substance presents some level of concern. Precisely because potential concerns about the chemical substance would be under review and because there might be an opportunity for a fuller IUR dataset to help inform that analysis and the development of risk management actions, EPA believes it is appropriate for the reduction of the 25,000 lb reporting threshold to be triggered when a rule is proposed. Furthermore, those chemical substances that are the subject of a rule proposed under TSCA sections 5(a)(2), 5(b)(4), or 6 are of demonstrated high interest to the Agency. In an effort to better understand the extent of manufacture, use, and potential exposure to such chemical substances, EPA believes it is appropriate to reduce the 25,000 lb threshold and require reporting on these chemical substances during the 2016 reporting cycle if they are manufactured (including imported) in volumes of 2,500 lb or more.

e. De minimis threshold volume. EPA asked for comment on whether a *de minimis* production volume threshold should be set for these chemical substances. Several commenters supported the concept of a *de minimis* threshold, although one of the commenters indicated that it would be difficult to choose an appropriate level to decrease the reporting burden due to the difficulty associated with definitively identifying a production volume level below which there are not chemicals of interest. A few of these commenters supported setting a *de minimis* threshold of 2,500 lb, as this is 10% of the

25,000 lb reporting threshold and is similar to the *de minimis* under the EU's REACH regulations. One commenter thought a *de minimis* volume should be set on a chemical-by-chemical basis for chemicals for which EPA needs specific information. Some commenters opposed setting a *de minimis* threshold, either because they felt that there should be no reporting threshold or they felt that the threshold should remain at 25,000 lb. One commenter specifically opposed a *de minimis* threshold for any persistent, bioaccumulative and toxic (PBT) chemical substances.

EPA agrees with some commenters who noted that a 2,500 lb threshold would provide sufficient data for the Agency to monitor production and compliance with certain proposed or promulgated rules and/or relief granted pursuant to actions. Therefore, the Agency has decided to lower the reporting threshold to 2,500 lb, instead of zero, beginning with the 2016 IUR. EPA believes that, at this time, the 2,500 lb threshold is a reasonable *de minimis* threshold that is low enough to help decrease the burden on submitters, yet will provide much needed data on chemical substances of known concern to the Agency. The reduced threshold is essential to ensuring that information is available on chemical substances that could pose health or environmental concerns at levels of production or import below the 25,000 lb threshold. In the future, EPA may find it necessary to collect information on these chemical substances at a reporting threshold below the 2,500 lb threshold introduced in this action.

EPA also believes that the regulated community should be sufficiently familiar with the 2,500 lb threshold as it is similar to the threshold that is used under the EU's REACH regulations to submit registration dossiers. Under REACH, a person who manufactures or imports a chemical substance in quantities of 1 tonne (metric tonne (mt)

or if converted to pounds, about 2,205 lb) or more per year within the European Economic Area (EEA) must register the chemical substance (Ref. 22).

EPA believes that setting a *de minimis* threshold on a chemical-by-chemical basis or special thresholds for PBTs or carcinogens would require more time and resources than are presently available. The Agency recognizes that because of this *de minimis* threshold, there may be some chemical substances for which the Agency will have an interest in the IUR data (e.g., for evaluating potential exposures), but for which IUR data are not reported because production volume is below 2,500 lb per site. However, EPA believes the 2,500 lb threshold will be sufficient for most circumstances. To address any future need for additional exposure-related information respecting chemical substances with per-site production volume below 2,500 lb, EPA may propose to amend the IUR further in the future, or may evaluate whether other action under TSCA would be appropriate.

D. Comments on Specific Data Elements

1. *Parent company and site identity.* Two comments were received in support of using the company name, address, and D&B number for reporting purposes, and clarifying the meaning of “company name.” Respecting the clarification, one commenter suggested that the word “ultimate” be removed from the phrase “ultimate domestic parent company” and that instead companies should be allowed to name their domestic company, as is understood within their particular corporate organization. The commenter also noted that the intended clarification was not reflected in the actual regulatory text at proposed 40 CFR 711.15(b)(2)(i), which only referred to “parent company name.”

During the 2006 submission period, submitters indicated that further clarification was needed to identify the correct company name for reporting purposes. Based on these previous comments, EPA has determined that the parent company's name, address, and D&B number is necessary to provide clarity as to which company name to use for reporting under the IUR. EPA agrees that further specification of "company name" is appropriate, and that the appropriate name for reporting should be clearly identified in the rule, but disagrees that "domestic parent company name" is sufficiently specific. As noted in the proposed rule (Ref. 1), EPA believes that using an approach that is consistent with the TRI reporting requirements would be most clear both for reporters and users of the data. EPA is therefore amending 40 CFR 711.15(b)(2)(i) to refer to "U.S. parent company name" and defining "U.S. parent company," at 40 CFR 711.3, to mean "the highest level company, located in the United States, that directly owns at least 50% of the voting stock of the manufacturer." The IUR definition of "U.S. parent company name" is consistent with the use of the term of "parent company" in section 5 of the 2009 Toxic Chemical Release Inventory Reporting Forms and Instructions (Ref. 15). EPA provides further clarification regarding the correct domestic (U.S.) parent company name in the Instructions document (Ref. 7).

2. *Technical contact.* EPA requested comment on requiring that the technical contact be a person knowledgeable about the reported chemical substance and be located at the manufacturing (including importing) site. Several commenters stated that companies should be able to use their discretion in identifying the most appropriate contact or contacts. They believe that the technical contact need not be physically located at the reporting site, and that information may be more reasonably generated by a

corporate contact rather than a technical contact at the production site. Some commenters said that the technical contact should be an employee of the submitting company.

EPA agrees with commenters who stated that companies should use their discretion in selecting a technical contact or multiple technical contacts, as permitted by the new e-CDRweb tool. However, EPA believes that a technical contact must be someone who can answer detailed follow-up questions that EPA may have regarding the submission. EPA has found that technical contacts not at the reporting site generally are less knowledgeable about the submission or chemical substance and therefore may not be able to discuss follow-up questions. Also, it has been EPA's general experience that short-term contractors have not been suitable technical contacts, because they may no longer be under contract with the submitting company when EPA contacts them a year or more after the submission is made.

3. Correct chemical name--a. Comments on imported chemical substances and joint submissions. EPA received several comments regarding its proposal to require that importers ensure that their supplier completes the joint reporting of the CA Index Name currently used to list the chemical substance on the TSCA Inventory. The comments indicated that it would be difficult for an importer to require that another party complete a joint submission because foreign suppliers are not subject to the same Federal regulations as U.S. companies, compliance with U.S. regulations is not their top priority, and in some cases they are slow to comply.

EPA agrees with the commenters that its proposed joint submission procedures for importers, which required the importer to ensure that a foreign supplier prepared a secondary submission on its behalf, presented implementation difficulties. This is

because, as the commenters suggested, the foreign supplier may not be subject to any direct legal obligation to provide the information to EPA. The Agency also notes that this issue extends to the regulations at 40 CFR 711.15(b)(3)(i)(B), as there may be circumstances in which the manufacture of a chemical substance is reportable under the IUR, yet the supplier of a reactant used in manufacturing that chemical substance would not have an independent legal obligation to report the chemical identity of the reactant under the IUR.

Therefore, the Agency has modified the requirements at 40 CFR 711.15(b)(3)(i) to reflect the primary submitter's underlying obligation to provide what it knows or can reasonably ascertain respecting the identity of a chemical substance subject to reporting. The joint submission requirement is no longer to ensure that suppliers provide secondary submissions to EPA, but to properly ask that they do so. Consistent with 40 CFR 711.15(b)(3)(i), a request for a secondary submission to EPA must be prepared using e-CDRweb, include instructions for electronically submitting the information to EPA, and explain how to provide a clear reference to the primary submission. Documentation of the request to the supplier must be submitted to EPA along with the rest of the primary submission.

Finally, EPA has also modified the requirements to more clearly reflect, see proposed rule (Ref. 1), that they only apply in cases where a supplier will not reveal the pertinent chemical identity information to the submitter. In the event that a manufacturer (including importer) actually knows the chemical identity of a chemical substance subject to IUR reporting, the manufacturer must provide that information irrespective of a supplier's confidentiality claims. EPA has modified the substantiation question at 40 CFR

711.30(b)(1)(i) to include information about harm to the submitter's competitive position "or to your supplier's competitive position."

b. *Comments on reporting International Union of Pure and Applied Chemistry (IUPAC) names as an alternate.* A commenter recommended allowing IUPAC names as a substitute for CA Index Names for discrete chemical substances, because the IUPAC nomenclature provides the exact chemical structure and because the commenter was concerned that submitters would be required to go through a particular fee-based service to obtain CA Index Names for chemical substances.

The Agency disagrees that IUPAC names should be allowed as a substitute for CA Index Names in reporting discrete chemical substances for the IUR. Chemical substances are listed on the TSCA Inventory using CA Index Names, and only chemical substances listed on the TSCA Inventory are to be reported for IUR. The requirement for using CA Index names is directly related to positively identifying the listed TSCA Inventory chemical substance. Using a different nomenclature for the purposes of reporting for IUR could create confusion, both for industry and for EPA.

Additionally, there will generally be no need for submitters to use a fee-based service to obtain the CA Index Name and corresponding CASRN for IUR reporting purposes. As part of the electronic reporting process for the IUR, submitters will be able to easily connect electronically from the IUR reporting tool directly to the Agency's SRS database in order to obtain CA Index Names and corresponding CASRNs for all of their non-confidential chemical substances on the TSCA Inventory. These data can then be electronically copied back to the IUR reporting tool.

4. *Chemical identifying number.* Some commenters were opposed to removing the PMN number as an allowed identifying number, suggesting that the Agency might be inundated with requests for TSCA Accession Numbers, and that for historical products, this may pose an extra burden for both industry and EPA. It was suggested that the Agency provide a cross-reference list of PMN numbers to TSCA Accession Numbers so that the information can be easily obtained without additional burden on industry and the Agency.

The Agency has added PMN numbers to the SRS listing to provide a cross-reference list, as suggested by the commenters. The e-CDRweb reporting tool allows the user to search SRS using the PMN number in order to populate the IUR report with the pertinent chemical identification information for confidential chemical substances listed on the TSCA Inventory.

There are certain circumstances where a submitter occasionally may not be sure of the particular PMN case number and TSCA Accession Number the Agency has assigned to one of its confidential substances, such that the submitter would not be able to definitely determine this solely from searching in the SRS. This could happen, for example, if the chemical substance were originally reported as part of a consolidated PMN and the submitter did not learn from EPA which particular case number in the consolidated PMN number sequence corresponds to which of the several reported confidential substances. This could also happen if a certain PMN represented a mixture of two or more confidential substances, such that multiple TSCA Accession Numbers were assigned to the different substances reported in that single PMN, and the submitter didn't already request the particular TSCA Accession Numbers from EPA for the individual

chemical substances comprising that multi-component type of PMN. In such circumstances, a submitter should contact EPA in writing, well before initiating IUR reporting, to obtain the required TSCA Accession Numbers from the Agency. The Agency will respond to such inquiries in as timely a manner as possible. It is the responsibility of the submitter to contact EPA for such information in sufficient time to allow for the Agency to respond.

5. *Production volume--a. Report production volume for each year.* EPA requested comment on the requirement to report production volume for each of the 5 years since the last IUR principal reporting year. Comments submitted on various topics are described in this unit.

i. *Insufficient time to collect data.* Most commenters stated that companies were prepared to compile and report the required information for the 2010 reporting year; some companies indicated, however, that they had not established systems to collect and compile information for 2006-2009. Several commenters recommended that EPA delay the implementation of the reporting requirement until the next reporting cycle to allow companies sufficient time to prepare for the additional data collection effort. One commenter was concerned that the short period of time given by EPA to collect the information will result in significantly decreased data quality and reliability. Another commenter said that most companies archive data after 18-24 months. Some found it confusing that the threshold to determine the need to report in one submission period would change to include production data from previous years, but that the reporting of production data from previous years would take effect in an earlier submission period.

EPA acknowledges the possibility that certain information respecting past production volume, for the years between 2006 and 2009, might not be known or reasonably ascertainable to a submitter in 2012. While submitters are free to designate as “not known or reasonably ascertainable” any information that has indeed passed out of the scope of reporting due to the passage of time, EPA has determined it is nevertheless appropriate to reduce the extent to which submitters will need to resort to such designations, and to focus on more recent production. EPA believes that phasing in the reporting of past production volumes as follows will both improve the quality of the information collected and reduce the burden of collecting it.

Based on the comments received, EPA is requiring that for the 2012 submission period, manufacturers (including importers) report the total annual volume (domestically manufactured and imported volumes in pounds) of each reportable chemical substance at each site during the calendar years 2010 and 2011. For submission periods subsequent to the 2012 submission period, the total annual volume (domestically manufactured and imported volumes in pounds) of each reportable chemical substance at each site for each complete calendar year since the last principal reporting year are required to be reported. EPA believes its decision to require the reporting of 2010 production volumes in a 2012 submission period is consistent with the comments noting that companies were prepared to report 2010 data and that the Agency’s decision to phase in reporting for each complete calendar year since the last principal reporting year is warranted in light of other simultaneous changes to the IUR rule which increased reporting burden. The Agency also believes the delay to report the production volume for each year since the

last principal reporting year will give companies adequate time to establish systems to collect and compile the required information.

ii. *Reporting burden.* Several commenters stated that the requirement is overly burdensome, especially for chemical substance importers and manufacturers who (according to the commenters) will need to analyze all products to track the volumes of all component chemicals. Another commenter acknowledges that, while the burden of reporting the data for each principal reporting year was minor, the information would be of little value to the Agency. On the other hand, one commenter stated that this requirement could increase the burden by at least three fold. Another commenter said that in some cases, businesses have no need to capture past production volumes. One commenter asserted that many companies will consider the production volume in every year to be CBI and will take the necessary steps to request CBI coverage of this information. The commenter acknowledged that the information will still be available to EPA for consideration, but was concerned that the burden on EPA of keeping the information confidential will increase substantially due to the potential number of CBI claims.

EPA's burden estimates represent the average burden across all sites for providing production volumes. As such, commenters should be aware that their particular circumstance may not be average and, therefore, the estimate may not accurately reflect their own individual circumstances. However, EPA is confident that the estimate does reflect the average burden across all sites and encompass the range of burdens faced by submitters.

In addition, some comments identified a misunderstanding of the reporting requirements with respect to byproducts. As described elsewhere in this unit, accounting for the manufacture of a byproduct does not necessarily entail accounting for each individual component chemical substance in the byproduct. See the more detailed discussion of issues related to byproducts in section F.3. of the Responses to Comments document (Ref. 12). The Agency does expect that the reporting burden will decrease in reporting cycles beyond 2016, as submitters put additional recordkeeping procedures into practice.

As with any data element, CBI claims should only be made when warranted. While more CBI claims may increase EPA's burden slightly, the Economic Analysis estimates the amendments will save EPA approximately \$68,000 in the first reporting year and \$175,000 in subsequent reporting cycles through efficiencies from electronic reporting (Ref. 14). CBI claims on production volumes are unlikely to create any significant burden beyond what is estimated in the Economic Analysis. CBI claims do, however, prevent valuable information about chemical substance manufacture (including import) from becoming publicly available.

iii. *Retroactive reporting.* Several commenters expressed concerns asserting that EPA retroactively is requiring historical data and that the requirement for past production information was beyond the scope of EPA's TSCA authority for IUR reporting. Another commenter said it was not feasible to accurately produce this historical data for the many byproducts that companies produce and send for recycling, primarily because manufacturers did not know they needed to have such data gathering mechanisms in place.

EPA disagrees with commenters' suggestion that requiring reporting information on past production constitutes an imposition of retroactive reporting requirements. This is because the final rule does not establish a new legal requirement to have taken some particular recordkeeping action in the past. Instead, it holds submitters to a prospective standard of reasonableness. To the extent that a particular piece of information about the past is indeed not known or reasonably ascertainable at the time that a person is obligated to make a submission (either because of the timing of a change in the reporting requirements or for some other reason), the submitter may simply indicate that the information is "not known or reasonably ascertainable."

iv. Alternate approaches. A few commenters suggested that burden would be reduced if companies reported in ranges or provided best estimates. Other commenters suggested that reporting be limited to a subset of industries or chemical substances, based on criteria to focus on data collection and evaluation activities that are more valuable to the Agency. Examples of criteria include substances with a history of fluctuations in chemical substance manufacture and import practices or substances that are considered hazardous.

EPA disagrees that reporting production volume in ranges or estimates would provide data of comparable value. Though EPA requires some of the IUR information to be reported in specified ranges, EPA sees little value in allowing submitters to report the production volumes in ranges. Similarly, EPA sees little value in allowing submitters to provide estimates that do not reflect all information known or reasonably ascertainable. EPA believes that a higher level of confidence in data accuracy will be achieved by requiring specific numeric data that reflect all information known or reasonably

ascertainable to the submitter. It is important to note that EPA is interested in use and other exposure-related data on all chemical substances that are not exempted from IUR reporting, and manufacturing exposure-related data on partially exempted chemical substances. Especially since there is a multi-year gap between IUR submission periods, the mere fact that a chemical substance is not known to be hazardous at this time does not mean that EPA is not interested in exposures and uses of that chemical substance. Under a contrary policy, EPA would potentially need to wait several years before obtaining the basic exposure information necessary to determine whether a hazardous chemical substance may present an unreasonable risk (since the collection of screening-level exposure information would not be triggered until hazard data had been assessed). In summary, after considering the suggestions, EPA believes its decision to collect multi-year production volume starting with the 2016 IUR submission period is still sound.

EPA disagrees with the suggestion that reporting be limited to a subset of industries or chemical substances. The IUR data are used extensively in the Agency's screening and prioritization process. As such, identifying a list of chemicals or industries prior to screening would not provide EPA with the data needed for its programs and defeats the purpose of collecting the data. EPA does not believe it practicable to provide a definitive list of chemical substances with a "known history of fluctuations." The Agency does not have such a list, and believes that because year to year fluctuation could be caused by such a wide variety of circumstances, including circumstances such as economic changes and manufacturing practices, that developing and maintaining such a list is not only not practicable, but confining that list to substances with a "history" of fluctuations would not capture the industry variability that EPA is seeking.

b. *Volume of chemical substances used on site.* One commenter stated that this data element was essential to improving accuracy and utility of the reported production volume and two commenters stated they thought there was no value in this data element and that the Agency should retain the site-limited check box because, the commenters stated, it was more informative for screening-level risk assessment. Five commenters expressed confusion about the requirements of reporting this data element. Specific concerns included a concern about duplicative reporting for this data element and the industrial processing and use information for chemical substances used on-site; whether this applied to chemicals used in synthesis or also to chemicals that were repackaged; and the need to identify the amount of a chemical substance present on site during a specific time period.

EPA agrees with the commenter who felt that reporting volumes of chemical substance used at a site will increase the accuracy and utility of the IUR reporting information. Reporting the volume used on-site provides valuable information related to potential exposures associated with the on-site volumes, providing the Agency with better information for exposure assessments. The usefulness of this IUR data element has been demonstrated by EPA's use of similar data in the 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 the IUR. Exposure-related data in PMNs include estimates of production volume, categories of use, percent production volume in the categories of use, maximum numbers of workers exposed, and concentrations and physical forms of the chemical substance. EPA uses these exposure-related data to generate screening-level risk assessments for regulatory decisionmaking

under TSCA section 5. The reporting obligation and the phrase “site use” applies to all nonexempt substances produced for commercial purposes that are on the TSCA Inventory.

Some of the commenters have misunderstood this data element, which provides more detailed and clearer information than did the previous site-limited check box. Previously, submitters checked a box to indicate that a reported chemical substance was site limited – in other words, that it was both manufactured and used on the site. Some submitters misreported, identifying an imported chemical substance as site-limited (a situation that is not possible because the imported chemical substance, by definition, is brought onto the site from outside of the United States, and therefore is not physically manufactured and used at the reporting site) or reporting the same substance twice, once for the volume that is site limited and once for the volume that is sent off site. Because of this confusion, EPA replaced the site-limited check box with reporting the volume of the chemical substance production volume reported on the form that is used on the site. For example, if 50,000 lb of a chemical substance was manufactured and used on the same site, the submitter would report 50,000 lb for domestically manufactured and 50,000 lb for the volume used on-site. If 70,000 lb of a chemical substance was manufactured, 25,000 lb was used on-site and 45,000 lb was shipped to a different site, the submitter would report 70,000 lb for domestically manufactured and 25,000 lb for the volume used on-site. If a site imported 30,000 lb and used it at the import site, the submitter would report 30,000 lb for imported production volume and 30,000 lb for the volume used on-site. If a site imported 100,000 lb and shipped it to an alternate site, the submitter would report 100,000 lb for imported production volume and 0 lb for the volume used on-site.

As these examples illustrate, the submitter is not identifying the amount of a chemical substance on-site during a particular time period, but rather that amount of a chemical substance that is manufactured (including imported) and used at the same site.

Commenters also asked for clarification regarding the activities considered to be “used at the reporting site.” For a domestically manufactured substance, if the volume would have been considered to be site-limited, then the chemical substance is used on site. If the chemical substance is domestically manufactured, temporarily stored, and then packaged for shipment off of the site, that volume would not be considered “used at the reporting site.” For an imported substance, any use at the importing site (e.g., consumed in a reaction or cross-linked or cured in an article) would be considered “used at the reporting site.”

EPA does not believe reporting the portion of the production volume that is both manufactured and used on site will result in duplicative reporting. Even with the previous site-limited check box, submitters provided information about the use of a chemical substance in both the manufacturing and industrial processing and use sections of the Form U. The information reported under the manufacturing section identifies that this substance is processed or used at that particular site and reports the number of workers associated with the manufacture of that substance. In the same report, the information reported under the industrial processing and use section provides more details about how the chemical substance is processed or use and, in the event that a substance has a use identified by the same combination of use, function, and NAICS code by another site, the production volumes, sites, and workers would be combined with the information describing the other sites’ processing or uses.

c. Report volume exported. The majority of the comments against reporting the volume directly exported stated that capturing the volumes for each chemical substance in each exported product was difficult and burdensome. These comments indicated a misunderstanding of the reporting requirement, and EPA believes that a better understanding will eliminate those concerns. For the chemical substance that was manufactured and is being reported, the submitter is to report the volume of that chemical substance that is directly exported. If the chemical substance is processed in any way (e.g., combined with other chemical substances to form a mixture), the chemical substance is not directly exported. Also, if a chemical substance is sent to a distributor who then exports it, the chemical substance is not directly exported. In both of these examples, the manufacturer would instead report either the processing to form a mixture or the transfer to a distributor under the processing and use portion of the IUR reporting form. “Directly Exported” and “Domestically Processed or Used” are mutually exclusive designations; only one designation applies to any particular portion of the production volume.

6. Identify whether a chemical substance is to be recycled, remanufactured, reprocessed, reused, or reworked. EPA received several comments on the proposal to add a checkbox indicating whether a manufactured chemical substance was or is expected to be recycled, including remanufactured, reprocessed, reused, or reworked. Some commenters were supportive of adding this reporting element, but several of the commenters were concerned that the term “recycle” has been difficult to define in other programs, indicated confusion about EPA’s purpose in including the checkbox, and expressed doubt that this data element would yield useful information.

EPA intends that this checkbox would be used by manufacturers to indicate whether a chemical substance they manufactured, such as a byproduct, which might otherwise be disposed of as waste, was or is expected to be recycled. EPA also included the terms remanufactured, reprocessed, reused, or reworked, intending to capture a broad array of similar, and perhaps synonymous, activities by which a substance (that would otherwise be disposed of as waste) may be put to use. EPA is interested in the exposures from these activities, and believes that having more information about which chemical substances are being recycled will help the Agency to refine future IUR reporting requirements (e.g., if EPA knows enough about exposures to a chemical substance from an on-site recycling use, EPA could consider an exemption in the future).

EPA also believes that this information would help the Agency to identify where this activity is already occurring, and could be used to recognize companies, industries, and sectors that are using “green” practices. This information would also help to identify sectors where recycling is not occurring, providing useful data to measure the effectiveness of various EPA programs, such as the Resource Conservation Challenge (RCC) Program, and informing other Agency efforts to encourage practices that reduce waste. EPA disagrees that a precise definition of “recycle” is needed to make this data element useful for the purposes that EPA has identified. Submitters should simply indicate, to the extent that they know or can reasonably ascertain, whether the reported volume of the chemical substance that they manufactured, which would otherwise be disposed of as waste, was or is expected to be recycled, remanufactured, reprocessed, or reused, as those terms are understood by the submitter.

One commenter indicated that many chemical substances are “reworked” in many industrial processes, at least at some point, so this box would be checked so often that it would provide little meaningful data. EPA agrees that the term may be interpreted and applied too broadly to provide the type of information that EPA is trying to collect, so has removed “reworked” from the list of recycling synonyms. Two commenters expressed concern that revealing whether a chemical substance they manufactured was recycled would reveal CBI. In such a situation, the submitter will be able to claim the information as confidential. Another commenter suggested that EPA collect information about recycling under a separate rulemaking. EPA disagrees that this would be an efficient way to collect the desired information. A separate rulemaking for one “yes or no” data element would be extremely inefficient and needlessly time-consuming for both the Agency and industry, particularly when the IUR rule already provides a suitable vehicle to collect chemical substance manufacturing, processing, and use information.

7. Industrial processing and use information--a. Industrial function categories.

The Agency received several comments regarding revising the list of industrial function categories for processing and use information. Some commenters were in favor of the changes and supported EPA’s efforts to work collaboratively with Canada to align the categories. Other commenters said that this would require additional effort by the regulated community to assign the new codes, and a clear explanation of the changes with the reporting instructions, e.g., a “read across” of old and new codes, including additional definitions to ensure that activities are consistently coded across companies. Commenters stated that providing a description for “other” will be challenging, may not provide useful information (e.g., due to lack of information from the downstream

customers), and would require additional burden to report. One commenter felt that the list of Industrial Function Category (IFC) codes is too limited for inorganic chemical substances, and suggested that the Agency add an IFC code for “Solid Manufacturing Materials.” The comment stated that such a code would alleviate the need to address many industrial uses in the "other" category, thereby reducing reporting burden.

EPA agrees with the commenters that a table indicating the relationship between the 2006 IFC codes and the new 2012 IFC codes would be useful, along with clear definitions for each code. Such information is contained in the 2012 IUR Instructions document (Ref 7).

EPA also recognizes that the requirement to report a description when the submitter selects the IFC code “Other” may be more burdensome than for the other IFC codes, but expects any increase to be minor. The descriptive information is essential to enable users of the data to estimate potential exposures associated with the overall processing or use of the chemical substance, of which the function is an important component. The Agency’s experience with the 2006 IUR data was that the category of “Other,” with no further description, was insufficient for the data to be of much use.

EPA disagrees with the suggestion to include a “Solid Manufacturing Materials” IFC code and believes such a code will not accurately describe the industrial function of the chemical substance. In addition, EPA believes the proposed list of IFC codes covers the majority of the industrial functions. This belief is based on the past experience of both the U.S. 2006 IUR and Canadian reporting. However, EPA does recognize that it did not collect such information for inorganic chemical substances in the past, and therefore will

use the written description for “Other” to help evaluate and improve the inclusiveness of future IFC codes, including those applicable to inorganic chemical substances.

b. *IS codes*. EPA proposed to replace the 5-digit NAICS code with a new code, Industrial Sector (IS), to describe the industrial setting. Some commenters were in favor of this change, noting that using code harmonized with Canadian codes would be helpful to both industry and data users. Other commenters stated that many companies have already begun the process of data collection based on the former system, which has precedent. The commenters believe NAICS codes are the classification system with which industry and regulators are most familiar, and in some cases, the IS codes are less descriptive than the NAICS codes. Commenters also asserted that the Agency should recognize that these changes will result in increased reporting burden and time.

EPA disagrees with the commenters that the use of IS codes in place of the NAICS codes will present increased burden on industry. The IS codes simply group together similar NAICS codes while still providing the sufficient differentiation needed to differentiate overall industrial processing and use scenarios. The IS codes span the entire range of NAICS codes and can be translated from known NAICS codes. Both the e-CDRweb reporting tool and the 2012 IUR Instructions document (Ref. 7) contain cross-walk tables for submitters to use to determine the proper IS code, based on the NAICS code information they may already have collected.

Information on the Agency’s development of the IS codes is described in the technical support document “Inventory Update Reporting (IUR) Technical Support Document -- Replacement of 5-digit NAICS Codes with Industrial Sector (IS) Codes” (Ref. 16). In developing the IS codes, EPA considered the level of detail required for

developing use and exposure scenarios, the number of 2006 IUR submissions using the code, the code definition, and the level of difficulty required in reporting more detailed codes. Submissions to the 2006 IUR reported over 340 unique 5-digit NAICS codes. In the 2006 IUR, the three-code combination of processing and use (P/U) code, NAICS code, and IFC codes resulted in a large number of possible exposure scenarios that could be reported. Although not all of the NAICS codes are applicable to chemical substance manufacturing and processing, the 2006 IUR database has over 2,300 unique combinations of P/U, NAICS, and IFC. Many of the NAICS codes reported are from similar industries that would have similar exposure scenarios.

EPA agrees that the new IS codes are less descriptive than NAICS codes, but believes the reduction in specificity will not adversely affect, and will actually improve, the Agency's ability to use the processing and use data for screening-level purposes. The large number of unique combinations increases the difficulty and time required to sort and classify chemical substances since EPA would either need to develop exposure scenarios for each unique combination or determine which three-code combinations have similar exposure scenarios and can be grouped together. By replacing the NAICS codes with the IS code, the number of potential three-code combinations is reduced from in excess of 100,000 possible combinations to 7,920 combinations. Based on information collected from the last reporting cycle the number of combinations actually reported would be significantly less. Additionally, the IS codes will more closely align to the EU Sector of Use codes which will allow EPA to compare U.S. data with that collected by the European Union.

8. *Consumer and commercial use--a. Consumer and commercial product categories.* Many commenters supported revising the list of consumer and commercial product categories for consumer and commercial use information. Those commenters stated that harmonizing codes with Canada, revising the product categories, and requiring descriptive information when the “Other” category is reported are essential to improving the consumer and commercial data. The commenters stated also that these changes will provide a better understanding of how chemical substances are used in downstream products and will help facilitate consistent reporting of chemical substance use information in the United States and Canada. Other commenters wanted more explanation as to why the categories are being revised and requested that the Agency provide more descriptive information for each product category, including a table identifying how the new categories relate to the previous categories. Some commenters stated that providing a description for the category “Other” will be challenging and may not provide useful information. One commenter stated that the Agency should not further complicated downstream reporting, noting that was already challenging to choose the top ten categories for substances with a large number of uses.

EPA appreciates the support for the harmonized consumer and commercial product categories, and agrees that the changes finalized in this rule will improve the IUR data. As described in Unit III.G.8.a., information from data collected during the 2006 IUR and from Canada was used to develop a more useable listing of product categories. EPA eliminated categories for which few chemical substances were reported, added categories identified as needed, and eliminated overlap in categories. In addition, some categories were renamed to better match their definitions, other categories descriptors

were improved, and categories were grouped to allow for easier identification. EPA believes these changes will make reporting easier for the submitter, and does not agree that these changes result in more complicated reporting. The Agency is providing more detailed descriptive information in the 2012 IUR Instructions document (Ref. 7) and other guidance materials.

EPA recognizes that the requirement to report a description when the submitter selects the product code “Other” may be more burdensome than for the other product codes, but expects any increase to be minor. The descriptive information is essential to enable users of the data to estimate potential exposures associated with the consumer or commercial use of the chemical substance. The Agency’s experience with the 2006 IUR data was that the category of “Other,” with no further description, was insufficient for the data to be of much use.

b. *Designation of consumer or commercial use.* Commenters had mixed viewpoints regarding the need to designate whether the indicated product category is consumer use, commercial use, or both. One commenter strongly in support of making this designation stated that such distinctions are critical to EPA’s ability to assess exposure at even the most basic level. Others did not oppose the added designation, but did ask for further clarification between consumer and commercial uses. Commenters opposing the added designation stated that they were too removed from the consumer and commercial uses to have a clear understanding of the uses at that level of distinction, especially for commodity chemical substances with a large number of uses. One commenter said suppliers to formulated products were less likely to know the distinction because of the confidentiality of the downstream user formulations.

The intent of the consumer and commercial use data element is to clearly identify the exposed populations. These two populations (i.e., consumers and commercial workers) are very different from each other, and the ability to distinguish uses between the two enables better exposure-based screening of chemical substances. EPA recognizes that submitters may not always have detailed information about how the chemical substance(s) they make are used and to what extent they are used. However, EPA believes a manufacturer generally has a certain awareness of the downstream uses of chemical substances it manufactures and sells, even if it does not control its customers' sites, and can report this information, based on what is known to or reasonably ascertainable by the submitter.

c. Number of commercial workers. Commenters strongly opposed EPA's proposal to require that submitters report the number of commercial workers reasonably likely to be exposed while using a product containing a reportable substance. Most commenters indicated that they do not have sufficient information about the work practices of eventual commercial users to estimate this number, that such information is not typically shared upstream, and that any such data EPA received would be, at best, an educated guess. It was suggested that the Agency rely on worker statistics from the Bureau of Labor Statistics as it conducts risk assessments, or gather additional data under a separate TSCA section 8(a) rule.

EPA is requiring this information to better assess the size of the commercial population in screening risk assessments. In the past, the Agency has used the Bureau of Labor Statistics for general workers statistics to conduct chemical-specific risk assessments; however, these worker statistics, which are industry-specific, overestimate

the exposures associated with a chemical substance because a chemical substance is likely to be used by only a portion of the industry. Identifying chemical-specific worker populations for downstream activities will fill this gap for the Agency. The knowledge of a chemical substance's uses in industry and the respective commercial population potentially affected by their uses provides the Agency a more complete picture of the potential risks associated with a chemical substance.

EPA recognizes that submitters may not always have detailed information about how the chemical substance(s) they manufacture are used and to what extent they are used in commercial enterprises. However, EPA believes that a manufacturer generally has a certain awareness of downstream uses of chemical substances it manufactures and sells, even if it does not control its customers' sites. Based on its experience with the PMN program, many stakeholder meetings, discussions about voluntary risk management programs, and industry's various self-regulation initiatives, the Agency believes that most submitters can report on downstream uses, including the information that would be reported under IUR, based on what is known to or reasonably ascertainable by the submitter. To reduce the burden in reporting, the IUR provides that the number of commercial workers need only be reported in ranges, and the ranges are the same as for manufacturing and industrial workers. Reporting in ranges will lessen the reporting burden when the precise number of workers for multiple end uses is not known. Although this may result in some uncertainty in the data reported, the chemical substance manufacturer or importer has fulfilled his obligation by providing information to the extent it is known or reasonably ascertainable. EPA believes that the data will be

sufficiently reliable for the Agency and others to use for screening-level risk assessments and prioritization.

E. Definitions and Clarification Requests

1. *Changing the reporting standard for processing and use information to “known to or reasonably ascertainable.”* A number of commenters requested further clarification (beyond that offered in section 4.0 of the Instructions document (Ref. 7)) of the scope of pre-reporting inquiry that would be required under the “known to or reasonably ascertainable by” reporting standard. Specifically, the commenters requested further clarification of how this reporting standard would apply in the case of information reported under 40 CFR 711.15(b)(4) (“specific information related to processing and use”). The commenters also expressed some confusion about how this standard would differ from the “readily obtainable” standard, previously applicable to such reporting, and whether the change of standard indicates that “extensive file searches and customer surveys” would now be expected of submitters. Other commenters from the chemical industry expressed their understanding that the change in reporting standard only altered the level of diligence with which submitters must search for information within their own organization. They requested confirmation that, as under the “not readily obtainable” standard, submitters would not be required to conduct customer surveys in order to assemble data for purposes of IUR.

The term *known to or reasonably ascertainable by* is defined at 40 CFR 704.3. It 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.” By contrast, “readily obtainable” information does not even cover all the information in a

submitter's possession or control. As defined for the 2006 IUR, it was limited to what was known by certain "management and supervisory employees of the submitter" (Ref. 4, p. 879).

Under the "known to" portion of the "known to or reasonably ascertainable by" standard, a submitter would therefore ascertain what it knows about the processing and use of a chemical substance it manufactures (including imports), without confining its inquiry solely to what is known to managerial and supervisory employees, but would also be expected to review other information which the manufacturer (including importer) may have in its possession. In response to comments regarding the level of diligence with which submitters must search for information within their organization, this standard requires that submitters conduct a reasonable inquiry within the full scope of their organization (not just the information known to managerial or supervisory employees). The inquiry would be as extensive as a reasonable person, similarly situated, might be expected to perform within the organization. Information derived from customer surveys or other customer contacts, like any other information, would be "known to" the submitter if it is available after a reasonable inquiry within the organization. The standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees.

EPA agrees that further clarification would be useful regarding what is "reasonably ascertainable" to submitters about processing and use information because this component of the reporting standard potentially may require submitters to obtain information previously unknown to them, for the purposes of reporting. This circumstance could arise if a submitter knows less than that what is reasonably

ascertainable to it. EPA is therefore offering the following further guidance regarding the interpretation of this term.

For many of the reasons identified by industry commenters (e.g., the expense and burden of surveying customers, and uncertainty as to the extent to which customers will respond to such surveys), EPA agrees that if particular information cannot be derived or reasonably estimated without conducting further customer surveys (i.e., without sending a comprehensive set of identical questions to multiple customers), it would not be “reasonably ascertainable” to the submitter. Thus there is not a need to conduct new customer surveys for purposes of the IUR. However, to the extent that customer surveys are already in the submitter’s possession or control, and to the extent that reasonable efforts to locate or analyze those surveys may result in additional processing and use information (or reasonable estimates of such information), the information is generally “reasonably ascertainable.” Also, as illustrated by the examples in Unit III.H., inquiry under the “reasonably ascertainable” standard may entail inquiries outside the organization to fill gaps in the submitter’s knowledge. Further examples of actions that would meet the “known to or reasonably ascertainable by” reporting standard are provided in Unit III.H.

A number of commenters objected to the “known to or reasonably ascertainable by” standard on the grounds that it was subjective or too vague to be appropriately applied to the collection of processing and use information outside of the submitter’s direct control. Other commenters objected to the standard’s reference to what a reasonable person similarly situated “might” be expected to possess, control, or know.

They suggested that the standard be amended to what a reasonable person “should” be expected to know.

EPA does not agree that the “known to or reasonably ascertainable” standard is subjective or excessively vague. The standard is set forth in EPA’s statutory authority to collect information under TSCA section 8(a), and EPA’s definition is consistent with Congressional intent to establish an objective standard: “The conferees intend that the ‘reasonably ascertainable’ standard be an objective rather than a subjective one. Thus, the manufacturer or processor must provide information of which a reasonable person similarly situated might be expected to have knowledge” (Ref. 23, p. 80). Thus, whether a particular level of diligence meets this standard does not depend on the submitter’s subjective view of what seems a reasonable person “should” be expected to know. It turns on an objective question: The level of diligence that a reasonable person, similarly situated, might expect to undertake. EPA believes it is appropriate to define the standard consistently for all persons reporting under TSCA section 8(a), and that the existing definition appropriately reflects Congressional intent. Finally, EPA does not think the standard of objective reasonableness will be unfamiliar to submitters. It is included into a wide variety of legal standards under State and Federal law, and in the 2006 IUR it applied to all aspects of the information collection other than processing and use information.

2. Clarifications to byproduct reporting--a. Concern that new byproduct reporting requirements are being added. In general, some commenters asserted that EPA’s explanation of the IUR byproduct-related reporting requirements reflect new requirements, inconsistent with current byproduct exemptions.

EPA is clarifying, not enlarging, the reporting requirements for byproducts, which have been in place for decades. The definitions of *byproduct* and *manufacture for commercial purposes* (referencing byproducts) at 40 CFR 704.3 have been in place since 1983 (Ref. 24), and have been applicable to the IUR since the IUR's inception in 1986 (Ref. 3, p. 21447 (incorporating definitions from 40 CFR 704.3)). The reporting exemptions for byproducts at 40 CFR 720.30(g) and (h) (cross-referenced at 40 CFR 711.10) have also been in place since 1983 (Ref. 25), and have also been applicable to the IUR since the IUR's inception (Ref. 3, p. 21447). While this final rule is modifying the definition of *manufacture*, the pertinent portion of the revised definition (providing that manufacture includes "the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances") is consolidated from materially identical language found in the previously applicable definitions of *manufacture* and *manufacturer* at 40 CFR 704.3. This specification of the scope of "manufacture" has been in force for IUR purposes since 1988. (See Ref. 3, p. 21447 (1986 incorporation of definitions from 40 CFR 704.3 into the IUR) and Ref. 26, p. 51716 (1988 revision to 40 CFR 704.3)).

In 1983, EPA promulgated a rule that made clear (for subsequent IUR and PMN purposes) that the reporting exemption for the manufacture of byproducts is only potentially applicable to the manufacture of the byproduct and would in no case apply to the manufacture of component substances extracted from the byproduct. 40 CFR 720.30(g)(3). Furthermore, it has been the Agency's position since at least 1991 that, in order for byproduct manufacture to qualify for the 40 CFR 720.30(g)(3) exemption, "the component to be extracted must be already existing as a distinct chemical substance in

the waste stream” (Ref.27). When the chemical substance present in the byproduct and the chemical substance extracted from the byproduct are distinct chemical substances, neither the manufacture of the byproduct nor the manufacture of the extracted chemical substance qualify for the 40 CFR 720.30(g)(3) exemption. See also the discussion in Unit IV.2. The guidance docketed with this final rule, which explains existing byproducts reporting requirements under the IUR, is consistent with past guidance issued in connection with the IUR and TSCA New Chemicals Program. For example: In a 2002 response to public comments on a previous proposed amendment to the TSCA Inventory Update Rule (Ref. 4), EPA explained that “distillation, extraction, refining, and similar activities may result in the manufacture of a chemical substance.” In a 2006 letter to the Aluminum Association, EPA described a circumstance in which the extraction of aluminum from aluminum dross byproduct constituted the reportable manufacture of aluminum, while cautioning that if the aluminum is “chemically changed during the extraction process,” then not only the extracted aluminum but also the dross byproduct would be reportable under the IUR (Ref. 28). In 2008, EPA provided similar guidance by letter to the Association Connecting Electronics Industries (IPC), another trade group (Ref. 29).

Due to the 2003 expansion of the IUR reporting requirements to inorganic chemical substances, many companies have recently become aware of their status as chemical substance manufacturers when they recycle their waste materials. Instead of disposing of those waste materials, the manufacturers return them to commerce by recycling the materials – either themselves or through a third party. Recycling may be beneficial for many reasons: It conserves resources, may reduce the expense of

purchasing new raw or starting materials, may reduce the reliance of the United States on foreign suppliers of raw materials, reduces the need for landfill or other disposal sites, and returns a waste to commerce. However, many recycling activities fit the TSCA and IUR rule definition of *manufacture*, and are likely to be considered “manufacture for a commercial purpose.” EPA has finalized the draft IUR guidance documents that were published with the proposed rule. These documents include examples of many common manufacturing scenarios to assist individuals in determining whether their company is manufacturing a chemical substance that needs to be reported under the IUR (Refs. 7 and 30).

b. *Concerns about the IUR byproduct reporting requirements, in relation to RCRA and the Toxics Release Inventory.* Some commenters asserted that byproducts should be regulated, if at all, under RCRA and/or reported under TRI, and should not be subject to IUR reporting requirements. One commenter suggested that EPA revisit the entire issue of the management of recycled materials to determine the appropriate roles for the TSCA and RCRA programs. Some commenters also asserted that reporting under IUR presents a disincentive for recycling.

In broad terms, the purpose of TSCA sections 8 (governing the IUR) and 5 (governing PMN reporting) is to understand the universe of chemical substances in commerce in the United States. (TSCA section 5 also provides EPA with the ability to control for risks of new chemical substances before they are placed into commerce.) The IUR requires reporting of manufacture, processing, and use information for chemical substances in commerce, and exemptions exist for those substances or manufacturing activities for which EPA has a low current interest. With limited exception, such as those

included in 40 CFR 720.30, all chemical substances in commerce in the United States are to be listed on the TSCA Inventory; companies can trigger the addition of a chemical substance to the TSCA Inventory by filing a PMN and meeting certain other requirements.

RCRA is focused on waste – it is concerned with the generation, transportation, treatment, storage, and disposal of hazardous wastes and the management of non-hazardous solid wastes. RCRA is also focused on waste minimization, phasing out land disposal of hazardous waste, corrective action for releases, and recycling. EPA notes that while RCRA or other statutes may exempt a certain chemical substance from reporting requirements based on certain treatments or disposals, RCRA exemptions in most cases are not relevant to TSCA reporting obligations. It is important to note that finding a commercial use for a substance previously treated as a waste under RCRA can relieve the manufacturer of that substance from some RCRA requirements, but may then subject that manufacturer to TSCA reporting requirements. Also note that 40 CFR 720.30(g) provides IUR exemptions for certain uses of byproducts. In certain circumstances, reporting under both RCRA and TSCA may be required. As noted earlier, the purposes for reporting under RCRA and the TSCA IUR are different, and therefore the required data sets are different. While the data sets are not duplicative, EPA recognizes that there may be limited circumstances where particular elements of the data sets overlap. EPA strives to reduce such overlap, while ensuring that it is administratively feasible to collect and collate the data that are needed for TSCA purposes. The TSCA program is continuing its work with the RCRA program to maintain coordination between the two programs. It is important to note that the application of RCRA regulations varies state-by-state, and

recent changes to RCRA regulations have not been adopted by all states. Therefore the overlap between RCRA reporting and IUR reporting may vary depending upon the state in which a submitter's site is located.

A similar situation exists for some sites that meet the requirements to report under both TRI and IUR. The TRI program goal is to provide communities with information about toxic chemical substance releases and waste management, and the TRI reporting requirements are designed to address that goal. Because the IUR program goals differ, the specific information collected under each program is not the same. Where a person must report for both for the same site, EPA and the public will have a broader picture of the exposure scenarios at that site, including environmental releases from that site; while the two information collections may be complementary, neither is an adequate substitute for the other. A more in-depth discussion is provided in the Responses to Comments document (Ref. 12).

EPA believes that commenters' concern that reporting under IUR would be a disincentive to recycle reflects certain misunderstandings of the IUR requirements. The Agency expects that revised byproduct guidance materials, as well as EPA's responses to the comments concerning, for instance, byproduct chemical identification requirements, will help to alleviate the majority of those concerns. EPA believes that many factors play into whether a company chooses to recycle, including the value of the recovered materials, the expense of disposal, desire to maintain or build a "green" reputation, technical limitations or flexibility, state and local requirements or incentives, and the incentives offered or requirements imposed by other federal laws (such as RCRA). EPA strongly believes that the benefits of recycling usually outweigh the burden associated

with IUR reporting for these materials, and, just as with any other chemical substance whose manufacture must be reported under the IUR, production volume, worker exposure and other IUR data collected on byproduct chemical substances support the Agency's mandate to protect human health and the environment.

c. Concerns about how to identify the byproduct chemical substance and with reporting both the byproduct and a chemical substance extracted from the byproduct.

Commenters stated that it is very difficult to identify the chemical substances in a byproduct mixture, and that the mixture can vary over time, depending upon the specific manufacturing situation. Commenters also argued that there would be duplicative reporting by the byproduct manufacturer and the recycler/processor who extracted a component chemical substance from the byproduct mixture.

The comments reflect a misperception that characterizing the identity of complex chemical substances, as are found in or comprise many byproducts, necessarily involves a detailed analysis of the "individual components of the chemical substance." In reality, a byproduct may be listed on the TSCA Inventory as a single chemical substance that represents, for TSCA purposes, what may be a complex composition of chemical substances. In this way, the chemical identity of a byproduct may represent a chemical substance process stream. Complex chemical substances are listed (or can be listed) on the TSCA Inventory as chemical substances of Unknown or Variable composition, Complex reaction products and Biological materials ("UVCB" chemical substances). As described by the commenters, the byproduct "mixture" is often complex and varies over time, making the identification of the individual components a very difficult task. This description itself indicates that the proper identification of such a reaction product is as a

UVCB chemical substance. As stated in EPA's on-line guidance, "Each combination of substances resulting from a reaction is considered by the Agency to be either (1) a mixture, composed of two or more well-defined chemical substances to be named and listed separately, or (2) a reaction product, to be listed as a single chemical substance, using one name that collectively describes the products, or, failing that, the reactants used to make the products." (See <http://www.epa.gov/oppt/newchems/pubs/rxnprods.txt>.) Situations may exist where the byproduct substance is actually a mixture, but as further described in the aforementioned guidance, "A combination of products resulting from a chemical reaction is considered a mixture provided that all of the component product substances are unambiguously identified and are represented as forming each time the reaction is run."

UVCB chemical substances in some cases include a TSCA Inventory definition to further describe the chemical substance. Here is one example from EPA's on-line guidance (see <http://www.epa.gov/oppt/newchems/pubs/uvcb.txt>):

Dust, iron-ore, sinter

CASRN 69012-53-9

Definition: Dust generated during the making, breaking and handling of sinter which is recovered through the use of pollution abatement equipment.

A byproduct manufacturer, therefore, would potentially report the UVCB name for the byproduct composition, while the subsequent recycler of the byproduct would potentially report the specific chemical identity of the chemical substance they chemically manufacture from the byproduct. EPA does not agree that such reporting is

duplicative, because reporting will fall into one of following two scenarios. If the chemical substance manufactured from the UVCB byproduct is already present as a constituent of the UVCB byproduct, then the byproduct manufacturer need not report the byproduct that is sent for such processing/recycling. If the chemical substance manufactured from the UVCB byproduct is distinct from any chemical substance present in the UVCB byproduct as a constituent, then the separate reporting by the byproduct manufacturer and the processor/recycler reflects a change in chemical composition. Either way, there is no duplication of reporting between the manufacturer of the UVCB byproduct and the processor/recycler. As a general matter, if there is to be appropriate stewardship of potential chemical substance risks, EPA believes that chemical substance manufacturers, processors, and users should know and understand the identities of chemical substances they handle.

Some commenters stated that many byproduct mixtures in the metals industry are processed to recover the metal values and indicated that the metal value should be considered a component chemical substance (i.e., that if Nickel (II) hydroxide ($\text{Ni}(\text{OH})_2$) is present in a byproduct mixture, then the elemental substance Nickel (Ni) should be considered the component chemical substance). EPA disagrees with this statement. (See Ref. 27 for a precedent from a 1991 prenotice communication.) Under TSCA, $\text{Ni}(\text{OH})_2$ and elemental Ni are two different chemical substances, with separate listings on the TSCA Inventory. If the byproduct contains $\text{Ni}(\text{OH})_2$ but not elemental Ni, only $\text{Ni}(\text{OH})_2$ is considered a component chemical substance of the byproduct. The manufacture of elemental Ni from either the $\text{Ni}(\text{OH})_2$ – bearing byproduct (or $\text{Ni}(\text{OH})_2$ itself) results in a potential need to report under IUR. That is, if the extracted component substance is an

oxide and used as an intermediate to form an elemental metal, then both the oxide and elemental metal are subject to reporting by their manufacturer(s). Note that information pertaining to manufacture of a chemical substance need only be reported to the extent that the information is known to or reasonably ascertainable by the submitter.

A second example of a metal-containing byproduct is:

Electrolytes, copper-manufg., spent

CASRN 69012-54-0

Definition: Spent copper sulfate electrolyte consisting of copper sulfate and sulfuric acid resulting from the electrolytic refining of copper.

This spent material is a UVCB chemical substance that is likely to be recycled. If the only commercial purpose for this spent material is to extract the component chemical substance copper sulfate, then the manufacture of the spent material is exempted from reporting (but the manufacture of the copper sulfate [via extraction from the byproduct] is subject to reporting). On the other hand, if the spent material is used directly to manufacture elemental copper, then both the spent material and the elemental copper are subject to reporting under the IUR by their respective manufacturers, because elemental copper is not a component chemical substance in the spent material byproduct.

d. Concerns regarding determining when a byproduct is manufactured.

Commenters stated that clarification is needed regarding purification and extraction and when a chemical substance is considered manufactured versus purified. Commenters asserted that where there is no change in chemical identity, only a change in purity, a

chemical substance should not be considered manufactured, regardless of the method of purification.

Much of the commenters' confusion regarding the differences between purification and extraction appears to concern whether extraction or purification involves a change in chemical identity; the potential for a change in chemical identity is closely linked with the proper identification of the manufactured substance, as described in the previous comment response. Where there is no change in chemical identity but rather just a change in purity (an impure chemical substance correctly identified for TSCA purposes as "chemical substance A," for example, undergoing purification to a more pure form of "chemical substance A"), the Agency agrees with the commenter that, for purposes of IUR, the chemical substance is not being manufactured. The chemical substance that appears on the TSCA Inventory may actually represent a category consisting of the same chemical substance in various degrees of purity. For example, if a company manufactures a specific, discrete chemical substance at 90% purity and it is correctly identified as that discrete substance (not having a UVCB name), then increasing the purity of the chemical substance (such that it retains its chemical identity) is considered purification and, for purposes of IUR, such purification is not considered manufacture.

Note, however, that the extraction of component chemical substances from certain complex byproduct mixtures or process streams (i.e., UVCB chemical substances), is not considered purification, because the complex byproduct mixture and the extracted substance do not have the same chemical identity. For example, a manufacturing process involving the use of solvent A results in the manufacture of a spent solvent. As a variable, complex mixture of solvent A, finished product, unreacted reactants, individual

byproduct substances, and other impurities, the spent solvent is considered to be a UVCB chemical substance. It is not unusual for the manufacturer to extract solvent A from this UVCB chemical substance. In such a case, the extracted solvent A is considered to be manufactured, and therefore is reportable for purposes of IUR. When the spent solvent is a byproduct whose only commercial purpose is the extraction of a component chemical substance, solvent A, the byproduct exemption at 40 CFR 720.30(g)(3) can be applied and the spent solvent byproduct does not need to be reported. The extracted solvent A is nevertheless reportable for purposes of IUR.

3. *Definitions of “manufacture” and “manufacturer.”* EPA received several comments on the definition of *manufacture*, asserting that the definition of *manufacture* included in the proposed rule was inconsistent with past definitions, over-broad, and confusing.

EPA disagrees, except with respect to minor typographical errors noted in this unit. EPA consolidated existing definitions into a single *manufacture* definition to reduce confusion. EPA also added a very short clarifying definition that “a manufacturer is a person who manufactures a chemical substance,” to direct the reader to the relevant language in the definition of *manufacture*, and to avoid confusion with an existing definition of *manufacturer* in 40 CFR 704.3. The definition of *manufacture* is consistent with established regulatory and statutory definitions, and is sufficiently flexible to accommodate the actual allocation of knowledge between toll manufacturers and contracting companies. EPA has separately addressed the comments received relating to the extraction of component chemical substances. (See the discussion on reporting byproducts and recycling in this unit.)

The first part of the definition of manufacture in this final rule is as follows: “Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of substances.” It is similar to the definitions of *manufacture* and *manufacturer* used for past IUR reporting (Ref. 31). For example, the definition of *manufacturer* in effect for the 2006 IUR reporting period is in 40 CFR 704.3: “Manufacturer means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance.” The two similar definitions of *manufacture* in effect for the 2006 IUR reporting period were found in 40 CFR 710.3 (“to manufacture, produce, or import for commercial purposes,” and 40 CFR 704.3 (“to manufacture for commercial purposes”). The 40 CFR part 711 definition of *manufacture* is also consistent with the established definition of *manufacturer* used for purposes of PMN reporting, at 40 CFR 720.3. Existing 40 CFR 704.3, which was not modified in this final rule, also includes a definition of *manufacture*: “Manufacture means to manufacture for commercial purposes,” and a definition of “manufacture for commercial purposes” that makes clear that byproducts produced during manufacturer are also “manufactured for a commercial purpose.”

The definition of *manufacture* in this final rule is also similar to and consistent with TSCA’s definition of *manufacture* at TSCA section 3: “‘manufacture’ means to import in the customs territory of the United States, produce, or manufacture,” and TSCA

section 8: “For purposes of this section, the term ‘manufacture’ . . . mean[s] manufacture . . . for commercial purposes.” Finally, EPA disagrees with one commenter’s suggestion that a new definition of *produce* is necessary to clarify that production involves a chemical substance that is “chemically different” from the chemical substance in the starting materials. “Chemically different” is itself an undefined term, so it would not bring additional clarity to a new definition of “produce.” Furthermore, the difference between one chemical substance and another (and hence, the question of whether a chemical substance is being produced) already has a basis in the statutory definition of *chemical substance* at TSCA section 3(2), and in the differences between the entries of the TSCA Inventory.

The second part of the definition, as noted in the preamble to the proposed rule, adds an explanation, derived from the definition of *manufacturer* in 40 CFR part 720, of the conditions under which a contract manufacturer would be considered to “manufacture,” and therefore be responsible for IUR reporting. Persons contracting with a toll manufacturer and toll manufacturers are now considered to be co-manufacturers of what is produced at the toll manufacturer’s site. Consistent with 40 CFR 711.22(c), such parties should coordinate amongst themselves to submit a single report, rather than duplicative individual reports, respecting what they have co-manufactured. The joint submission mechanism, under 40 CFR 711.15(b)(3)(i), is not available to co-manufacturers. The joint submission mechanism addresses distinct circumstances: Those in which one party is the manufacturer/importer, and a second party (not a manufacturer of the chemical substance in question) possesses confidential information needed to determine the chemical identity of what the first party has manufactured/imported. In the

final rule, EPA uses the term *co-manufactured* rather than the proposed term *jointly manufactured*. This change of terminology is intended to avoid confusion between the reporting provisions at 40 CFR 711.22(c) and those at 40 CFR 711.15(b)(3)(i).

EPA notes that one change to the definition of *manufacture* was made to correct a typographical error in the definition as proposed and to address a comment that the definition used confusing syntax. The words “and” and “then” were added to make clear that the conditions in paragraph (1), and the conditions in paragraph (2) (up to the comma), must both be satisfied before a chemical substance will be considered “co-manufactured” by the producing manufacturer (i.e., the toll manufacturer) and the person contracting for such production (i.e., the contracting company).

Several commenters suggested that the toll manufacturer should be primarily or solely responsible for IUR reporting, or expressed concern that the rule would compel contracting companies to submit information on behalf of toll manufacturers. Another commenter supported the assignment of responsibility as proposed. Some commenters also suggested that EPA should “acknowledge the complexity of contractual mechanisms and not offer a blanket, ‘one size fits all’ requirement for reporting responsibilities.”

EPA agrees that a diversity of contractual arrangements may exist, and notes that there was nothing in the proposed rule to prevent toll and contracting manufacturers from sharing information and agreeing between themselves that one or the other will undertake all or a portion of the work associated with IUR reporting for a given chemical substance, though comments indicated that there was some confusion caused by EPA’s assignment of “primary” responsibility for reporting to the contracting manufacturer (see 40 CFR 711.22(c)). EPA expects that in most instances, a person that contracts with a toll

manufacturer will generally know more about the particular chemical substances, and will usually be in a better position to report on industrial processing and use of a chemical substance, and on commercial and consumer uses of products containing the chemical substance. Similarly, EPA expects that the toll manufacturer will generally be in a better position to report on the number of workers and other information about their plant. In light of the contracting company's control over the "total amount produced and the basic technology for the plant process," and based on EPA's expectations of the relative knowledge of the contracting company, EPA initially indicated, in proposed 40 CFR 711.22(c), that the contracting company would be "primarily responsible" for IUR reporting. However, given the confusion introduced by indicating that one party or the other is "primarily" responsible for reporting, and not wishing to interfere in contractual agreements to the contrary, EPA has decided not to allocate "primary" responsibility to either party in the final rule. Conforming changes have been made to 40 CFR 711.22(c) in this final rule. However, the enforceability of the final rule requires EPA to specify the persons who are legally responsible for reporting. In fairness, EPA has chosen to make both parties responsible for reporting on the chemical substances they have co-manufactured, as specified in the proposed rule.

4. *Definition of "site."* Several commenters asserted that the proposed revision to the definition of "site" would force different companies that are at the same site to report together. EPA disagrees with this assertion. In the proposed rule, EPA added explanations to accommodate manufacturing under contract and for portable manufacturing units, and clarified that an importer's site must be a U.S. address. The definition of *site* used in the past, at 40 CFR 710.3, was not otherwise significantly

changed. The old definition states that “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. ...” This portion of the definition was retained, with slight wording change (“More than one plant may be located on a single site.”), in the proposed rule.

The statement “More than one plant may be located on a single site” is meant to guide companies that have multiple plants at one site to sum production volumes and other IUR-reportable data across all of their plants at one site and produce one report for each reportable substance at each site (not at each plant). The definition does not require different companies located at the same site to report together.

5. *Processing and use-related definitions.* EPA received comments in favor of the amended definitions for *commercial use* and *consumer use*. However, a commenter indicated that the definitions of “industrial,” “commercial,” “function,” and “use,” were unclear and referred to problems in reporting both product- and substance-level information. EPA appreciates the support for amending the terms *commercial use* and *consumer use* to harmonize the definitions developed by the United States and Canada.

EPA feels the terms “industrial” and “commercial” are adequately defined. To clarify, EPA defines *industrial function* as “the intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used.” This definition can be found in the “IUR Modifications Rule: Development of Definitions for Proposed 40 CFR 711.3” (Ref. 8). EPA also notes that the terms *use*,

industrial use, consumer use, and commercial use have already been in use for IUR and were previously defined in 40 CFR 710.43 (relocated in this final rule to 40 CFR 711.3).

F. Confidential Business Information

1. *Release of information not validly claimed as CBI.* The Agency received comments about the proposed change to make information claimed as CBI available to the public without further notice to the submitter, in the circumstance that the required substantiation is not submitted with the claim. Opponents of the change are concerned that a reporting error could result in public release of legitimate CBI. They suggested notifying the submitter if further substantiation is needed prior to releasing data to the public. The commenters are in favor of a warning system that would allow submitters time to provide additional substantiation on CBI claims before the Agency determines the data is non-CBI and releases it as public information.

There are three situations during which the Agency will release IUR information claimed as CBI without further notice to the submitter. First is the circumstance that a CBI claim is made for the identity of a chemical substance already listed on the non-confidential portion of the Master Inventory File. Any such CBI claims were invalid under the previous IUR regulations (applicable to the 2006 and earlier submission periods).

The second is the circumstance that a submission lacks the certification required under 40 CFR 711.15(b)(1). 40 CFR 711.15(b)(1) requires a certification stating that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the Form U are true and correct. The certification must be signed and dated by the authorized official for the submitter

company, and provide that person's name, official title, and e-mail address. Consistent with this regulatory provision, the e-CDRweb tool is designed to entirely block the submission of a Form U lacking an appropriate certification.

The third is the circumstance that a particular CBI claim is not accompanied by upfront substantiation required under 40 CFR 711.30(b), (c), or (d) (e.g., upfront substantiation of processing and use information). The e-CDRweb reporting tool is designed to protect against a company not providing an upfront substantiation. When a CBI claim is made and substantiation is required, the reporting tool will open the substantiation question page. Should the submitter choose not to complete the substantiation at that time, or to only partially complete it, the validation portion of the tool will again alert the submitter to the need for substantiation. The tool also includes warnings that information with unsubstantiated CBI claims will be released without further notice to the submitter. EPA believes these reminders provide sufficient notice to the submitter of the need to substantiate these claims.

2. Upfront substantiation for processing and use information. The Agency received comments both for and against the proposed upfront substantiation requirement when processing and use information is claimed as confidential. Commenters opposing the proposed change explained that processing and use information is often considered confidential by customers to protect their competitive positions in the market. Commenters voiced concern that the proposed change will impact their ability to remain competitive or will reduce innovation. These commenters were concerned that the manufacturers of the chemical substances would not correctly identify CBI associated with downstream uses, and that confidentiality agreements between the chemical

substance manufacturer and the downstream users would not provide sufficient substantiation for the processing and use information. The Agency believes that the processing and use information in the publicly released IUR reports is sufficiently agglomerated to address these concerns. However, the Agency also recognizes that there are circumstances when the release of information about a particular use could harm the competitive position of the submitter's customer. Therefore, EPA has modified the substantiation question at proposed 40 CFR 711.30(d)(1)(ii) to include information about harm to the submitter's competitive position "or to your customer's competitive position." EPA also notes that under its confidentiality regulations, the Agency normally solicits input from all affected businesses when making a final confidentiality determination respecting information claimed as CBI.

Some commenters stated that providing written explanations for multiple scenarios would be burdensome. Another commenter argued, however, that requiring such explanations will help to limit CBI claims to information that in fact warrants protection as a legitimate trade secret. The commenter asserted that the frequency with which site information was claimed as CBI dropped from 28% to 7% after EPA added an upfront substantiation requirement for that data element, and suggested that the drop represented an elimination of "excessive" trade secrecy claims.

The Agency recognizes that there is a burden associated with providing written explanations. However, based on the significant number of CBI claims for processing and use information in the last information collection, EPA believes that allowing submitters to assert CBI claims merely by checking a box encourages submitters to assert such claims without sufficiently considering whether there is a basis for the claim. While EPA

believes that such claims are appropriate under certain circumstances, the Agency wants to ensure that all such claims are carefully considered and only information that is truly confidential, the release of which would substantially injure the competitive position of the submitter, is claimed as CBI. A substantiation requirement for such claims helps ensure that this consideration takes place.

3. *Prohibition of confidentiality claims for data elements designated as “not known or reasonably ascertainable.”* Commenters agreed with prohibiting CBI claims for processing and use information when designated as “not known or reasonably ascertainable.” The primary reason cited by supporters was that the proposed change will reduce the potential for unwarranted CBI claims.

G. Administrative Comments

1. *Changes to reporting frequency.* The Agency received comments regarding the proposed change to increase the IUR reporting frequency from every 5 years to every 4 years. Some commenters suggested a change to the reporting frequency would still present a burden to industry and that EPA has not provided adequate justification to warrant or support any increase in the reporting frequency. Other commenters expressed support for the return to the reporting frequency of every 4 years but some felt that to increase the frequency further would be problematic. Additional commenters suggesting even more frequent reporting cycles and these comments are addressed in more detail in the Responses to Comments document (Ref. 12).

In the 2003 IUR Amendments, EPA changed its reporting requirement from every 4 years to every 5 years to lessen the burden associated with complying with the amendments. However, EPA has decided to return to the reporting frequency of every 4

years, in order to better meet Agency needs. EPA has determined that reporting every 5 years is too infrequent, and does not provide enough data to sufficiently cover the Agency's and public's needs. As discussed in Unit III.D.1. of the proposed rule, many chemical substances, even larger volume chemical substances, often experience wide fluctuations in manufacturing volume from year to year. This can result in the production volume of a chemical substance exceeding the threshold for several years, then falling below the threshold during the IUR principal reporting year. A review of the previous reporting under the IUR indicates an approximately 30% change in the chemical substances that are reported from one reporting period to the next. Therefore, the 1-year snapshot of production volume does not provide an accurate picture of the chemical substances in commerce, and may provide an erroneous view of the exposure scenarios associated with a particular chemical substance. In addition, EPA has been criticized for using outdated information, which will be remedied with more frequent reporting. As such, EPA has determined that the value gained through obtaining more current and useful data is essential to fulfilling the Agency's statutory obligations under TSCA, and outweighs the incremental burden to submitters.

2. *Remove superfluous text regarding production volume.* The Agency received comments on the proposal to remove superfluous text associated with reporting production volumes, in particular the +/- 10% standard of precision. All commenters opposed changing the current language. Several commenters indicated that reporting accurately to two significant figures is not equivalent to reporting to a precision of +/- 10%. One commenter indicated that, if reporting to two significant figures, at higher production volumes there would be a narrower allowable range of variation.

EPA is replacing “provided that the reported figures are within +/-10% of the actual volume” currently found in 40 CFR 710.52(c)(3)(iv) with “This amount must be reported to two significant figures of accuracy.” The phrase that was removed is superfluous because any number reported accurately to two significant figures is within 10% of the correct value. EPA recognizes some commenters’ concern that this will result in a sliding precision scale between 1% and 10% that is solely based on the reported digits. However, EPA believes that reporting to two significant figures will maintain a balance between data needs for exposure screening and the industry burden associated with data collection. In the 2006 IUR data collection, nearly all manufacturers reported production volumes in greater precision (i.e., more significant figures) than is required for 2012 reporting. Based on years of experience assessing chemical substance risks through programs such as the New Chemicals Program, the Agency believes requiring reporting to two or more significant figures is appropriate to facilitate the Agency’s initial exposure screens of chemical substances, and to prioritize and make basic risk management decisions about those chemical substances of greatest concern. Those decisions then can prompt more detailed assessments as necessary.

H. Economic Impact Estimates

1. *General burden comments.* The Agency received a number of comments expressing concerns about the Economic Analysis (Ref. 14); the majority of which suggest that the Agency has significantly underestimated the effort required to collect, organize, verify and report IUR data. Commenters disagreed with EPA’s burden estimates for several proposed modifications to the rule, including the retroactive reporting of production volumes, reporting on imported mixtures, mandatory electronic

submission, the lowering of the threshold for downstream processing and use information, the change in the standard of reporting from “readily obtainable” to “known to or reasonably ascertainable by,” and the change in the reporting cycle from every 5 to every 4 years. Several commenters asserted that the reporting burden will increase to between two and six times the burden for reporting in 2006. However, few commenters provided specific reasons for why they believe that the Agency’s estimates were low, and no commenters provided any analytical basis for revising EPA’s estimates or substantiated their alternative estimates. The Agency has used the best available data to estimate the burden associated with the modifications to the IUR rule, and disagrees with the commenters. The burden estimates presented in the economic analysis are reasonable estimates for the average IUR submitter.

a. *Identification of affected entities.* In general, commenters stated that the Economic Analysis (Ref. 14) does not identify all affected entities, and EPA has inaccurately assumed that the proposed rule will affect only chemical substance manufacturers. Another commenter noted that a wide range of industries manufacture byproducts, so to accurately estimate the burden of the proposed rule, EPA must identify all affected industries and facilities. The commenter further stated that byproducts sent for recycling are new chemical substances reportable under the IUR rule and the Economic Analysis fails to identify these manufacturers.

The Economic Analysis assumes that all companies manufacturing (including importing) chemical substances annually in amounts of 25,000 lb or greater that are listed on the TSCA Inventory will report under this rule. Chemical substance users and processors who may manufacture a byproduct chemical substance for a commercial

purpose, e.g., utilities, paper manufacturers, primary metal manufacturers, and semiconductor and other electronic component manufacturers (NAICS codes 22, 322, 331, and 3344), are considered to be chemical substance manufacturers for the purposes of the IUR rule. Sites that manufactured a byproduct in a volume above the 25,000 lb threshold during the 2006 submission period were required to report under IUR, and therefore are included in the 2006 baseline estimates.

b. *Total industry compliance determination burden.* Commenters made a number of specific points regarding the compliance determination burden. According to one commenter, provisions requiring reporting of more data for many chemical substances, replacing NAICS codes with EU IS codes, and requiring upfront substantiation for CBI claims for Part III, Form U, information will contribute to the increased effort required to report.

EPA disagrees that the Economic Analysis underestimates the reporting costs and burdens of this final rule amendments as asserted by the commenters. EPA does agree that many of the amended rule requirements, including provisions requiring reporting of more data for many chemical substances, replacing NAICS codes with Industrial Sector codes, and requiring upfront substantiation for CBI claims for Part III, Form U, information, will cause an increase in burden and cost. While EPA does state throughout the Economic Analysis that the burdens and costs may be overestimated, the analysis also says that they may be underestimated. The statements regarding limitations of the study serve to make the analysis more transparent. EPA does not have the ability to take into account the effects of individual company circumstances concerning downsizing, growth,

mergers and acquisitions, on estimates of reporting burden and cost, as mentioned by one commenter.

Several commenters asserted that EPA underestimated the burden associated with IUR compliance determination by estimating the burden on a per-report basis. According to the comments, this methodology does not capture the burden associated with tracking, screening, and keeping records for chemical substances that ultimately are not required to be reported to IUR because they are manufactured or imported in quantities below the reporting threshold.

Compliance determination occurs on a per-site basis and is based on a manufacturer (including importer) determining that it manufactures at least one chemical substance at or above the threshold, thus necessitating that the site complete and submit a Form U. The Economic Analysis assumes all sites that report to the IUR incur the same average cost for compliance determination regardless of the number of chemical substances reported. EPA expects that it is standard company practice to track and maintain records of production volumes for all chemical substances manufactured at a given site. Therefore, EPA expects that the burden associated with compliance determination should not be substantial. The commenters appear to have misinterpreted EPA's compliance determination burden to include the burden of actually reporting for the chemical substances subject to the IUR, but this is not the case. See section 4.2.2 of the Economic Analysis (Ref. 14) for further clarification.

Finally, EPA notes that the IUR does not require submitters to retain documentation showing that particular chemical substances did not need to be included in a given year's report. In addition, once a submitter has made a compliance determination

that it has reporting obligations under the IUR, it can rely on production volume information already reasonably available, in the ordinary course of business, to determine that particular chemical substances do not need to be reported under the IUR. For this reason, EPA believes it is unreasonable to attribute to the rule the costs of tracking, screening, and keeping records of the various production volumes of chemical substances that ultimately are not required to be reported to IUR because they are below the reporting threshold.

c. Underlying assumptions and data: Baseline costs. Commenters questioned the baseline number of reports EPA used in calculating baseline costs. One commenter questioned whether EPA's estimate included inorganic substances. Another commenter questioned whether EPA has adjusted the baseline estimates to account for new manufacturing facilities that never previously reported under the IUR rule, the elimination the 300,000 lb threshold for processing and use data, and the change in the method of determining the eligibility to report.

The 2006 IUR submission data provide the best estimate for the number of reports that would be submitted under the baseline scenario. The baseline scenario in the Economic Analysis assumes no changes have been made to the 2006 reporting requirements. This cost is used as a basis on which to calculate the incremental cost of the rule. Therefore, in the baseline, the number of reports should not be adjusted to account for any proposed modifications. The Economic Analysis does estimate the additional number of Part III of Form U reports that will be submitted as a result of this final rule, including the elimination of the 300,000 lb threshold (see section 4.4.4 of the Economic Analysis (Ref. 14)), as well as the additional number of reports submitted as a

result of the change in the method of determining the eligibility to report (see section 4.4.3 of the Economic Analysis (Ref. 14)). In addition, the Economic Analysis accounts for rule familiarization costs for any new companies submitting data (see section 4.2.2 of the Economic Analysis (Ref. 14)). The 2006 data do include reports for inorganic chemical substances, because while inorganic chemical substance manufacturers were exempt from submitting downstream processing and use information in the 2006 submission period, they were required to submit Parts I and II of Form U, and therefore are included in the baseline number of reports.

I. Request for Comment on Additional Issues

EPA requested comment on several additional topics in Unit V. of the proposed rule (Ref. 1, p. 49676). The comment summaries and responses to these issues are contained in the Responses to Comments document (Ref. 12).

VI. References

As indicated under **ADDRESSES**, a docket has been established for this rulemaking under docket ID number EPA-HQ-OPPT-2009-0187. The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA in developing this final rule, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Inventory Update Reporting Modifications; Proposed Rule.

Federal Register (75 FR 49656, August 13, 2010) (FRL-8833-5).

2. EPA. Inventory Reporting Regulations; Final Rule. **Federal Register** (42 FR 64572, December 23, 1977) (FRL-817-1).
3. EPA. Partial Updating of TSCA Inventory Data Base; Production and Site Reports; Final Rule. **Federal Register** (51 FR 21438, June 12, 1986) (FRL-2973-3).
4. EPA. TSCA Inventory Update Rule Amendments; Final Rule. **Federal Register** (68 FR 848, January 7, 2003) (FRL-6767-4).
5. EPA. OPPT. Enhancing EPA's Chemical Management Program. Available on-line at <http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html>.
6. EPA. TSCA Inventory Update Reporting Modifications; Submission Period Suspension; Final Rule. **Federal Register** (76 FR 27271, May 11, 2011) (FRL-8874-2).
7. EPA. Instructions for the 2012 TSCA Chemical Data Reporting. July 2011. Also available on-line at <http://www.epa.gov/cdr>.
8. EPA. OPPT. IUR Modifications Rule: Development of Definitions for Proposed 40 CFR 711.3. July 8, 2010.
9. EPA. TSCA Inventory Update Reporting Revisions; Final Rule. **Federal Register** (70 FR 75059, December 19, 2005) (FRL-7743-9).
10. EPA. OPPT. Electronic Signature Agreement. August 2009.
11. EPA/Environment Canada/Health Canada, Overview of Harmonized U.S.-Canada Industrial Function and Consumer and Commercial Product Codes for Chemical Inventory Reporting. November 2009.
12. EPA. OPPT. Summary of EPA's Responses to Public Comments Submitted in Response to Proposed TSCA Inventory Update Reporting Modifications Rule.

13. EPA. OPPT. 2006 IUR Database Statistics for the IUR Modifications Rule. December 17, 2008.
14. EPA. OPPT. Economics, Exposure and Technology Division (EETD). Economic Analysis for the Final Inventory Update Reporting (IUR) Modifications Rule. July 2011.
15. EPA. Toxic Chemical Release Inventory Reporting Forms and Instructions. October 2009. Available on-line at <http://www.epa.gov/tri/report/rfi/ry2009rfi121709.pdf>.
16. EPA. OPPT. EETD. Inventory Update Reporting (IUR) Technical Support Document -- Replacement of 5-digit NAICS Codes with Industrial Sector (IS) Codes. October 2009.
17. Environmental Defense Fund, Letter to Docket ID Number EPA-HQ-OPPT-2009-0187 (on behalf of 32 organizations), from Richard Denison, PhD, October 12, 2010.
18. Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999. Greatest Potential for Human Exposure. Canada, 2003.
19. EPA. OPPT. Screening-Level Hazard Characterization and Prioritization Document. March 2009. Available on-line at http://www.epa.gov/chemrtk/hpvis/rbp/Butenedioic%20Acid%20Dialkyl%20Esters_HBP_March%202009.pdf.
20. NOVA Chemicals, Letter to Docket ID No. EPA-HQ-OPPT-2009-0187, from Linda Santry. October 7, 2010.

21. EPA. OPPT. Initial Risk-Based Prioritization of High Production Volume (HPV) Chemicals. April 2009. Available on-line at http://www.epa.gov/chemrtk/hpvis/rbp/Category_Chlorobenzenes_Web_April%202009.pdf.
22. European Commission. REACH. January 2011. Available on-line at http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm.
23. H.R. Rep. 94-1679, 94th Congress, 2d Session (1976), reprinted in Environmental and Natural Resources Policy Division of the Library of Congress, 94th Congress, 2d Session, A Legislative History of the Toxic Substances Control Act, (Committee Print 1976) (Legislative History, pp. 667-721).
24. EPA. Recordkeeping and Reporting Requirements; Recodification; Final Rule. **Federal Register** (48 FR 23420, May 25, 1983) (FRL-2370-70).
25. EPA. Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures; Final Rule. **Federal Register** (48 FR 21722, May 13, 1983) (FRL 2998-5).
26. EPA. Comprehensive Assessment Information Rule; Final Rule. **Federal Register** (53 FR 51698, December 22, 1988) (FRL-3368-1).
27. Prenotice Communication Letter from Mary E. Cushmac, EPA. July 29, 1991.
28. Letter from Susan Sharkey, EPA, to Robert P. Strieter, The Aluminum Association. October 24, 2006.
29. Letter from Charles M. Auer, EPA, to Fern Abrams, IPC. August 27, 2008.

30. EPA. OPPT. Q&A Document: Recycling and the TSCA Chemical Substance Inventory -- Premanufacture Notification and Chemical Data Reporting Requirements. May 2011.

31. EPA. Table of Comparison of 2012 CDR v 2006 IUR Definitions. February 9, 2011.

32. EPA. Agency Information Collection Activities; Final Collection; Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports; EPA ICR No. 1884.05, OMB Control No. 2070-0162.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), this action has been designated a “significant regulatory action” by the Office of Management and Budget (OMB). Accordingly, EPA submitted this action to OMB for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA has prepared an economic analysis of the potential impacts associated with this action. A copy of this Economic Analysis (Ref. 14) is available in the docket and is briefly summarized in this unit. The Agency, in promulgating this final rule, is required under TSCA to consider the potential costs and benefits associated with IUR. The analysis was therefore used by the decisionmakers to help in the selection of the final rule requirements presented in this document.

The amendments in this final rule affect the number of reports submitted during a submission period, the burden to prepare a report, and the reporting frequency. EPA

estimates that the combined impact of all the amendments will increase the total burden and cost to industry associated with IUR reporting.

In its Economic Analysis, EPA estimated industry cost and burden on a per-report and a per-site basis and at the industry level. Industry cost and burden are incurred by performing activities to comply with the amendments, including compliance determination, rule familiarization, preparation and submission of reports, and recordkeeping.

On a per-report basis, EPA estimated incremental increases of 0.47 hours and \$118 for a site to complete a partial report for 1 chemical substance and 13.57 hours and \$1,176 to complete a full report for 1 chemical substance, in the first reporting cycle after the effective date of the final rule amendments. A partial report includes Parts I and II of Form U. A full report includes Parts I, II, and III of Form U. For future reporting cycles, EPA estimated incremental increases of 2.26 hours and \$212 for a site to complete a partial report for 1 chemical substance and 11.96 hours and \$1,012 to complete a full report for 1 chemical substance

As a result of the amendments, EPA estimates that the average site will submit approximately 0.90 and 2.01 fewer partial reports in the first reporting cycle and future reporting cycles, respectively. An increase in full reports per site of 0.89 in the first reporting period and 2.88 in future reporting periods is expected. For the average site, this will increase the burden by 121 hours during the first reporting cycle and 249 hours for all subsequent reporting cycles. EPA estimates that the average site will incur a net cost increase of \$9,000 during the first reporting cycle and \$16,551 during all future reporting cycles.

At the industry level for all sites submitting a Form U, EPA estimates a net total burden increase of 0.50 million hours in the first reporting cycle, and 1.14 million hours for all subsequent reporting cycles. EPA estimates a net cost increase of \$36.76 million in the first reporting cycle of the final rule, and \$75.12 million in all subsequent reporting cycles.

EPA estimates that the Agency will experience a reduction in both burden and cost to administer the IUR rule as a result of the amendments. Specifically, EPA expects to experience a net burden reduction of 940 hours in the first reporting cycle and 1,678 in subsequent reporting cycles. The Agency estimates it will experience a net savings of approximately \$68,000 during the first reporting cycle and \$175,000 in subsequent reporting cycles. This information will be reflected in the ICR that is submitted every 3 years to OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

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.).

B. Paperwork Reduction Act

The information collection requirements in 40 CFR part 710 related to the submission of Form Us are already approved by OMB under PRA. That ICR has been assigned EPA ICR No. 1884 and OMB control no. 2070-0162. Because this final rule involves new or revised information collection activities that require additional OMB approval, EPA has prepared an addendum to the currently approved ICR (Ref. 32). An

agency may not conduct or sponsor, and a person is not required to respond to an information collection request subject to PRA, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and included on any related collection instrument (e.g., on the form or survey).

Under PRA, the term "burden" is interpreted as the total time, effort, or financial resources expended by people to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed by regulated entities to review instructions and to develop, acquire, install, and use technology and systems to collect, validate, verify, and disclose information. Time taken to adjust existing ways to comply with any previously applicable instructions and requirements and to train personnel to respond to the information collection task is also included. In this analysis, total industry burden hours represent the sum of time spent on reporting and on other administrative activities. Industry will spend time on the following activities associated with the IUR rule: Compliance determination, rule familiarization, preparation and submission of reports, and recordkeeping.

As presented in the Economic Analysis (Ref. 14) and the addendum ICR (Ref. 32), EPA estimates that the final rule would generate a total incremental industry burden of 0.50 million hours in the first reporting cycle. The burden for a site to complete a full IUR report for one chemical substance in the first reporting cycle is estimated to be 136.57 hours, which is an incremental burden increase of 13.57 hours over the current estimated burden. The burden for a site to complete a partial IUR report for one chemical substance in the first reporting cycle is estimated to be 53.55 hours, which is an incremental burden increase of 0.47 hours over the current estimated burden. For future

reporting cycles, EPA estimates that the final rule would create a total incremental industry burden of 1.14 million hours. The burden to complete a full report is estimated to be 94.01 hours, which is an incremental increase of 11.94 hours over the current estimated future burden. The burden for a partial report is estimated to be 28.38 hours, which is an incremental increase of 2.24 hours over the current estimate.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant adverse economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in the Economic Analysis (Ref. 14).

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this final rule on small entities, small entity is defined as:

1. A small business, as defined by the SBA's regulations at 13 CFR 121.201. The SBA definitions typically are based upon either a sales or an employment level, depending on the nature of the industry. Companies engaged in chemical substance manufacturing (NAICS code 325) or petroleum refining (NAICS code 324110) are the most likely to report under the IUR rule. These employee size standards range from 500 employees to 1,500 employees for NAICS codes 325 and 324110.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Since the regulated community does not include small governmental jurisdictions or small not-for-profit organizations, the analysis focuses on small businesses.

The existing IUR rule, at 40 CFR 710.49, generally exempts from reporting small businesses, defined at 40 CFR 704.3 as entities with annual sales of less than \$40 million and less than 100,000 lb production of any given chemical substance at a site; or annual sales of less than \$4 million. This exemption is maintained in this final rule. A small business would be required to report under the final rule, however, if it produces any chemical substance that is the subject of a regulation 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 (40 CFR 711.9 and TSCA section 8(a)(3)(A)(ii)). A small business may also report voluntarily.

EPA analyzed potential small business impacts from this final rule using both the SBA employee size standards and the TSCA sales-based definition of small business. EPA estimates that 466 small firms potentially would be affected by this final rule using the employment-based definition, and 280 small firms potentially would be affected using the sales-based definition. Based on costs annualized over a 4-year period and average sales data for the parent companies, EPA estimated that the cost-to-sales ratio of the final rule would be less than 0.1% for an average small company subject to the rule. For a company to have a cost-to-sales ratio larger than 1%, company sales would have to be less than \$0.81 million. Because the small businesses affected by the final rule have average sales of more than \$412.7 million under the employment-based definition, and

\$116 million under the sales-based definition, small entities will not be affected by the amendments to the IUR rule at a cost-to-sales ratio of greater than 1% (Ref. 14).

D. Unfunded Mandates Reform Act

This action does not contain any Federal mandates for State, local, or Tribal governments or the private sector under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531-1538. EPA has determined that this regulatory action will not result in annual expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or for the private sector. The costs associated with this action are briefly described in Unit V.A., and is contained in the Economic Analysis (Ref. 14).

Based on EPA's past experience, State, local, and Tribal governments have not been affected by this reporting requirement, and EPA does not have any reason to believe that any State, local, or Tribal government will be affected by this final rule. As such, EPA has determined that this final rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments. Accordingly, this final rule is not subject to the requirements of sections 202, 203, or 205 of UMRA.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), EPA has determined that 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 the Executive Order. This final rule simply amends the IUR rule in several ways to provide information

to better address Agency and public information needs, improve the usability and reliability of the reported data, and ensure that data are available in a timely manner. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances covered by this action, the final rule does not apply directly to States and localities and will not affect State and local governments. Thus, Executive Order 13132 does not apply to the final rule.

F. Executive Order 13175

As required by Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), EPA has determined that this final rule does not have Tribal implications because it will not have any effect on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in the Order. Thus, Executive Order 13175 does not apply to this final rule.

G. Executive Order 13045

EPA interprets Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. Nevertheless, the information obtained by the reporting required by this final rule will be used to inform the Agency’s decisionmaking process regarding chemical substances to

which children may be disproportionately exposed. This information will also assist the Agency and others in determining whether the chemical substances in this final rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Executive Order 13211

This action is not a “significant energy action” as defined in Executive Order 13211, entitled “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 as described in the Executive Order.

I. National Technology Transfer and Advancement Act

Since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

The final rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities that require special consideration by the Agency under 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 believes that the information collected under this final rule will assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by the final rule. Because the IUR rule is an information collection requirement, the information that will become available

through the rule will enable the Agency to target educational, regulatory, or enforcement activities towards industries or chemical substances that pose the greatest risks and/or to target programs for geographic areas that are at the highest risk. Thus, the information to be gathered under the final rule will help EPA make decisions that will benefit potentially at-risk communities, some of which may be disadvantaged.

The final rule is directed at manufacturers (including importers) of chemical substances. All consumers of these chemical products and all workers who come into contact with these chemical substances could benefit if data regarding the chemical substances' health and environmental effects were developed. Therefore, it does not appear that the costs and the benefits of the final rule will be disproportionately distributed across different geographic regions or among different categories of individuals.

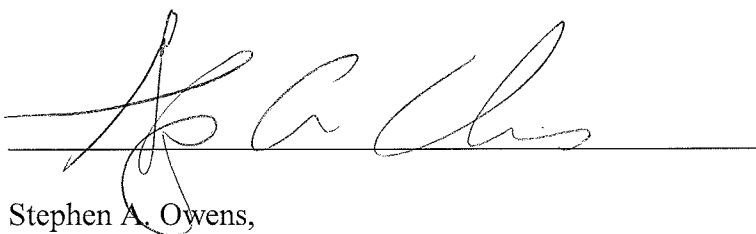
VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 Parts 704, 710, and 711

Environmental protection, Chemicals, Confidential Business Information (CBI), Hazardous materials, Importer, Manufacturer, Reporting and recordkeeping requirements.

Dated: 8-1-2011


A handwritten signature in cursive script, appearing to read 'S. A. Owens', is written over a horizontal line.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 704—[AMENDED]

1. The authority citation for part 704 continues to read as follows:

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

§ 704.3 [Amended]

2. In § 704.3, remove the phrase “(as defined in 19 CFR 1.11)” in paragraph (2) of the definition *importer*.

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

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

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

4. Revise the heading for part 710 to read as set forth above.

5. Remove the heading “Subpart A--General Provisions.”

6. Revise paragraph (b) of § 710.1 to read as follows:

§ 710.1 Scope and compliance.

* * * * *

(b) This part applies to the activities associated with the compilation of the TSCA Chemical Substance Inventory (TSCA Inventory) and the update of information on a subset of the chemical substances included on the TSCA Inventory.

* * * * *

7. Section 710.3 is amended as follows:

i. Remove the phrase “(as defined in 19 CFR 1.11)” in paragraph (2) of the definition *importer*.

ii. Remove the definition *non-isolated intermediate*.

iii. Revise the introductory text of the section to read as follows:

§ 710.3 Definitions.

For purposes of this part:

* * * * *

Subpart B §§ 710.23-710.39 [Removed]

8. Remove subpart B, consisting of §§ 710.23-710.39.

Subpart C §§ 710.43-710.59 [Removed]

9. Remove subpart C, consisting of §§ 710.43-710.59.

10. Add new part 711 to subchapter R to read as follows:

PART 711—TSCA CHEMICAL DATA REPORTING REQUIREMENTS

Sec.

711.1 Scope and compliance.

711.3 Definitions.

711.5 Chemical substances for which information must be reported.

711.6 Chemical substances for which information is not required.

711.8 Persons who must report.

711.9 Persons not subject to this part.

711.10 Activities for which reporting is not required.

711.15 Reporting information to EPA.

711.20 When to report.

711.22 Duplicative reporting.

711.25 Recordkeeping requirements.

711.30 Confidentiality claims.

711.35 Electronic filing.

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

§ 711.1 Scope and compliance.

(a) This part specifies reporting and recordkeeping procedures under section 8(a) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(a)) for certain manufacturers (including importers) of chemical substances. Section 8(a) of TSCA authorizes the EPA Administrator to require reporting of information necessary for administration of TSCA, including issuing regulations for the purpose of compiling and keeping current the TSCA Chemical Substance Inventory (TSCA Inventory) as required by TSCA section 8(b). In accordance with TSCA section 8(b), EPA amends the TSCA Inventory to include new chemical substances manufactured (including imported) in the United States and reported under TSCA section 5(a)(1). EPA also revises the categories of chemical substances and makes other amendments as appropriate.

(b) This part applies to the activities associated with the periodic update of information on a subset of the chemical substances included on the TSCA Inventory.

(c) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under this part. In addition, TSCA section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by this part. Section 16 of TSCA provides that any person who violates a provision of TSCA section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to TSCA section 17, the Federal Government may seek judicial relief to compel submission of TSCA section 8(a) information and to otherwise restrain

any violation of TSCA section 15. (EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.)

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

§ 711.3 Definitions.

The definitions in this section and the definitions in TSCA section 3 apply to this part. In addition, the definitions in 40 CFR 704.3 also apply to this part, except the definitions *manufacture* and *manufacturer* in 40 CFR 704.3.

CDX or Central Data Exchange means EPA's centralized electronic document receiving system, or its successors.

Commercial use means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.

Consumer use means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.

e-CDRweb means the electronic, web-based tool provided by EPA for the completion and submission of the CDR data.

Industrial function means the intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used.

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?

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is:

(1) Produced exclusively for another person who contracts for such production,
and

(2) That other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that

chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

Manufacturer means a person who manufactures a chemical substance.

Master Inventory File means EPA's comprehensive list of chemical substances which constitutes the TSCA Inventory compiled under TSCA section 8(b). It includes chemical substances reported under 40 CFR part 710 and substances reported under 40 CFR part 720 for which a Notice of Commencement of Manufacture or Import has been received under 40 CFR 720.120.

Principal reporting year means the latest complete calendar year preceding the submission period.

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 § 711.5.

Site means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. More than one manufacturing plant may be located on a single site.

(1) For chemical substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured.

(2) The site for an importer who imports a chemical substance described in § 711.5 is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

(3) For portable manufacturing units sent to different locations from a single distribution center, the distribution center shall be considered the site.

Site-limited means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a chemical substance or as part of a mixture or article outside the site. Imported chemical 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 chemical substance is considered to have been manufactured and processed for commercial purposes.

Submission period means the period in which the manufacturing, processing, and use data are submitted to EPA.

U.S. parent company means the highest level company, located in the United States, that directly owns at least 50% of the voting stock of the manufacturer.

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.

§ 711.5 Chemical substances for which information must be reported.

Any chemical substance that is in the Master Inventory File at the beginning of a submission period described in § 711.20, unless the chemical substance is specifically excluded by § 711.6.

§ 711.6 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 part, 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 part if that chemical substance is the subject of a rule proposed or promulgated under TSCA section 4, 5(a)(2), 5(b)(4), or 6, or is the subject of an enforceable consent agreement (ECA) developed under the procedures of 40 CFR part 790, or is the subject of an order issued under TSCA section 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7.

(a) *Full exemptions.* The following categories of chemical substances are exempted from the reporting requirements of this part.

(1) *Polymers*—(i) Any chemical substance described with the word fragments “*polym,” “*alkyd,” or “*oxylated” in the Chemical Abstracts (CA) Index Name in the Master Inventory File, where the asterisk (*) in the listed word fragments indicates that any sets of characters may precede, or follow, the character string defined.

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

(iii) This exclusion does not apply to a polymeric substance that has been depolymerized, hydrolyzed, 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 40 CFR 725.3. Any chemical substance produced from a living microorganism is reportable under this part unless otherwise excluded.

(3) *Naturally occurring chemical substances.* Any naturally occurring chemical substance, as described in 40 CFR 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the chemical substance in question. Some chemical substances can be manufactured both as described in 40 CFR 710.4(b) and by means other than those described in 40 CFR 710.4(b). If a person described in § 711.8 manufactures a chemical substance by means other than those described in 40 CFR 710.4(b), the person must report regardless of

whether the chemical substance also could have been produced as described in 40 CFR 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in 40 CFR 710.4(b) is reportable unless otherwise excluded.

(4) *Certain forms of natural gas and water.* Chemical substances with the following Chemical Abstracts Service Registry Number (CASRN): CASRN 7732-18-5, water; CASRN 8006-14-2, natural gas; CASRN 8006-61-9, gasoline, natural; CASRN 64741-48-6, natural gas (petroleum), raw liq. mix; CASRN 68410-63-9, natural gas, dried; CASRN 68425-31-0, gasoline (natural gas), natural; and CASRN 68919-39-1, natural gas condensates.

(b) *Partial exemptions.* The following groups of chemical substances are partially exempted from the reporting requirements of this part (i.e., the information described in § 711.15(b)(4) need not be reported for these chemical substances). Such chemical substances are not excluded from the other reporting requirements under this part.

(1) *Petroleum process streams.* EPA has designated the chemical substances listed in Table 1 of this paragraph by CASRN, as partially exempt from reporting under the IUR.

Table 1.--CASRNs of Partially Exempt Chemical Substances Termed “Petroleum Process Streams” for Purposes of Inventory Update Reporting

CASRN	Product
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
61789-60-4	Pitch
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
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
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
67254-74-4	Naphthenic oils
67674-12-8	Residual oils (petroleum), oxidized, compounds with triethanolamine
67674-13-9	Petrolatum (petroleum), oxidized, partially deacidified
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.
67891-81-0	Distillates (petroleum), oxidized light, potassium salts
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
67891-86-5	Hydrocarbon waxes (petroleum), oxidized, compds. with diisopropanolamine
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-temperature 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
68476-27-7	Fuel gases, amine system residues

68476-28-8	Fuel gases, C6-8 catalytic reformer
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 polyimd. 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
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-concentration 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
68477-98-5	Gases (petroleum), hydrotreater blend oil recycle, hydrogen-nitrogen rich
68477-99-6	Gases (petroleum), isomerized naphtha fractionater, C4-rich, hydrogen sulfide- free
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
68478-31-9	Tail gas (petroleum), isomerized naphtha fractionates, hydrogen sulfide-free
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
68513-03-1	Naphtha (petroleum), light catalytic reformed, arom.-free
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 non-extractable raffinate

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
68514-35-2	Hydrocarbons, C14-30, olefin-rich
68514-36-3	Hydrocarbons, C1-4, sweetened
68514-37-4	Hydrocarbons, C4-5-unsatd.
68514-38-5	Hydrocarbons, C4-10-unsatd.
68514-39-6	Naphtha (petroleum), light steam-cracked, isoprene-rich
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 depentanizer 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.
68606-31-5	Hydrocarbons, C3-5, butadiene purification (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, <i>o</i> -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
68814-87-9	Distillates (petroleum), full-range straight-run middle
68814-89-1	Extracts (petroleum), heavy paraffinic distillates, solvent-deasphalted
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 depentanizer 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
68919-16-4	Hydrocarbons, catalytic alkylation, by-products, C3-6
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
68921-07-3	Distillates (petroleum), hydrotreated light catalytic cracked
68921-08-4	Distillates (petroleum), light straight-run gasoline fractionation stabilizer overheads
68921-09-5	Distillates (petroleum), naphtha unifiner stripper
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
73138-65-5	Hydrocarbon waxes (petroleum), oxidized, magnesium salts
92045-43-7	Lubricating oils (petroleum), hydrocracked non-arom. solvent deparaffined
92045-58-4	Naphtha (petroleum), isomerization, C6-fraction

92062-09-4	Slack wax (petroleum), hydrotreated
93762-80-2	Alkenes, C15-18
98859-55-3	Distillates (petroleum), oxidized heavy, compds. with diethanolamine
98859-56-4	Distillates (petroleum), oxidized heavy, sodium salts
101316-73-8	Lubricating oils (petroleum), used, non-catalytically refined
164907-78-2	Extracts (petroleum), asphaltene-low vacuum residue solvent
164907-79-3	Residues (petroleum), vacuum, asphaltene-low
178603-63-9	Gas oils (petroleum), vacuum, hydrocracked, hydroisomerized, hydrogenated, C10-25
178603-64-0	Gas oils (petroleum), vacuum, hydrocracked, hydroisomerized, hydrogenated, C15-30, branched and cyclic
178603-65-1	Gas oils (petroleum), vacuum, hydrocracked, hydroisomerized, hydrogenated, C20-40, branched and cyclic
178603-66-2	Gas oils (petroleum), vacuum, hydrocracked, hydroisomerized, hydrogenated, C25-55, branched and cyclic
212210-93-0	Solvent naphtha (petroleum), heavy arom., distn. residues
221120-39-4	Distillates (petroleum), cracked steam-cracked, C5-12 fraction
445411-73-4	Gas oils (petroleum), vacuum, hydrocracked, hydroisomerized, hydrogenated, C10-25, branched and cyclic

(2) *Specific exempted chemical substances--(i) Exemption.* EPA has determined that, at this time, the information in § 711.15(b)(4) associated with the chemical substances 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 substance qualifies or has qualified in past IUR collections for the reporting of the information described in § 711.15(b)(4).

(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.

(iii) *Amendments*. EPA may amend the chemical substance 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 § 711.15(b)(4) is of low interest.

(A) Any person may request that EPA amend the chemical substance list in Table 2 in paragraph (b)(2)(iv) of this section. Your request must be in writing and must be submitted to the following address: OPPT IUR Submission Coordinator (7407M), Attention: Inventory Update Reporting, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Requests must identify the chemical substance in question, as well as its CASRN or other chemical identification number as identified in § 711.15(b)(3)(i), and must contain a written rationale for the request that provides sufficient specific

information, addressing the considerations listed in § 711.6(b)(2)(ii), including cites and relevant documents, to demonstrate to EPA that the collection of the information in § 711.15(b)(4) for the chemical substance in question either is or is not of low current interest. If a request related to a particular chemical substance 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 docket that will be established for each reporting cycle.

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

(C) To assist EPA in reaching a decision regarding a particular request prior to a given principal reporting year, requests must be submitted to EPA no later than 12 months prior to the start of the next principal reporting year.

(iv) *List of chemical substances.* EPA has designated the chemical substances listed in Table 2 of this paragraph by CASRN, as partially exempt from reporting under the IUR.

Table 2.--CASRN of Partially Exempt Chemical Substances

CASRN	Chemical
50-70-4	<i>D</i> -glucitol
50-81-7	<i>L</i> -ascorbic acid
50-99-7	<i>D</i> -glucose
56-81-5	1,2,3-Propanetriol

56-87-1	<i>L</i> -lysine
57-50-1	.alpha.- <i>D</i> -Glucopyranoside, .beta.- <i>D</i> -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	<i>D</i> -mannitol
87-79-6	<i>L</i> -sorbose
87-99-0	Xylitol
96-10-6	Aluminum, chlorodiethyl-
97-93-8	Aluminum, triethyl-
100-99-2	Aluminum, tris(2-methylpropyl)-
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 salt (2:1)
142-47-2	<i>L</i> -glutamic acid, monosodium salt
150-30-1	Phenylalanine
563-43-9	Aluminum, dichloroethyl-
1070-00-4	Aluminum, trioctyl-
1116-70-7	Aluminum, tributyl-
1116-73-0	Aluminum, trihexyl-
1191-15-7	Aluminum, hydrobis(2-methylpropyl)-
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
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
11103-57-4	Vitamin A
12075-68-2	Aluminum, di-.mu.-chlorochlorotriethyldi-

12542-85-7	Aluminum, trichlorotrimethyl-di-
16291-96-6	Charcoal
26836-47-5	<i>D</i> -glucitol, mono-octadecanoate
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
68308-36-1	Soybean meal
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
68648-87-3	Benzene, C10-16-alkyl derivs.
68918-42-3	Soaps, stocks, soya
68952-94-3	Soaps, stocks, vegetable-oil
68956-68-3	Fats and glyceridic oils, vegetable
68989-98-0	Fats and glyceridic oils, vegetable, residues
73138-67-7	Lard, hydrogenated
120962-03-0	Canola oil
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.

§ 711.8 Persons who must report.

Except as provided in §§ 711.9 and 711.10, the following persons are subject to the requirements of this part. Persons must determine whether they must report under this section for each chemical substance that they manufacture (including import) at an individual site.

(a) *Persons subject to recurring reporting*--(1) For the 2012 submission period, any person who manufactured (including imported) for commercial purposes 25,000 lb (11,340 kilogram (kg)) or more of a chemical substance described in § 711.5 at any single site owned or controlled by that person during the principal reporting year (i.e., calendar year 2011) is subject to reporting.

(2) For the submission periods subsequent to the 2012 submission period, any person who manufactured (including imported) for commercial purposes 25,000 lb (11,340 kg) or more of a chemical substance described in § 711.5 at any single site owned or controlled by that person during any calendar year since the last principal reporting year (e.g., for the 2016 submission period, consider calendar years 2012, 2013, 2014, and 2015, given that 2011 was the last principal reporting year).

(b) *Exceptions.* For the 2016 submission period and subsequent submission periods, any person who manufactured (including imported) for commercial purposes any chemical substance that is the subject of a rule proposed or promulgated under TSCA section 5(a)(2), 5(b)(4), or 6, or is the subject of an order in effect under TSCA section 5(e) or 5(f), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7 is subject to reporting as described in § 711.8(a), except that the applicable production volume threshold is 2,500 lb (1,134 kg).

§ 711.9 Persons not subject to this part.

A person described in § 711.8 is not subject to the requirements of this part if that person qualifies as a small manufacturer as that term is defined in 40 CFR 704.3. Notwithstanding this exclusion, a person who qualifies as a small manufacturer is subject to this part 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 is the subject of an order in effect under TSCA section 5(e), or is the subject of relief that has been granted under a civil action under TSCA section 5 or 7.

§ 711.10 Activities for which reporting is not required.

A person described in § 711.8 is not subject to the requirements of this part with respect to any chemical substance described in § 711.5 that the person solely manufactured or imported under the following circumstances:

- (a) The person manufactured or imported the chemical substance described in § 711.5 solely in small quantities for research and development.
- (b) The person imported the chemical substance described in § 711.5 as part of an article.
- (c) The person manufactured the chemical substance described in § 711.5 in a manner described in 40 CFR 720.30(g) or (h).

§ 711.15 Reporting information to EPA.

For the 2012 submission period, any person who must report under this part, as described in § 711.8, must submit the information described in this section for each chemical substance described in § 711.5 that the person manufactured (including imported) for commercial purposes in an amount of 25,000 lb (11,340 kg) or more at any one site during the principal reporting year (i.e., calendar year 2011). For the submission periods subsequent to the 2012 submission period, any person who must report under this part, as described in § 711.8, must submit the information described in this section for each chemical substance described in § 711.5 that the person manufactured (including imported) for commercial purposes in an amount of 25,000 lb (11,340 kg) or more (or in an amount of 2,500 lb (1,134 kg) or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)) at any one site during any calendar year since the last principal reporting year (e.g., for the 2016 submission period, consider calendar

years 2012, 2013, 2014, and 2015, because 2011 was the last principal reporting year). The principal reporting year for each submission period is the previous calendar year (e.g., the principal reporting year for the 2016 submission period is calendar year 2015). For all submission periods, a separate report must be submitted for each chemical substance at each site for which the submitter is required to report. A submitter of information under this part must report information as described in this section to the extent that such information is known to or reasonably ascertainable by that person.

(a) *Reporting information to EPA.* Any person who reports information to EPA must do so using the e-CDRweb reporting tool provided by EPA at the address set forth in § 711.35. The submission must include all information described in paragraph (b) of this section. Persons must submit a separate Form U for each site for which the person is required to report. The e-CDRweb reporting tool is described in the instructions available from EPA at the website set forth in § 711.35.

(b) *Information to be reported.* For the 2012 submission period, manufacturers (including importers) of a reportable chemical substance in an amount of 25,000 lb (11,340 kg) or more at a site during the principal reporting year (i.e., 2011) must report the information described in paragraphs (b)(1), (b)(2), and (b)(3) of this section. For the 2012 submission period, manufacturers (including importers) of a reportable chemical substance in an amount of 100,000 lb (45,359 kg) or more at a site during the principal reporting year (i.e., 2011) must additionally report the information described in paragraph (b)(4) of this section. For submission periods subsequent to the 2012 submission period, the information described in paragraphs (b)(1), (b)(2), (b)(3), and (b)(4) of this section must be reported for each chemical substance manufactured (including imported) in an

amount of 25,000 lb (11,340 kg) or more (or in an amount of 2,500 lb (1,134 kg) or more for chemical substances subject to the rules, orders, or actions described in § 711.8(b)) at any one site during any calendar year since the last principal reporting year. The requirement to report information described in paragraph (b)(4) of this section is subject to exemption as described in § 711.6.

(1) *A certification statement signed and dated by an authorized official of the submitter company.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the Form U are true and correct. The certification must be signed and dated by the authorized official for the submitter company, and provide that person's name, official title, and e-mail address.

(2) *Company and plant site information.* The following currently correct company and plant site information must be reported for each site at which a reportable chemical substance is manufactured (including imported) above the applicable production volume threshold, as described in this section (see § 711.3 for the "site" for importers):

(i) The U.S. parent company name, address, and Dun and Bradstreet D-U-N-S® (D&B) number. A submitter under this part must obtain a D&B number for the U.S. parent company if none exists.

(ii) 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 contact person's full mailing address, telephone number, and e-mail address.

(iii) The name and full street address of each site. A submitter under this part must include the appropriate D&B number for each plant site reported, and the county or parish (or other jurisdictional indicator) in which the plant site is located. A submitter under this part must obtain a D&B number for the site reported if none exists.

(3) *Chemical-specific information.* The following chemical-specific information must be reported for each reportable chemical substance manufactured (including imported) above the applicable production volume threshold, as described in paragraph (b) of this section:

(i) The specific, currently correct CA Index name as used to list the chemical substance on the TSCA Inventory and the correct corresponding CASRN for each reportable chemical substance at each site. A submitter under this part may use an EPA-designated TSCA Accession Number for a chemical substance in lieu of a CASRN when a CASRN is not known to or reasonably ascertainable by the submitter. Submitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to report the chemical substance using a TSCA Accession Number.

In addition to reporting the number itself, submitters must specify the type of number they are reporting by selecting from among the codes in Table 3 of this paragraph.

Table 3.--Codes to Specify Type of Chemical Identifying Number

Code	Number Type
A	TSCA Accession Number
C	Chemical Abstracts Service Registry Number (CASRN)

(A) If an importer submitting a report cannot provide the information specified in § 711.15(b)(3)(i) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must use e-CDRweb to ask the supplier to provide the correct chemical identity information directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically, using e-CDRweb and CDX (see § 711.35), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other designation for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission respecting the chemical substance.

(B) If a manufacturer submitting a report cannot provide the information specified in § 711.15(b)(3)(i) because the reportable chemical substance is manufactured using a reactant having a specific chemical identity that is unknown to the manufacturer and claimed as confidential by its supplier, the manufacturer must use e-CDRweb to ask the supplier of the confidential reactant to provide the correct chemical identity of the confidential reactant directly to EPA in a joint submission. Such request must include instructions for submitting chemical identity information electronically using e-CDRweb and CDX (see § 711.35), and for clearly referencing the manufacturer's submission. Contact information for the supplier, a trade name or other designation for the chemical substance, and a copy of the request to the supplier must be included with the importer's submission respecting the chemical substance.

(C) EPA will only accept joint submissions that are submitted electronically using e-CDRweb and CDX (see § 711.35) and that clearly reference the primary submission to which they refer.

(ii) For the principal reporting year only, a statement indicating, for each reportable chemical substance at each site, whether the chemical 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) For the principal reporting year, the total annual volume (in pounds) of each reportable chemical substance domestically manufactured or imported at each site. The total annual domestically manufactured volume (not including imported volume) and the total annual imported volume must be separately reported. These amounts must be reported to two significant figures of accuracy. In addition, for the 2012 submission period only, the total annual volume (domestically manufactured plus imported volumes in pounds) of each reportable chemical substance at each site during calendar year 2010. In addition, for submission periods subsequent to the 2012 submission period, the total annual volume (domestically manufactured plus imported volumes in pounds) of each reportable chemical substance at each site for each complete calendar year since the last principal reporting year.

(iv) For the principal reporting year only, the volume used on site and the volume directly exported of each reportable chemical substance domestically manufactured or imported at each site. These amounts must be reported to two significant figures of accuracy.

(v) For the principal reporting year only, a designation indicating, for each imported reportable chemical substance at each site, whether the imported chemical substance is physically present at the reporting site.

(vi) For the principal reporting year only, a designation indicating, for each reportable chemical substance at each site, whether the chemical substance is being recycled, remanufactured, reprocessed, reused, or otherwise used for a commercial purpose instead of being disposed of as a waste or included in a waste stream.

(vii) For the principal reporting year only, the total number of workers reasonably likely to be exposed to each reportable chemical substance at each site. For each reportable chemical substance at each site, the submitter must select from among the ranges of workers listed in Table 4 of this paragraph and report the corresponding code (i.e., W1 through W8):

Table 4.--Codes for Reporting Number of Workers Reasonably Likely To Be Exposed

Code	Range
W1	Fewer than 10 workers
W2	At least 10 but fewer than 25 workers
W3	At least 25 but fewer than 50 workers
W4	At least 50 but fewer than 100 workers
W5	At least 100 but fewer than 500 workers
W6	At least 500 but fewer than 1,000 workers
W7	At least 1,000 but fewer than 10,000 workers
W8	At least 10,000 workers

(viii) For the principal reporting year only, 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 substance 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 chemical substance is sent off-site/reacted on-site. For each chemical substance at each site, select the maximum concentration of the chemical substance from among the ranges listed in Table 5 of this paragraph and report the corresponding code (i.e., M1 through M5):

Table 5.—Codes for Reporting Maximum Concentration of Chemical Substance

Code	Concentration Range (% weight)
M1	Less than 1% by weight
M2	At least 1 but less than 30% by weight
M3	At least 30 but less than 60% by weight
M4	At least 60 but less than 90% by weight
M5	At least 90% by weight

(ix) For the principal reporting year only, the physical form(s) of the reportable chemical substance as it is sent off-site from each site. If the chemical substance 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 chemical substance at each site, the submitter must report as many physical forms as applicable from among the physical forms listed in this unit:

(A) Dry powder.

(B) Pellets or large crystals.

(C) Water- or solvent-wet solid.

(D) Other solid.

(E) Gas or vapor.

(F) Liquid.

(x) For the principal reporting year only, 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 (b)(3)(iii) of this section, that is associated with each physical form reported under paragraph (b)(3)(ix) of this section.

(4) *Chemical-specific information related to processing and use.* The following chemical-specific information must be reported for each reportable chemical substance manufactured (including imported) above the applicable production volume threshold, as described in this section. Persons subject to paragraph (b)(4) of this section must report the information described in paragraphs (b)(4)(i) and (b)(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 for the principal reporting year only and only to the extent that it is known to or reasonably ascertainable by the submitter. Information required to be reported under this paragraph is limited to domestic (i.e., within the customs territory of the United States) processing and use activities. If information responsive to a given data requirement under this paragraph, including information in the

form of an estimate, is not known or reasonably ascertainable, 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 chemical 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) listed in Table 6 of this paragraph. A particular designation may need to be reported more than once, to the extent that a submitter reports more than one sector (under paragraph (b)(4)(i)(B) of this section) that applies to a given designation under this paragraph.

Table 6.--Codes for Reporting Type of Industrial Processing or Use Operation

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) A code indicating the sector(s) that best describe the industrial activities associated with each industrial processing or use operation reported under paragraph (b)(4)(i)(A) of this section. For each chemical substance, report the code that corresponds to the appropriate sector(s) listed in Table 7 of this paragraph. A particular sector code may need to be reported more than once, to the extent that a submitter reports more than

one industrial function code (under paragraph (b)(4)(i)(C) of this section) that applies to a given sector code under this paragraph.

Table 7.--Codes for Reporting Industrial Sectors

Code	Sector Description
IS1	Agriculture, forestry, fishing, and hunting
IS2	Oil and gas drilling, extraction, and support activities
IS3	Mining (except oil and gas) and support activities
IS4	Utilities
IS5	Construction
IS6	Food, beverage, and tobacco product manufacturing
IS7	Textiles, apparel, and leather manufacturing
IS8	Wood product manufacturing
IS9	Paper manufacturing
IS10	Printing and related support activities
IS11	Petroleum refineries
IS12	Asphalt paving, roofing, and coating materials manufacturing
IS13	Petroleum lubricating oil and grease manufacturing
IS14	All other petroleum and coal products manufacturing
IS15	Petrochemical manufacturing
IS16	Industrial gas manufacturing
IS17	Synthetic dye and pigment manufacturing
IS18	Carbon black manufacturing
IS19	All other basic inorganic chemical manufacturing
IS20	Cyclic crude and intermediate manufacturing
IS21	All other basic organic chemical manufacturing

IS22	Plastics material and resin manufacturing
IS23	Synthetic rubber manufacturing
IS24	Organic fiber manufacturing
IS25	Pesticide, fertilizer, and other agricultural chemical manufacturing
IS26	Pharmaceutical and medicine manufacturing
IS27	Paint and coating manufacturing
IS28	Adhesive manufacturing
IS29	Soap, cleaning compound, and toilet preparation manufacturing
IS30	Printing ink manufacturing
IS31	Explosives manufacturing
IS32	Custom compounding of purchased resins
IS33	Photographic film, paper, plate, and chemical manufacturing
IS34	All other chemical product and preparation manufacturing
IS35	Plastics product manufacturing
IS36	Rubber product manufacturing
IS37	Non-metallic mineral product manufacturing (includes cement, clay, concrete, glass, gypsum, lime, and other non-metallic mineral product manufacturing)
IS38	Primary metal manufacturing
IS39	Fabricated metal product manufacturing
IS40	Machinery manufacturing
IS41	Computer and electronic product manufacturing
IS42	Electrical equipment, appliance, and component manufacturing
IS43	Transportation equipment manufacturing
IS44	Furniture and related product manufacturing
IS45	Miscellaneous manufacturing

IS46	Wholesale and retail trade
IS47	Services
IS48	Other (requires additional information)

(C) For each sector reported under paragraph (b)(4)(i)(B) of this section, code(s) from Table 8 of this paragraph 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/sector combination (under paragraphs (b)(4)(i)(A) and (b)(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/sector/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 substance, measured by weight. If none of the listed industrial function categories accurately describes a use of a chemical substance, the category "Other" may be used, and must include a description of the use.

Table 8.--Codes for Reporting Industrial Function Categories

Code	Category
U001	Abrasives
U002	Adhesives and sealant chemicals
U003	Adsorbents and absorbents
U004	Agricultural chemicals (non-pesticidal)

U005	Anti-adhesive agents
U006	Bleaching agents
U007	Corrosion inhibitors and anti-scaling agents
U008	Dyes
U009	Fillers
U010	Finishing agents
U011	Flame retardants
U012	Fuels and fuel additives
U013	Functional fluids (closed systems)
U014	Functional fluids (open systems)
U015	Intermediates
U016	Ion exchange agents
U017	Lubricants and lubricant additives
U018	Odor agents
U019	Oxidizing/reducing agents
U020	Photosensitive chemicals
U021	Pigments
U022	Plasticizers
U023	Plating agents and surface treating agents
U024	Process regulators
U025	Processing aids, specific to petroleum production
U026	Processing aids, not otherwise listed
U027	Propellants and blowing agents
U028	Solids separation agents
U029	Solvents (for cleaning or degreasing)

U030	Solvents (which become part of product formulation or mixture)
U031	Surface active agents
U032	Viscosity adjustors
U033	Laboratory chemicals
U034	Paint additives and coating additives not described by other categories
U999	Other (specify)

(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, sector, and industrial function category. Where a particular combination of industrial processing or use operation, sector, and industrial function category accounts for less than 5% of the submitter's site's total production volume of a reportable chemical substance, the percentage must not be rounded off to 0% if the production volume attributable to that industrial processing or use operation, sector, and industrial function category combination is 25,000 lb (11,340 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, sector, and industrial function category.

(E) For each combination of industrial processing or use operation, sector, 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 chemical substance, the submitter must select from among the ranges of sites

listed in Table 9 of this paragraph and report the corresponding code (i.e., S1 through S7):

Table 9.--Codes for Reporting Numbers of Sites

Code	Range
S1	Fewer than 10 sites
S2	At least 10 but fewer than 25 sites
S3	At least 25 but fewer than 100 sites
S4	At least 100 but fewer than 250 sites
S5	At least 250 but fewer than 1,000 sites
S6	At least 1,000 but fewer than 10,000 sites
S7	At least 10,000 sites

(F) For each combination of industrial processing or use operation, sector, 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 chemical substance, the submitter must select from among the worker ranges listed in paragraph (b)(3)(ii) of this section and report the corresponding code (i.e., W1 through W8).

(ii) *Consumer and commercial use information*--(A) Using the codes listed in Table 10 of this paragraph, submitters must designate the consumer and commercial product category or categories that best describe the consumer and commercial 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. If none of the listed consumer and commercial product categories accurately describes the consumer and commercial products in which each reportable chemical substance is used, the category "Other" may be used, and must include a description of the use.

Table 10.--Codes for Reporting Consumer and Commercial Product Categories

Code	Category
Chemical Substances in Furnishing, Cleaning, Treatment Care Products	
C101	Floor coverings
C102	Foam seating and bedding products
C103	Furniture and furnishings not covered elsewhere
C104	Fabric, textile, and leather products not covered elsewhere
C105	Cleaning and furnishing care products
C106	Laundry and dishwashing products
C107	Water treatment products
C108	Personal care products
C109	Air care products
C110	Apparel and footwear care products
Chemical Substances in Construction, Paint, Electrical, and Metal Products	
C201	Adhesives and sealants
C202	Paints and coatings
C203	Building/construction materials -- wood and engineered wood products
C204	Building/construction materials not covered elsewhere
C205	Electrical and electronic products
C206	Metal products not covered elsewhere

C207	Batteries
Chemical Substances in Packaging, Paper, Plastic, Toys, Hobby Products	
C301	Food packaging
C302	Paper products
C303	Plastic and rubber products not covered elsewhere
C304	Toys, playground, and sporting equipment
C305	Arts, crafts, and hobby materials
C306	Ink, toner, and colorant products
C307	Photographic supplies, film, and photochemicals
Chemical Substances in Automotive, Fuel, Agriculture, Outdoor Use Products	
C401	Automotive care products
C402	Lubricants and greases
C403	Anti-freeze and de-icing products
C404	Fuels and related products
C405	Explosive materials
C406	Agricultural products (non-pesticidal)
C407	Lawn and garden care products
Chemical Substances in Products not Described by Other Codes	
C980	Non-TSCA use
C909	Other (specify)

(B) An indication, within each consumer and commercial product category reported under paragraph (b)(4)(ii)(A) of this section, whether the use is a consumer or a commercial use.

(C) Submitters must determine, within each consumer and commercial product category reported under paragraph (b)(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 substance 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 age 14 or younger, regardless of the concentration of the chemical 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 known to or reasonably ascertainable by the submitter.

(D) 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 consumer and commercial product category. Where a particular consumer and commercial product category accounts for less than 5% of the total production volume of a reportable chemical substance, the percentage must not be rounded off to 0% if the production volume attributable to that commercial and consumer product category is 25,000 lb (11,340 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 consumer and commercial product category.

(E) Where the reportable chemical substance is used in consumer or commercial products, the estimated typical maximum concentration, measured by weight, of the chemical substance in each consumer and commercial product category reported under

paragraph (b)(4)(ii)(A) of this section. For each chemical substance in each commercial and consumer product category reported under paragraph (b)(4)(ii)(A) of this section, submitters must select from among the ranges of concentrations listed in Table 5 in paragraph (b)(3)(viii) of this section and report the corresponding code (i.e., M1 through M5).

(F) Where the reportable chemical substance is used in a commercial product, the submitter must estimate the number of commercial 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 Table 4 in paragraph (b)(3)(vii) of this section and report the corresponding code (i.e., W1 through W8).

§ 711.20 When to report.

All information reported to EPA in response to the requirements of this part must be submitted during an applicable submission period. For the 2012 IUR, the submission period is from February 1, 2012 to June 30, 2012. Subsequent recurring submission periods are from June 1 to September 30 at 4-year intervals, beginning in 2016. In each submission period, any person described in § 711.8 must report as described in this part.

§ 711.22 Duplicative reporting.

(a) *With regard to TSCA section 8(a) rules.* Any person subject to the requirements of this part who previously has complied with reporting requirements of a rule under TSCA section 8(a) by submitting the information described in § 711.15 for a chemical substance described in § 711.5 to EPA, and has done so within 1 year of the

start of a submission period described in § 711.20, is not required to report again on the manufacture of that chemical 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 § 711.5. 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 40 CFR 704.3, 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.

(c) *Toll manufacturers and persons contracting with a toll manufacturer.* This part requires that only one report per site be submitted on each chemical substance described in § 711.5. When a company contracts with a toll manufacturer to manufacture a chemical substance, and each party meets the Agency's definition of "manufacturer" as set forth in § 711.3, they may determine among themselves who should submit the required report for that site. However, both the contracting company and the toll manufacturer are liable if no report is made.

§ 711.25 Recordkeeping requirements.

Each person who is subject to the reporting requirements of this part must retain 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 on the last day of the submission period. Submitters are encouraged to retain their records longer than 5 years to ensure that past records are available as a reference when new submissions are being generated.

§ 711.30 Confidentiality claims.

(a) *Confidentiality claims.* Any person submitting information under this part may assert a business confidentiality claim for the information at the time it is submitted. Any such confidentiality claims must be made at the time the information is submitted.

Confidentiality claims cannot be made when a response is left blank or designated as not known or reasonably ascertainable. These claims will apply only to the information submitted with the claim. New confidentiality claims, if appropriate, must be asserted with regard to information submitted during a different submission period. Guidance for asserting confidentiality claims is provided in the instructions identified in § 711.35. Information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2.

(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 chemical substance is treated as confidential in the Master Inventory File as of the time the report is submitted for that chemical substance under this part. 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, or to your supplier's competitive position, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this part? How could a

competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

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

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

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

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

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

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

(viii) Does this particular chemical substance leave the site of manufacture (including import) in any form, e.g., as product, effluent, emission? 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 chemical substance be identified by analysis of the product?

(x) For what purpose do you manufacture (including import) the chemical 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 (CBI), 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 substance 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 part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(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 CBI, 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) *Processing and use information.* A submitter may assert a claim of confidentiality for each data element required by § 711.15(b)(4) only if the linkage of the information with a reportable chemical substance is confidential and not publicly available. The following steps must be taken to assert a claim of confidentiality for each data element, individually, required by § 711.15(b)(4):

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

(i) Is the identified use of this chemical substance publicly known? For example, is information on the use available in advertisements or other marketing materials, professional journals or other similar materials, or in non-confidential mandatory or voluntary government filings or publications? Has your company ever provided use information on the chemical substance that was not claimed as confidential?

(ii) What harmful effect, if any, to your competitive position or to your customer's competitive position do you think would result from the information reported as required by § 711.15(b)(4) and the chemical substance being disclosed in connection with reporting under this part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the substantial harmful effects?

(2) If any of the information contained in the answers to the questions listed in paragraph (d)(1) of this section is asserted to contain CBI, 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."

(e) *No claim of confidentiality.* If no claim of confidentiality is indicated on Form U submitted to EPA under this part; if Form U lacks the certification required by § 711.15(b)(1); if confidentiality claim substantiation required under paragraphs (b), (c), and (d) of this section is not submitted with Form U; or if the identity of a chemical substance listed on the non-confidential portion of the Master Inventory File is claimed as confidential, EPA may make the information available to the public without further notice to the submitter.

§ 711.35 Electronic filing.

(a) You must use e-CDRweb to complete and submit Form U (EPA Form 7740-8). Submissions may only be made as set forth in this section.

(b) Submissions must be sent electronically to EPA via CDX.

(c) Access e-CDRweb and instructions, as follows:

(1) *By website.* Go to the EPA Inventory Update Reporting Internet homepage at <http://www.epa.gov/iur> and follow the appropriate links.

(2) *By phone or e-mail.* Contact the EPA TSCA Hotline at (202) 554-1404 or TSCA-Hotline@epa.gov for a CD-ROM containing the instructions.