Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

Title: Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports

EPA ICR No.: 1884.04 OMB Control No.: 2070-0162

1(b) Short Characterization

This document provides the estimated burden hours and costs associated with the information collection activities of the Inventory Update Reporting (IUR) program under the Toxic Substances Control Act (TSCA). Under TSCA section 8(b) (15 USC 2607), the Environmental Protection Agency (EPA) is required to compile and keep current, via periodic inquiry, the Inventory of Chemical Substances in Commerce (TSCA Inventory). The TSCA Inventory is a listing of chemical substances manufactured, imported and processed for commercial purposes in the United States. The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has used the IUR to update the basic chemical production information for selected larger volume chemicals in the TCSA Inventory six times (every four years), beginning in 1986.

Prior to the 2006 collection, EPA implemented various amendments[1] to the IUR, including the requirement to report manufacturing, processing, and use exposure-related information; changes to the chemical substances subject to reporting, such as the addition of inorganic chemical substance to the reporting requirement and the addition of partially-exempted chemical substance lists; changes to the reporting frequency and the records retention period; revisions to certain CBI requirements; and changes to the reporting threshold. The next collection, in 2011, will also include the manufacturing, processing, and use exposure-related data elements.

OPPTS will use the updated IUR data in its risk-management efforts. Individual plant or factory sites producing or importing chemicals will submit the required information. The information will be stored and used in both hard-copy and electronic forms for reference by EPA staff and others. Further discussion of how the information is used, stored, and collected is included in this document.

EPA maintains databases containing the IUR data. Information submitted prior to the 2006 IUR is maintained in a series of databases called the Chemical Update System (CUS). The 2006 IUR and future submissions are maintained in an IUR database in the Manage Toxic Substances (MTS) system. Respondents either mail or electronically

[1] The 2003 Amendments were published on January 7, 2003. See 68 FR 848.

submit a completed Form U (EPA Form 7740-8), the IUR reporting form, to EPA during the reporting cycle that now occurs every five years.

The collection is expected to involve about 4,200 respondents at an annual cost of $20 million. The details of the paperwork burden cost estimates are discussed in this document.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Under TSCA, EPA is required to identify, assess, and control risks of injury to human health and the environment posed by commercial chemicals. Under TSCA section 8(b), EPA is required to compile and keep current a complete list of chemical substances manufactured or processed in the United States. Under TSCA section 8(a) the Administrator shall promulgate rules to provide for the maintenance and collection of records from manufacturers, importers and processors of commercial chemicals. The Inventory Update Reporting (IUR) rule is codified at 40 CFR 710. Copies of the relevant sections of TSCA and of the Code of Federal Regulations (CFR) are attached (see Attachments 1 and 2).

Sections 8(a)(1) and (2) of TSCA authorize the Agency to collect information on the chemical manufacturing and importing industry. Table 1 contains examples of the type of information TSCA authorizes EPA to collect, although it is not all currently being collected. EPA possesses broad discretion in determining the information to be reported under TSCA section 8(a).

Table 1. Examples of Chemical-specific Information EPA is Authorized to Collect Under Section 8(a) of the Toxic Substances Control Act

1. Common or trade name, chemical identity, and molecular structure of each chemical substance or mixture for which reports are required.
2. Categories or proposed categories of use for each substance or mixture reported.
3. The total amount of each substance and mixture manufactured or processed and each of its categories of use; reasonable estimates of the total amount to be manufactured or processed and each of its categories of use.
4. A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.
5. All existing data concerning the environmental and health effects of such substances or mixtures.
6. The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substances or mixtures in their places of employment and the duration of such exposure.
7. The manner or method of disposal, and in any subsequent report on such substance or mixture, any change in the manner or method.

EPA collected basic production and site identification information under the original IUR. The basic production information included chemical name, chemical identification number, annual production volume, and chemical site-limited status. Site identification information included manufacturer or importer and site name and address and the name, address, and phone number of a technical contact. EPA will continue to collect this information.

Beginning with the 2006 IUR, the Agency collected basic exposure-related manufacturing, processing and use information in addition to the production and site identification information. These data are used to augment and expand databases of exposure-related information that the Agency uses in everyday, basic decision-making. Because exposure is a key component of risk, the IUR exposure-related information allows OPPT to screen chemicals based on the potential for risk in order to protect human health and the environment, as required by TSCA. The exposure-related data on manufacturing, processing, and use allow the Agency and others to potentially avoid more burdensome requirements. These data allow a more effective and efficient screening level review of chemicals to identify candidates for further evaluation. By providing the means for better prioritization of limited resources on the basis of risk, the 2006 IUR greatly enhances the Agency's efforts to achieve better public health, sustainable development, environmental justice, pollution prevention, sound science, partnerships, and ecosystem protection. The success of the New Chemicals Program—where over 47,000 chemicals have been screened using data similar to the IUR data—demonstrates the value of having sufficient information to screen chemicals based on an adequate representation of potential risk. These improvements will continue with the information from the 2011 IUR.

2(b) Practical Utility/Users of the Data

The IUR information collection enables EPA to collect basic information on TSCA commercial chemicals, including current production volume, site-related data, and manufacturing, processing, and use exposure-related data. This information collection is necessary because it is the only mechanism through which EPA's need for basic information on chemicals manufactured, produced, or imported can be fully and effectively satisfied. The information collected is utilized in the following ways:

(1) Parent company and technical contact identification information: These data are collected to identify the parent company responsible for the data.

(2) Plant site identification information: Collected to identify the physical site where the manufacturing and import takes place, these data can assist EPA in estimating human and environmental exposure and to identify specific plant site operators in order to be able to communicate with them. As such, this information is sought for purposes related to regulatory activities under TSCA sections 4, 6 and 8.

(3) Chemical identification information: This information is necessary for EPA to properly identify the chemical.

(4) Manufacturing-related information for each chemical, including whether the chemical is manufactured or imported, its reporting year production volume, whether it is site-limited, the number of workers reasonably likely to be exposed to the chemical, its maximum concentration, and its physical form(s) and related percent production volume. This information is used in chemical exposure and risk screening, testing and/or review priority setting and exposure estimation required by the Interagency Testing Committee (ITC) under TSCA section 4; for EPA monitoring activities of newly manufactured substances that have completed PMN review under TSCA section 5(a); to support the development of TSCA regulations under section 6; and to measure potential of human and environmental exposure under TSCA section 8(e). Each data element corresponds to a data point necessary for basic risk-screening -- for example, a site-limited intermediate chemical is presumed to have lower exposure potential because it is not distributed outside the manufacturing plant for commercial purposes.

Some respondents must also report for chemicals produced in excess of 300,000 pounds on a per-site basis:

(5) Industrial processing and use data, including types of industrial use and associated industry NAICS codes, industrial function, estimated number of sites, and estimated numbers of workers reasonably likely to be exposed: These data are used to determine exposure potential based on industrial processing and use, including related environmental releases.

(6) Commercial and consumer end-use exposure data, including categories of products, the maximum concentration in each category, and whether the chemical is used in products intended for children: These data are used to determine exposure potential based on consumer and commercial use, including related environmental releases.

Information secured through the IUR collections is increasingly used by a wide variety of governmental and non-governmental users. Consistent with Congress's intent that TSCA data be used to facilitate any government public health and environment efforts, IUR data have been used by EPA's Office of Water, Office of Solid Waste and Emergency Response, and Office of Air and Radiation to identify and characterize particular chemical substances. Non-confidential IUR data are incorporated into a number of databases and products maintained by organizations including Right-To-Know-Net and INFORM[2]. IUR data were used to identify chemicals of particular concern for the National Institutes of Health. Non-confidential IUR data were also released to selected states to help them identify facilities manufacturing suspected endocrine disrupters.

[2] INFORM is a nonprofit environmental research organization.

Under TSCA, EPA has an obligation to protect human health and the environment from unreasonable risks associated with chemicals under its jurisdiction. In order to evaluate potential chemical risks, EPA has determined that a portion of the chemicals (both organic and inorganic) on the TSCA Inventory currently warrant the continued collection of manufacturing information, and that a subset of those chemicals (i.e., those produced in quantities of 300,000 pounds or more at a site) currently warrant the collection of supplementary processing and use information. The IUR provides an accurate and readily available source of basic manufacturing information for about 7,600 of the 83,000 substances listed on the Inventory and basic processing and use information for a subset of about 4,500 substances, thus significantly limiting industry's reporting burden while providing EPA with information necessary to conduct screening level assessments for risks to human health and the environment.

Improving the Agency's ability to set priorities results in a variety of benefits. Agency resources will be more efficiently and effectively directed to high priority chemicals of concern. Industry efforts to address chemicals of concern will also be better targeted. Overall, public and private resources will be maximized and public health and the environment will be better protected.

EPA uses the information submitted through this collection to update the Agency's comprehensive chemical manufacturing, exposure, and use database, maintained as part of the Manage Toxic Substances (MTS) system. IUR data prior to the 2006 collection are maintained in a series of databases known as the Chemical Update System (CUS). The MTS IUR data, combined with CUS and the Chemicals in Commerce Information System (CICIS) database, serves as a primary source of information for EPA, as well as other Federal Agencies, about the chemical industry - the chemicals used, where they are produced, how much is produced or imported, and how they are processed and used. The chemical industry is dynamic, therefore continual updating of the database is necessary.

EPA collects readily obtainable (to the manufacturer or importer) exposure-related data that can be used to better establish priorities for EPA's Existing Chemical Assessment program. The IUR data elements are related to or are indicative of three components of exposure. These components are: (1) the size of human populations potentially exposed, (2) the potential routes of exposures experienced by the environment or humans, and (3) the frequency and duration of potential exposures. Examples of data elements of interest for each component are:

- The size of human populations potentially exposed can be estimated based on several factors: production volume, number of workers reasonably likely to be exposed, downstream industrial and commercial uses, and types of industries using the chemical substance.

- The potential routes, magnitudes, and concentrations of exposures can be estimated based on the physical state of the chemical, how it is used, and the concentration of the chemical.

- The frequency and duration of potential exposures can be estimated based on the type of industrial or commercial and consumer use and the type of population.

EPA has demonstrated the usability of the 2006 IUR data by making public, less than a year after the close of the 2006 IUR submission period, risk-based prioritization documents providing screening-level exposure and risk assessments for a number of chemicals in the Agency's HPV Challenge program. These screening-level assessments rely on the IUR manufacturing, processing, and use exposure-related information.

EPA's careful design of the IUR data collection facilitated efficient data management and use. Data collected through the 2006 IUR are placed into a relational database in the Agency's Manage Toxic Chemicals (MTS) system, which can be easily searched, compared, and used. The collection of specific data, organized by codes, instead of textual information presented in an unstructured manner, lends itself to such a database format. In addition, electronic IUR submissions allow data to be entered into the database more accurately and expeditiously, resulting in a quick turnaround between the submission of the data to the Agency and the availability of the data for use. More than half of all reports were submitted electronically for the 2006 IUR, and the Agency expects that figure to increase in subsequent years.

Data Uses

Data generated by the IUR are used in a wide variety of programs fundamental to fulfilling the Agency's TSCA statutory mandate. EPA's primary use of these data is to identify priority TSCA chemicals for more detailed information gathering, risk assessment, and risk management, and to develop targeted programs to protect human health and the environment. Since screening chemical risks generally requires a combination of both hazard and exposure information, the absence of exposure-related data beyond production volume data in the previous collection cycles severely limited the utility of the IUR data for risk screening. This lack of exposure-related data made it difficult for EPA and others to identify chemicals of concern, or resulted in generating overly conservative exposure assessments based on incomplete information. The IUR manufacturing, processing, and use exposure-related data, compiled into a searchable database format, enable EPA and others to more readily screen chemicals for potential exposure and risk. These reviews allow EPA and others to better prioritize chemicals to identify those warranting more detailed assessments, and to reprioritize chemicals of lower concern for review. Current and potential uses of these data by EPA and others are discussed below. Note that these examples are illustrative, not exhaustive. Programs using the IUR data range from the more traditional existing chemicals risk screening efforts, such as the Chemical Assessment and Management Program (ChAMP), to voluntary programs, such as Design for the Environment (DfE), to individual requests for analysis of chemicals not specifically associated with a particular program. The Agency

anticipates that, as was true even for the basic production data reported under previous collections, new uses of current IUR data by EPA and by others will continually emerge and cannot be predicted at this time.

The New Chemicals Program's PMN review process provides an excellent example of how IUR data can assist EPA in protecting human health and the natural environment. EPA uses exposure-related data from PMNs to generate screening-level risk assessments for regulatory decision making under TSCA section 5. Using this information in combination with technical references and other research, EPA is able to estimate the number of manufacturers who may use a new substance. EPA also is able to estimate releases of the new substance from processing and from product manufacturing, resulting in estimated environmental concentrations of the new substance due to its release and estimated general population exposures to a new substance. EPA also uses the information on processing and use in combination with data and modeling to estimate the numbers of workers and consumers who may be exposed to a new substance, and their estimated exposures to a new substance. Based on the estimated hazards of a new substance, it is determined whether the exposures to the new substance estimated for potentially-exposed workers, general population, consumers, and aquatic species fall below levels of concern. A similar process for existing chemicals is now possible with the IUR data.

Current Uses of the 2006 IUR Data

- The Security and Prosperity Partnership of North America (SPP) program is a collaboration among the United States, Canada, and Mexico to accelerate and improve effectiveness of actions to safeguard the health and environment, provide cost-effectiveness for businesses and governments, and strengthen regulatory authority.

- EPA initiated the Chemical Assessment and Management Program (ChAMP) to fulfill commitments made under SPP. The Agency is developing screening-level Risk-based Prioritization (RBP) documents that summarize basic hazard and exposure information on HPV Challenge program chemicals, identify potential risks, note scientific issues and uncertainties, and indicate the initial priority being assigned by the Agency for potential future appropriate action. The 2006 IUR data is essential to the development of these RBP documents, providing the screening level exposure-related data necessary for the initial priority determination.

- The IUR data provides EPA with the ability to access and initiate appropriate action on over 6,750 existing chemicals which have production volumes of 25,000 pounds per year by 2012. The Agency is using the 2006 IUR data to develop screening-level assessments for Medium Production Volume (MPV) Chemicals.

- The TSCA Interagency Testing Committee (ITC) has requested IUR data to identify chemicals as candidates to recommend for further testing or information reporting. In this process, the ITC eliminates many chemicals for which the ITC does not recommend further testing. The ITC has fourteen (14) U.S. Government member organizations**:** the Agency for Toxic Substances and Disease Registry (ATSDR), Council on Environmental Quality (CEQ), Consumer Product Safety Commission (CPSC), Department of Agriculture (USDA), Department of Defense (DOD), Food and Drug Administration (FDA), Department of the Interior (DOI), EPA, Department of Commerce (DOC), National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH), National Science Foundation (NSF), and Occupational Safety and Health Administration (OSHA). The ITC will use the IUR information to refine its selection of chemicals for testing, information reporting, or another recommendation. In the past, the primary exposure information the ITC used is production volume from the IUR; the addition of use and exposure information allows ITC to refine its recommendations. For instance, in 1991, OSHA asked ITC to review a list of chemicals to recommend for dermal absorption testing - ITC recommended 80 chemicals for testing. With the additional IUR information, ITC could have screened those 80 chemicals and provided a more accurate, targeted recommendation.

- The U.S. Geological Survey (USGS) has requested IUR information to help prioritize chemicals in their National Water Quality Assessment Program.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

The data included in this information collection (i.e., production volume, chemical manufacture, exposure, and use data) are not otherwise comprehensively or systematically collected at the national level. There are a variety of sources for pieces of the information, but the sources are either incomplete or incompatible. For instance, information currently available at both the federal and state levels is collected to support specific federal and state programs, initiatives, or regulatory actions. As an example, under EPCRA sections 311 and 312, states collect data on the maximum and average amount of a chemical onsite for the purposes of emergency response planning. This information does not substitute for the annual volume of a chemical and is not available for use in a national-level screening program.

In the past, EPA explored a wide variety of public data sources, as demonstrated by the following three documents: *Inventory Update Reporting Rule (IUR) Amendments Technical Support Document: Exposure-Related Data Useful for Chemical Risk Screening* (EPA 1996a), *Revised Economic Analysis of the Amended Inventory Update*

Reporting Rule (EPA 2002a), and *A Review of Existing Exposure-Related Data Sources and Approaches to Screening Chemicals: A Response to CMA* (EPA 1999). These documents contain extensive discussions of chemical information collections and conclude that the information collected in the IUR program is not available elsewhere. EPA has spent considerable effort and resources evaluating other data sources that could potentially provide the accurate and up-to-date information that the Agency needs. A primary consideration, as mandated by TSCA, was to not subject industry to unnecessary or duplicative reporting. The information sought under the IUR is not accessible to EPA through other means. Although some useful data exist in some sources, the data are insufficient due to a lack of scope, currency, and detail. Without the IUR, EPA can not update the TSCA Inventory as required by law, and remains unable to efficiently screen potential risks posed by a large number of chemicals on the TSCA Inventory.

One mechanism in particular received scrutiny from EPA as an alternative to the current IUR: the TSCA Preliminary Assessment Information Reporting (PAIR) rule (40 CFR part 712). However, PAIR would not be an efficient or cost-effective way to compile a database to allow the large-scale risk screening of chemicals on the TSCA Inventory. Although PAIR is a useful data collection tool when one or a small group of chemicals is targeted for risk assessment, it is limited when collecting information on a large number of chemicals. Additionally, the PAIR rule has fewer, less definitive data elements than the IUR, is a one-time collection versus the five year collection cycle of the IUR, and will not provide data sufficient to meet the goals of the IUR. Use of PAIR only implies that EPA should continue to set risk-screening priorities based on hazard and production volume alone, or in response to requests from others. This approach greatly hinders EPA's ability to make effective and efficient risk management decisions.

EPA continues to use existing data sources and information sets. However, the existing sources are generally best used when conducting a more detailed risk assessment of a specific chemical of concern, rather than preliminary risk screening of a large set of chemicals. The 2006 and later IUR submissions provide a consistent set of screening-level exposure data that allow EPA to better identify on a relative basis the chemicals of highest priority for further risk evaluation. EPA uses the IUR data to identify those specific chemicals that are of potential concern and need follow up assessment. For instance, the IUR exposure-related data coupled with the HPV Challenge Program hazard data provide the input needed to effectively develop risk-based priorities for more detailed assessment of chemicals. Once EPA has determined that a specific chemical (or group of chemicals) has sufficient potential for exposure to warrant further assessment, the Agency will utilize the other information sources and data gathering tools as appropriate.

The IUR focuses on information specific to the manufacture and use of chemicals, including exposure potentials during various activities; this information is not available elsewhere. One past source of data, NIOSH's National Occupational Exposure Survey (NOES), represented a valuable source of data concerning the number of exposed workers. NOES was completed in 1981 and is now recognized as being significantly

dated. Furthermore, information regarding chemical use has never been collected in a systematic manner.

3(b) Public Notice Required Prior to ICR Submission to OMB

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on November 4, 2008 (73 FR 51805, September 5, 2008). EPA received comments from the American Petroleum Institute (API) and the Consumer Specialty Products Association (CSPA). These comments are addressed in Attachment 5.

3(c) Consultations

Additionally, under 5 CFR 1320.8(d)(1), OMB requires agencies to consult with potential ICR respondents and data users about specific aspects of ICRs before submitting an ICR to OMB for review and approval. In accordance with this regulation, EPA submitted questions to nine parties via email. The individuals contacted were:

Bill Allmond
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Synthetic Organic Chemical Manufacturers Association
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William Carteaux
President
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Rod Dwyer
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Dennis Griesing

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EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above nine potential respondents is provided in Attachment 6.

3(d) Effects of Less Frequent Collection

The Agency needs to be able to make accurate chemical regulatory decisions in a timely and cost effective manner, especially since alternative data sources do not exist for these data. The effect of less frequent collection of these data is to significantly diminish the Agency's ability to understand the chemical industry and monitor the production levels of chemicals produced or imported in the United States. Based on IUR data, the statistics show that chemical industry product lines and manufacturing in the United States change rapidly from one reporting period to the next. This demonstrates that the

IUR collection needs to be undertaken on an ongoing basis in order for the Agency to fulfill its mandate to keep the TSCA Inventory current under section 8(b) of TSCA.

Despite these issues, EPA *decreased* the frequency of collection from every four years to every five years when promulgating the 2003 Amendment (*see* 68 FR 848, January 7, 2003). Any further decrease in the reporting frequency would jeopardize the utility of the data in decision making. Experience with past IUR collections illustrates that from one collection to the next collection, there was a turnover in chemicals reported of about 25-30%; that is, twenty-five to thirty percent of the chemicals reported in one collection year were not reported in the next collection year. Less frequent collection is expected to increase this turnover, reducing the utility of the database.

Other dynamic aspects of the chemical industry are less easy to measure. Production volumes or chemical uses can change from one year to the next, due to activities such as changing market conditions, batch processing, or the development of new uses for the chemical. Production sites switch owners and the products produced at a site can change. Less frequent collection would mean the EPA could be using outdated information, making decisions that reflect a situation no longer in existence.

3(e) General Guidelines

This collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6, with the exceptions listed below.

The record retention period of this collection is five years, exceeding the PRA maximum of three years. This is necessary to ensure companies retain records long enough to facilitate completion of Form U (EPA Form 7740-8) in the next collection, which is in five years, and to allow EPA's enforcement activities to cover two IUR reporting cycles.

Confidential Business Information (CBI) claims limit access to the IUR data, especially by the general public. EPA recognizes that some information submitted to the Agency is legitimately business confidential; because of this, EPA's review of CBI data is an inherently governmental function that EPA must perform to protect human health and the environment.

3(f) Confidentiality

Respondents may claim information submitted to EPA under this rule as confidential if such information would reveal the submitters' trade secrets or proprietary information as defined by TSCA section 14 and existing TSCA regulations. EPA has long-established procedures for handling, storing, processing and disposing of TSCA confidential information. Transfers of this information to other governmental agencies can only be accomplished if the other agency agrees to adhere to all TSCA confidentiality provisions. EPA will maintain standard CBI procedures to protect any confidential, trade

secret, or proprietary information from disclosure in accordance with EPA's confidentiality regulation, 40 CFR Part 2, Subpart B.

3(g) Sensitive Questions

This collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondent NAICS Codes

The regulated community consists of companies manufacturing or importing chemicals listed on the TSCA Inventory and regulated under TSCA section 8. In general, the industry segments that compose the regulated community for the rule are those that produce or import organic and inorganic chemicals. Most respondents previously reported information under the IUR. Due to the past experience the Agency has had with respondents to the IUR, it is anticipated that the majority of the respondents affected by this collection activity are from the following North American Industrial Classification System (NAICS) code categories:

325 - Chemical Manufacturing (including importing)
324 - Petroleum and Coal Product Manufacturing (including importing)

The subsectors identified above represent the designation of sites that would likely be subject to IUR reporting. However, many factors relate to the nature of these sites, making identification of the regulated community more difficult. For example, NAICS codes reflect a site's *primary* activity, omitting substantial participation a company may have in other industry activities. Secondly, NAICS codes assigned to parent companies reflect the parent company's primary activity, although many parent companies are primarily holding companies with small subsidiaries. Each of these small subsidiaries may belong in a completely different industry classification based on its own primary activity. Information on parent company NAICS codes does not provide a very accurate characterization of the types of sites subject to reporting, and facilities that do not fall under these categories must still report if they meet the reporting criteria.

Generally, TSCA section 8 excludes small manufacturers (including importers) from reporting. EPA defines small manufacturers (including importers) for purposes of IUR and certain other reporting in 40 CFR 704.3.

4(b) Information Requested

(i) Data items

The IUR data elements are primarily related to or indicative of three components of exposure. These components are: (1) the number of ecosystems or size of human populations potentially exposed, (2) the potential exposures or concentrations experienced by the environment or humans, and (3) the frequency and duration of potential exposures. The data enhances EPA's ability to evaluate each of these components of exposure. Respondents are required to submit certain known or reasonably ascertainable manufacturing exposure- related information and readily obtainable processing and use exposure-related information.

Using Form U (EPA Form 7740-8; see Attachment 4), respondents report on data items as follows:

- *Certification.* Company Official must certify by signature and date that to the best of their knowledge and belief 1) all information entered on Form U has been completed in compliance with the regulatory requirements; and 2) that the confidentiality statements on Form U are true and correct.

- *Parent Company and Technical Contact Information.* Company name and Dun and Bradstreet number; Technical Contact name, phone number, mailing address, and email address.

- *Plant Site Identification.* Plant Site name, Dun and Bradstreet number, and street address (including county).

- *Chemical Identification (for chemicals with reporting year, site-specific production volume of 25,000 pounds or more).* Specific chemical name and CAS registry or accession number, as applicable.

- *Manufacturing Information.* Whether chemical is site-limited or not, whether chemical is manufactured or imported, manufactured production volume, imported production volume, number of workers reasonably likely to be exposed (in ranges), maximum concentration of chemical (in ranges), and physical form of chemical with associated percent production volume.

- *Industrial Processing and Use Data (only for chemicals with reporting year, site-specific production volumes greater than or equal to 300,000 pounds).*[3] Up to 10 unique combinations of type of process or use (code), North American Industrial Classification System (NAICS) code associated with specific combination, and industrial function category. For each unique combination, the percentage of

[3] Certain chemicals, specifically listed in the IUR regulation at 40 CFR 710.46(b), are partially exempt and only report Parts I and II of Form U, regardless of their production volume.

respondent's production volume, number of processing and use sites (in ranges), and number of reasonably likely to be exposed workers (in ranges).

- *Commercial and Consumer End-use Exposure Data (only for chemicals with reporting year, site-specific production volumes greater than or equal to 300,000 pounds).*[4] Commercial/consumer use category whether a chemical is intended for use in children's products, percentages of respondent's production volume in each commercial/consumer use category, and maximum concentration of chemical in each commercial/consumer use category (in ranges).

(ii) Respondent Activities

A representative respondent would engage in the following activities:

(i) *Compliance Determination* -- determine whether reporting is required for a chemical manufactured at a particular site, based on the production volume thresholds and the applicability of certain reporting exemptions;

(ii) *Rule Familiarization* -- become familiar with the full requirements of the rule, which entails reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which reporting requirements will be met for each chemical;

(iii) *Preparation and Submission of Reports* -- compile the required information and complete a reporting form, including determining the CBI status of information and fulfilling appropriate substantiation measures. Respondents use a software program (eIUR) to complete Form U (EPA Form 7740-8), and either complete only Parts I and II for chemicals produced in quantities less than 300,000 pounds or complete the full form for chemicals produced in quantities of 300,000 pounds or greater. Respondents must complete the form as applicable and submit information associated with this data collection either via the Internet, as a file on a CD-ROM, or as a printed paper copy; and

(iv) *Recordkeeping* -- retain records for five years following a submission period.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY AND INFORMATION MANAGEMENT

5(a) Agency Activities

The activities routinely conducted by EPA related to the processing, analysis and storage of the information collected under this rule include the following:

[4] Ibid.

- review and verify forms as they are received
- answer respondent's questions and provide any necessary assistance
- process submissions for inclusion in IUR database
- review requests for confidentiality in the submissions
- maintain the database
- distribute the data

5(b) Collection Methodology and Management

The information collection activity under this rule includes an initial reporting period in 1986 and subsequent reporting periods every four years to 2006. The 2003 Amendments to the IUR extended the reporting cycle to five years, therefore the next reporting will occur in 2011. For each reporting period, all manufacturers (including importers), except for those defined as "small manufacturers," are required to submit information on every substance required under this rule that they manufacture, including import, in sufficient quantities.

(i) Collection Methodology

All manufacturers (including importers) of subject chemicals are required to report under the IUR rule. Potential reporters are notified of the need to report in three ways: (1) EPA publishes a Federal Register notice, (2) letters are sent to previous IUR submitters, and (3) articles are published in the trade press. Reporting materials, including the eIUR reporting software and a variety of guidance documents (Instruction Manual, Q&As, Case Studies), are available on the EPA's IUR website. In addition, respondents can obtain the reporting materials from the TSCA Hotline.

To aid persons subject to this information collection, the Agency's TSCA Hotline is also available to answer questions regarding the IUR requirements or submission process. When Hotline staff are unable to answer questions, the submitter is referred to OPPT's Information Management Division (IMD) or Chemical Control Division (CCD), as appropriate. Other Divisions within OPPT are used as necessary.

Respondents can submit information associated with this data collection either through the Internet, as a file on a CD, or as a printed paper copy. Initial data receipt and processing activities (data entry, quality assurance, CBI claim reviews, etc.) will be expedited by the receipt of the data electronically. Internet submissions require the use of the eIUR software and the Agency's Central Data Exchange (CDX). Reporting via the Internet is the most efficient of the choices, as the respondent receives almost immediate feedback of the receipt of their submission and EPA is able to directly load the information into the IUR database. Information submitted on a CD involves different levels of human intervention, depending upon the format of the file – those prepared with the eIUR software as encrypted files simply needed to be uploaded to the IUR database, which those submitted as PDFs have to be printed out and handled as paper submissions. Paper submissions are scanned using Optical Character Recognition (OCR) technology

and hand checked for accuracy. Those that were handwritten or scanned poorly were key-entered.

(ii) Data Management

This section describes the Agency tasks required for efficiently processing submissions under the IUR. The tasks for which the Agency is responsible are presented under four main categories: database systems development, guidance document development, Form U processing, and additional tasks. The task descriptions presented below generally do not change.

IUR data are used to update and augment the Chemical Update System (CUS) database. Once updated, the database is then available to EPA technical reviewers for export into their various analytical modeling systems and databases. The IUR database is also available for quick screening and other direct uses. Non-CBI information is publicly available.

- Database Systems Development and Maintenance -- The Agency is responsible for having adequate information systems in place to support the CUS database that serves as the primary data storage medium for IUR collections. File servers with appropriate backup are used to contain the IUR databases. Following the 2006 IUR collection, EPA updated the technology used to store the IUR data, storing it in a larger Manage Toxic Substances (MTS) database. In addition, IUR data are tracked via the correspondence tracking system utilized by the Confidential Business Information Tracking System (CBITS) located within the Confidential Business Information Center (CBIC).

- Guidance Document Development -- The Agency is responsible for developing guidance to assist reporters in complying with IUR requirements. The guidance documents usually are developed by a contractor with oversight by Agency personnel.

- Form U Processing -- The Agency is responsible for handling processing of IUR submissions. This includes developing standard operating procedures and documentation for all stages in the IUR document life cycle, document receipt and tracking, data input, quality control, file and database maintenance, information security, CBI aggregation policy, data dissemination, and staff training. For the 2006 IUR submission period, EPA developed new processes to receive IUR submissions over the Internet, using the Agency's Central Data Exchange (CDX) system.

- Additional Activities -- The Agency develops reporting software and makes it available on the Internet, along with various supporting documents. In addition, the Agency is responsible for providing the TSCA Hotline with standardized responses for frequently asked questions; preparing mailings, mailing lists, and labels; and developing outgoing information materials.

5(c) Small Entity Flexibility

Ample flexibility is provided. This regulation affects only businesses -- governmental jurisdictions and not-for-profit organizations are not required to take any action. Small manufacturers (including importers), in accordance with TSCA section 8(b) (40 CFR Sections 710.29 and 710.28), are exempt and therefore are generally not subject to any of the reporting or recordkeeping requirements. A manufacturer (including importer) is considered a small business if (1) the firm's total annual sales when combined with those of its parent company (if any) are less than $40 million for the reporting period and (2) its total production and/or importation of the chemical substances, mixture or category, for the reporting period, does not exceed 100,000 pounds (45,000 kilograms) at an individual site owned and controlled by the firm. The *Revised Economic Analysis for the Amended Inventory Update Final Rule* determined that the impact on these companies is significantly less than 1% of revenues (EPA 2002a). EPA has determined that there is not a significant economic impact on a significant number of small entities.

5(d) Collection Schedule

The reporting period shall be from June 1, 2011 to September 30, 2011. This reporting period/schedule follows the requirements of 40 CFR 710.53.

Federal Register Notice	February 2011
Send out letter to 2006 IUR mailing list with instructions describing how to obtain the reporting documents	March 2011
Going Public efforts: articles in industry press, meetings with regulated community, and information on the IUR website	March 2011
Open period for filing 2011 IUR Forms	June 1, 2011 - September 30, 2011

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

This ICR estimates burden for an information collection effort that reflects the requirements of the 2003 Amendments to the Inventory Update Reporting rule (IUR). The previous IUR, which covered one collection from 2003 to 2008, required chemical manufacturers and importers to collect, maintain, and submit location and production volume information for chemicals with annual production volumes of 25,000 pounds or higher and required site and production information. The Amendments also require sites

with production volumes of 300,000 pounds or higher of a reportable chemical to collect, maintain, and submit additional information to EPA regarding chemical processing and use. In the 2006 collection, manufacturers of inorganic chemicals, regardless of production volume, were partially exempt (i.e., submitters do not report processing and use information for inorganic chemicals). For the reporting period covered by this ICR, the partial exemption for inorganic chemical manufacturers is no longer applicable and submitters are required to fully report information on inorganic chemical substances when production volumes at a site are 300,000 pounds or higher. However, petroleum process streams and other chemical substances specifically listed are partially exempt from the information collection. Manufacturers of such substances are not required to report processing and use information.

For this ICR, the burden estimates for report preparation and submission were derived from a survey conducted by EPA in 1996 (under OMB Control No. 2070-0034) to assess the potential burden associated with the amended IUR. The survey was distributed to previous IUR reporters selected from the IUR database. Burden estimates are developed for the compliance activities and then multiplied by the number of facilities or reports (as appropriate) to estimate the total burden to respondents. Estimates of facilities and reports are taken from the October 2007 version of the IUR database which includes data from the most recent (2006) IUR collection. The amount of effort (and therefore cost) required for each of these steps varies depending on the type of chemical, company size, and the variety of uses of the chemical. The tasks associated with IUR reporting during the period of this ICR are those listed in Section 4(b)(ii). To complete the collection, the respondent would:

$ Determine compliance;
$ Become familiar with rule;
$ Prepare and submit report; and
$ Keep records.

Worksheet 1 illustrates the respondents' burden of collection on a per-collection basis. All burden hour estimates are based on the "high" scenarios in the *Revised Economic Analysis of the Amended Inventory Update Reporting Rule, Final Report* (EPA 2002) (IUR EA). Estimates for numbers of reporters and reports come directly from 2006 reported data. This analysis estimates that a total of 4,190 Form U's will be received with a total of 28,398 reports where reports represent a unique site/chemical combination. Of the 28,398 reports, 51% are estimated to be full reports and 49% are estimated to be partial reports. The total number of chemicals with reports is 7,641.

The IUR requires reporting on a "per site" basis rather than a "per company" basis, therefore, each site is considered a respondent. A total of 4,190 respondents are estimated to report to this information collection. The Agency estimates the typical annual burden per respondent for this information collection activity to be 98 hours (a collection occurs once every five years). This burden estimate assumes that each of the respondents will report IUR information for an average of 3.3 full reports and 3.4 partial reports. There are no third party burdens associated with these activities.

6(b) Estimating Respondent Cost

Worksheet 1 provides the respondents' cost of reporting on a per-collection basis. The costs in worksheet 1 have been updated to reflect wages rates in 2007 dollars.

Worksheet 1: Respondent Burden and Cost Estimates, Per Activity (2007$)

Activity		Burden Hours			Total Hours per Activity	Cost per Unit	Units per Site	Total Cost per Activity	Total Burden Hours per site
		Managerial @$68.18	Technical @$55.44	Clerical @$27.47					
Compliance Determination (per site)		0.00	4.00	0.00	4.00	$221.76	1 (4,190 sites)	$221.76	4.00
Rule Familiarization (per site)		2.00	2.00	0.00	4.00	$247.24	1 (4,190 sites)	$247.24	4.00
Report Preparation and Submission (per report)	Partial Form	5.73	11.36	2.56	19.65	$1,090.79	3.34 (13,989 partial reports)	$3,599.61	64.85
	Full Form	25.98	66.75	12.54	105.27	$5,816.41	3.44 (14,409 full reports	$19,775.79	357.92
Recordkeeping (per Report)		2.00	4.00	2.00	8.00	$413.06	6.78 (28,398 reports)	$2,808.81	54.4
Total Units/Site							15.56		
Total Hours		35.71	88.11	17.1	140.92				485
Total Costs		$2,434.71	$4,884.82	$469.74		$7,789.27			

6(c) Estimating Agency Burden and Cost

Annual costs and burden to the Agency under the IUR have been estimated by calculating the number of full-time equivalents (FTEs) required to undertake certain prescribed tasks. These tasks are outlined in the IUR EA. FTE requirements have been reduced from four FTE's in the EA to two because many activities in the EA were estimated to be one-time costs. One time costs, associated with the requirements of the IUR amendments, are not considered in this ICR. FTEs are converted to dollars by multiplying estimated FTE yearly earnings for the appropriate staff level (GS level) by the number of FTEs for each staff level, and then summing the products. Yearly earnings have been calculated to include fringe benefits of 41 percent of the base salary and overhead costs of 17 percent of the base salary plus the fringe benefits.

EPA costs also include payment for extramural task completed by contractors. These costs were estimated at $84,960 for document receipt and tracking entry and

$53,100 for backup systems operation in the previous ICR (2005). Costs were inflated from 2005 to 2007 dollars using the Employment Cost Index (ECI), seasonally adjusted, for white-collar occupations in private industry (BLS, 2008). The ECI for 4th quarter 2005 was 100.2 and 106.8 for 4th quarter 2007. Using these indices, the costs for document receipt and tracking entry and systems operation are estimated at $90,737 and $56,711, respectively.

Additional Agency costs have been estimated based on the budget that is appropriated for the IUR and found in the previous ICR.

Worksheet 2 presents the per-cycle Agency costs of the IUR information collection. The Agency expects only one collection to occur during the time period that this ICR is effective. Therefore, the estimated total annualized cost incurred by the Agency is calculated by summing the recurring costs and the one-time costs, and dividing by the five years of the reporting cycle, which yields $88,077.

Worksheet 2. Estimated Per-Cycle Agency Costs for the IUR (recurring every five years)

Task	**IUR Costs (2007 $)**
Tasks Performed by Agency Personnel	
Quality Control of Data Entry	$111,622 (1 FTE, GS-12, Step 1)
Data Processing, Systems Development, and Contract Oversight and Management	$132,737(1 FTE, GS-13, Step 1)
Subtotal	$244,359
Extramural Tasks (contractor)	
Document Receipt and Tracking and Data Entry	$90,737
Backup Systems Operation	$56,711
Subtotal	$147,448
Additional Tasks	
Publication and Printing Forms and Materials	$5,298
Hotline	$42,855
Mailing	$426
Subtotal	$48,579
Total Cost per Collection	$440,386
Total Annual Cost (one collection per 5 years)	$88,077

Note: All costs associated with FTEs include 41 percent fringe benefits and 17 percent overhead. For example, the GS-12 Step 1 salary for 2007 was $69,764. This was multiplied by an assumed loading factor of 1.6 (rounded) to reflect fringe benefits and overhead, resulting in a fully loaded cost per FTE of 1.6 X $69,764 = $111,622.

Sources:

Office of Personnel Management, 2007. "2007 General Schedule Locality Notes of Pay for Washington-Baltimore, DC-MD-VA-WV." <http://www.opm.gov/oca/2008tbls/GSannual/html/GSDCB.HTM> As obtained on April 16, 2008.

Information Management Division, 1996. Questions for Branches within OPPT with Responsibility for IUR Data Collection, Processing, and Storage. Information Management Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Washington, DC.

EPA, 1996b. Transcribed Telephone Conversation with Ruth Heikkinen on Hotline and Mailing Costs, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Washington, DC.

EPA, 1996c. IUR Amendments—Agency Costs Question. Memorandum from Ward Penberthy to Susan Krueger, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency., Washington, DC.

6(d) Bottom Line Burden Hours and Cost: Master Table

The total burden per reporting cycle collection is estimated to be 2,052,423 hours. Given that there is only one collection every five years, the annual burden is estimated to be 410,485 hours. The total cost per reporting cycle collection is estimated to be $113.1 million. The cost per year is estimated to be $22.6 million. Details are provided in Worksheet 4.

EPA estimates that Agency costs will be $886,607 for the collection, or $221,652 annually.

Worksheet 4: Total Estimated Burden Hours and Costs (2007 $)

Activity		Unit of Analysis	Total per Unit		Number of Units	Totals per Collection	
			Hours	Cost		Hours	Cost
Compliance Determination		Site	4.00	$ 221.76	4,190	16,760	$ 929,174
Rule Familiarization		Site	4.00	$ 247.24	4,190	16,760	$ 1,035,936
Report Preparation and Submission	Partial Form	Report	19.65	$1,090.79	13,989	274,884	$ 15,259,061
	Full Form	Report	105.27	$5,842.66	14,409	1,516,835	$ 84,186,888
Recordkeeping		Report	8.00	$ 413.06	28,398	227,184	$ 11,730,078
Subtotal per Collection (five years)					65,176	2,052,423	$113,141,137
Subtotal Annually [1]					13,035	410,485	$ 22,628,227

[1] This collection occurs once every five years; therefore the annual totals are equal to the totals for the collection divided by five.

The IUR EA estimated that there would be 3,036 respondents of which 758, or 25%, would be small. Applying the 25% to the 4,190 estimated respondents for this ICR results in an estimated 1,048 small respondents. It is important to note that this is very likely an overestimate. The IUR exempts small businesses from reporting. However, there are some cases where a small business does report (e.g., they company may report a chemical subject to certain sections of TSCA that require reporting) so an estimate is presented in this ICR. Worksheet 5 includes summary burden estimates.

Worksheet 5. Summary Burden Estimates (see Worksheets 1 and 4)

Number of Small Respondents	Number of Respondents	Units (Responses) per Respondent	Total Annual Responses	Total Annual Hours	Burden Hours per Response
1,048	4,190	15.56	13,035	410,485	31.5

6(e) Reasons for Change in Burden

There is a net decrease in the annual burden of 3,090 hours (from 413,575 hours to 410,485) from the estimates in the information collection request most recently approved by OMB. This is due to both program changes and adjustments, as detailed below.

In the 2006 ICR, reporting was required every four years. EPA has revised the reporting period to once every five years. This results in the total estimated burden for reporting to be divided over five years rather than four in order to calculate annual burden. This represents a program change and decreases the annual burden by an estimated 102,621 hours.

In the collection covered by the previous ICR, inorganic chemicals were, in some cases (i.e., when produced in quantities less than 300,000 lbs.), exempt from full reporting and, therefore, only partial reports were required. In subsequent reporting periods, however, including the period covered by this ICR, respondents with inorganic chemicals must complete full reports in all cases. This represents a program change and increases the annual burden by an estimated 77,650 hours.

Program changes therefore net to an overall estimated decrease of 24,971 hours.

EPA used data reported to the 2006 IUR collection to estimate the total number of respondents. Total sites reporting were estimated to be 4,190 for this collection. In the previous ICR, the number of sites responding was estimated to be 3,026 or an additional 1,164 respondents. This represents an adjustment and increases the annual burden by an estimated 130,821 hours.

An additional adjustment is reflected in a reduction in the estimated burden hours for rule familiarization from 30 hours per site to 4 hours per site. This change is made because significant rule changes were made in the period covered by the previous IUR and extra hours were allocated to interpret new requirements. During the period covered by this ICR, the rule is not expected to change significantly; therefore, those additional hours were removed. This represents an adjustment and decreases the annual burden by an estimated 108,940 hours.

Adjustments therefore net to an overall estimated increase of 21,881 hours. The net change to the annual burden between program changes and adjustments therefore is an estimated decrease of 3,090 hours.

6(f) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0162, is estimated to average approximately 31.5 hours per response. According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register when approved, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a docket for this ICR under Docket ID No. EPA-HQ-OPPT-2008-0504, which is available for public viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1544 and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

An electronic version of this docket is available at http://www.regulations.gov/. Use the federal government wide electronic docket and comment system at www.regulations.gov to submit or view public comments, access the index listing of the docket contents, and to access those documents in the docket that are available electronically. Once in the system, select "advance search," then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. EPA-HQ-OPPT-2008-0504 and OMB control number 2070-0162 in any correspondence.

SOURCES

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ATTACHMENTS TO THE SUPPORTING STATEMENT

These attachments are available in the electronic docket at www.regulations.gov, under Docket ID No. EPA-HQ-OPPT-2008-0504.

Attachment 1	Toxic Substances Control Act, Section 8(b) (15 USC 2607(b))
Attachment 2	40 CFR 710 - TSCA Inventory Update Reporting Rule
Attachment 3	IUR ICR Calculations
Attachment 4	Form U - EPA Form 7740-8
Attachment 5	Public Comments on Renewal and EPA Response to Comments
Attachment 6	Consultation Process: EPA's Solicitation for Comments