March 8, 2011

**SUPPORTING STATEMENT FOR A REQUEST FOR OMB REVIEW UNDER THE PAPERWORK REDUCTION ACT**

## 1. IDENTIFICATION OF THE INFORMATION COLLECTION

### l(a). Title and Number of the Information Collection

**TITLE: Correction of Misreported Chemical Substances on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory**

**EPA ICR No.: 1741.06 OMB Control No.: 2070-0145**

### l(b). Short Characterization

Section 8(b) of the Toxic Substances Control Act (TSCA), requires the Environmental Protection Agency (EPA) to compile and keep current an Inventory of Chemical Substances in Commerce (hereinafter "the Inventory"), which is a listing of chemical substances manufactured, imported and processed for commercial purposes in the United States. Individual plant or factory sites producing chemicals submit the required information.

This information collection request pertains to the use of the TSCA Chemical Substance Inventory Reporting Form C (EPA Form 7710-3C; see Attachment 4), which the chemical industry uses exclusively in submitting requests to EPA's Office of Pollution Prevention and Toxics (OPPT) for correcting misreported chemical identities of substances listed on the Inventory. Such requests pertain only to errors discovered in the original submissions to the Inventory when the Inventory was first established in 1979.

Each year, OPPT receives a small number of such correction requests from chemical companies or their legal representatives. In almost all cases, a submitter who wishes to correct the chemical identity of a substance that was previously misreported for the Inventory initiates these requests for correction. The correction mechanism allows the submitter to add the correct substance to the Inventory without having to file a Premanufacture Notice (PMN) under TSCA section 5.

In submitting a request for correction, the submitter provides certain basic information to EPA on Form C. This information is stored in one of EPA's mainframe computers. This information allows OPPT to establish a correct chemical identity that accurately reflects the substance the submitter manufactures. Since the Inventory performs a regulatory function by distinguishing between an existing chemical and a new chemical, it is imperative that the Inventory be accurate. A correct Inventory also ensures the accuracy of EPA's chemical screening and risk assessment activities.

## 2. NEED FOR AND USE OF THE COLLECTION

### 2(a). Need/Authority for the Collection

TSCA requires EPA to identify, assess and control risks of injury to human health and the environment posed by commercial chemicals. TSCA section 8(b) requires EPA to compile and keep current a complete list of chemical substances manufactured or processed in, or imported into, the United States. Under TSCA section 8(a) the Administrator of EPA promulgates rules to provide for the maintenance and collection of records from manufacturers, importers and processors of commercial chemicals. The Inventory Update Rule (IUR), which EPA uses periodically to update the TSCA section 8(b) Inventory, is codified at 40 CFR 710 (see Attachments 1 and 2).

The purpose of the Inventory is to define, for the purpose of TSCA, what chemical substances exist in U.S. commerce. Substances not included on the Inventory are considered to be new substances that are subject to the Premanufacture Notification (PMN) requirements stipulated under section 5(a) of TSCA.

The need for correcting chemical identities listed on the Inventory arose following the initial Inventory reporting period, when both EPA and the chemical industry recognized that substances submitted for inclusion in the initial Inventory could be, for various reasons, incorrectly described by reporting companies. EPA determined that reported substances may have been unintentionally misidentified as a result of simple typographical errors, the misidentification of substances, or the lack of sufficient technical or analytical capabilities to fully characterize the exact chemical substances. Although not required to do so under TSCA, EPA developed guidelines, at the request of industry, under which industry could correct the chemical identities of incorrectly described substances listed in the Inventory. EPA published these guidelines in the Federal Register on July 29, 1980 (45 FR 50544); see Attachment 3.

For the Inventory to perform its regulatory function, it must accurately identify those substances that exist in U.S. commerce. Otherwise the Inventory will not be able to provide reliable information that EPA needs in performing chemical screening and risk assessment activities under TSCA. The submitter, on the other hand, must be certain that the substance they manufacture or import is correctly identified on the Inventory, so that they will be in full compliance with TSCA reporting requirements. The correction mechanism ensures the accuracy of the Inventory without imposing an unreasonable burden on the chemical industry. Without the Inventory correction mechanism, a submitter would have to file a PMN to place the correct chemical substance on the Inventory whenever finding that the previously reported substance was misidentified. This would impose a much greater burden on both EPA and the submitter than the existing correction mechanism.

### 2(b). Practical Utility/Users of the Data

OPPT will use the data contained in the correction request to alter the incorrect chemical identities in the Inventory so that the information is complete and accurate. Many branches of the Agency rely on the Inventory when making regulatory decisions. Within OPPT, the Chemical Control Division (CCD) and the Interagency Testing Committee (ITC) frequently use the Inventory. Both CCD and the ITC rely on the accuracy of the Inventory for screening chemical substances for further attention or testing. If the Inventory data were inaccurate, CCD or the ITC could inadvertently screen a fictitious chemical, i.e., a misreported substance not yet corrected on the Inventory.

As well as providing vital government service, the Inventory provides information necessary to members of industry. Correspondence between the private and public sectors of the U.S. concerning the Inventory is ceaseless. OPPT receives hundreds of inquiries regarding the Inventory each year. These letters are primarily requests for Chemical Abstracts Service (CAS) Registry Numbers or Accession Numbers assigned to a substance, although the Agency also receives a variety of other requests regarding TSCA.

One such request expresses a bona fide intent to manufacture a chemical substance. A "bona fide" letter requests a formal search of the Inventory for a particular chemical substance. If the substance is included on the Inventory, the potential manufacturer need not submit a PMN. Since failure to submit a PMN for a substance not included on the Inventory, i.e., a new chemical, would constitute a violation of TSCA, the Inventory must be correct to ensure that only substances that are actually manufactured are included. An Inventory correction letter requests a change in the Inventory to correct a previously misreported substance. This correction mechanism allows the Inventory to be kept accurately, thus ensuring that the Agency's responses to industry inquiries, e.g., bona fide, Accession Number and CAS Registry Number requests, are accurate. Furthermore, an accurate Inventory also ensures that the Agency performs risk assessments on the correct chemical substance and that industry will not need to submit unnecessary PMNs.

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

### 3(a). Non-Duplication

Not applicable: the required data can only be provided by the submitter and no other government agency collects such information.

### 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 October 5, 2010 (75 FR 47589, August 6, 2010). EPA received one comment from the American Chemistry Council (ACC). This comment is 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 several parties via email. The individuals contacted were:

Richard Denison, Senior Scientist
Environmental Defense
E-mail: rdenison@edf.org

Brent Erickson, Executive Vice President
Industrial and Environmental Section
Biotechnology Industry Organization
E-mail: berickson@bio.org

Howard Feldman, Director
Regulatory and Scientific Affairs
American Petroleum Institute
E-mail: feldman@api.org

Douglas Fratz, Vice President
Scientific and Technical Affairs
Consumer Specialty Products Association
E-mail: dfratz@cspa.org

Linda Greer
Natural Resources Defense Council
E-mail: lgreer@nrdc.org

Terry L. Medley, J.D., Global Director
Corporate Regulatory Affairs
DuPont Environment and Sustainable Growth Center
Fax: 302-773-1361
E-mail: Terry.L.Medley@USA.dupont.com

Thomas G. Neltner, Executive Director
Improving Kids' Environment Coalition
E-mail: tneltner@gmail.com

Dan Newton, Manager
Government Relations
SOCMA
E-mail: newtond@socma.com

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

**3(d). Effects of Less Frequent Collection**

Not applicable, since the frequency of correction depends wholly on industry.

**3(e). General Guidelines**

To the best of EPA's knowledge, this collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6.

**3(f). Confidentiality**

Respondents may claim information submitted to EPA on the correction form as confidential if release of such information would reveal the submitter's trade secrets or proprietary information, as defined by TSCA section 14. A respondent may claim as confidential any information submitted on the reporting form, except the identity of a chemical substance that the respondent has not claimed as confidential in the existing Inventory data base.

Respondents must assert claims of confidentiality at the time they submit the information to EPA and only in the manner specified by EPA.

EPA has established procedures for handling, storing, processing, and disposing of TSCA confidential business information (CBI), in accordance with stipulations set forth at 40 CFR Part 2, subpart B. In general, EPA houses confidential information in secured areas and only persons specifically authorized by EPA may access such information. EPA further restricts access to computer systems containing TSCA CBI to those who have a need for access. Such systems may be accessed only via special computer terminals in restricted areas. Furthermore, the procedures set forth in 40 CFR Part 2, subpart B, strictly govern any transfer of TSCA CBI from EPA to another agency, and the Agency receiving such information must agree to comply fully with EPA procedures.

Furthermore, this information collection fully complies with the requirements of the Privacy Act of 1974 and OMB Circular A-108.

### 3(g). Sensitive Questions

Not applicable; this information collection does not include questions of a sensitive nature.

## 4. THE RESPONDENTS AND THE INFORMATION REQUESTED

### 4(a). Respondents/NAICS Codes

The respondent community consists of persons manufacturing or importing chemicals listed on the Inventory and regulated under TSCA section 8. In general, the industry segments that compose the respondent community for this information collection are those that produce or import organic chemicals, who have already reported to the initial Inventory effort, and who need to make a correction to that submission. Using North American Industry Classification System (NAICS) codes, these persons are typically classified under *Chemical Manufacturing* (NAICS 325) and *Petroleum and Coal Product Manufacturing* (NAICS 324).

### 4(b). Information Requested

#### 4(b)(i). Data Items

The correction request form requires the submitter to include information concerning the chemical substance's identity, plant site, production volume, site limitations, and import/export of the substance, if applicable.

#### 4(b)(ii). Respondent Activities

Most of the information contained on the Form C reporting form is readily accessible to the submitter as "customary business practices," such as production and site-limitation data. The

remaining information is equally apparent, e.g., plant site location and whether the submitter imports or manufactures.

With regard to the chemical substance identity requirement, such data should be predetermined before the time of an Inventory correction submission. Since industry almost exclusively initiates corrections to the Inventory, the submitter presumably has already determined the new chemical substance identity before he/she is able to conclude that the substance was previously misidentified. Therefore, the information required to submit a correction request is readily available to the submitter, who needs only to transpose the data to the form the Agency provides.

Furthermore, if, for whatever reason, the submitter is unable to produce a suitable technical name for the corrected substance, he/she need only provide the Agency with information concerning the reaction mechanism, including all reactants. In such a case, EPA will devise an appropriate name for the chemical substance.

It is significant to note that in almost all cases it is industry, not EPA, that initiates correction requests. The Agency does not require industry to provide correction information nor does EPA have an obligation to provide a correction mechanism or to specify a reporting format. The correction mechanism exists at the request of industry and the EPA form is used because it reduces the burden on both the Agency and industry by providing a clear format for the data. Because the Form C has been in use since the initial Inventory reporting period, submitters are generally familiar with the format and with the information needed to complete the form. Furthermore, use of the form guards against delays due to incomplete submissions, as the form clearly outlines the required information.

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

### 5(a). Agency Activities

As a result of the correction mechanism, the Agency must review the original submissions to determine whether a correction is needed. Once EPA confirms the validity of the correction, the Agency will process the correction information. EPA will maintain the confidentiality of the information at the request of the submitter, and will forward the results to the Chemical Abstracts Service (CAS) where the data are stored. EPA will add the corrected chemical substance to the Inventory while the incorrectly reported substance will become a candidate for deletion from the Inventory, if no other person has reported the same substance, through notice and comment rulemaking.

### 5(b). Collection Methodology and Management

EPA sends all of the submitted information, after processing, to an EPA contractor, Chemical Abstracts Service (CAS), whereupon the contractor enters the information to a computerized system. The public is able to access non-confidential data through commercial on-

line systems, or on compact discs (CDs) available from the National Technical Information Service (NTIS).

### 5(c). Small Entity Flexibility

No small entity exemption exists. A small entity exemption would be meaningless or counterproductive to the interests of small entities who may wish to submit corrections. In addition, the amount of information required to complete a correction request is minimal. Furthermore, the correction cannot be processed without each piece of information requested, as only essential data are solicited. Any small entity simplification of the correction process would fail to provide the Agency with the pertinent information needed to make a correction.

### 5(d). Collection Schedule

Not applicable since industry, not EPA, initiates corrections as necessary.

## 6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

### 6(a). Estimating Respondent Burden

This ICR addresses an information collection effort that has been undertaken in the same manner since 1980. As time goes by, the need for correcting the initial Inventory entries diminishes as most of the corrections needed presumably would have been discovered and made by now, after 30 years and several Inventory Update Rule (IUR) reporting cycles. At this time EPA estimates the number of respondents to be no more than nine per year, based on recent experience. It is anticipated that these respondents will incur a minimal reporting burden in providing information to the Agency, estimated at 2.0 hours per report, and a recordkeeping burden estimated at 0.25 hours per report, for a total estimated burden of 2.25 hours per report. Worksheet 1, below, illustrates the estimated burden per respondent for responding to this information collection.

### 6(b). Estimating Respondent Cost

Table 2 illustrates the estimated costs per respondent for responding to this information collection. This information is derived from information provided by submitters, individuals involved in the processing of the forms received, and previous experience.

Respondent hourly costs in this ICR have been updated using the data sources that have been used for this purpose in the past. The underlying data come from the Bureau of Labor Statistics' Employer Costs for Employee Compensation *Supplementary Tables: Historical Data December 2006 – December 2008*, US Bureau of Labor Statistics, March 12, 2009. These hourly cost estimates include wages, fringe benefits, and overhead. The wage and fringe benefit numbers are from the BLS data, and the overhead allowance is calculated at 17% of the hourly wage.

**Table 1. Hourly costs**

| Category | Hourly wage | Fringe benefits | Overhead | Total hourly cost |
|---|---|---|---|---|
| Managerial | $43.22 | $19.46 | $7.35 | $70.03 |
| Technical | $35.29 | $17.55 | $6.00 | $58.84 |
| Clerical | $17.22 | $8.33 | $2.93 | $28.48 |

**Table 2. Annual respondent burden / cost estimates**

| | Managerial ($70.03/hr.) | Technical ($58.84/hr.) | Clerical ($28.48/hr.) | Total Hours | Total Costs |
|---|---|---|---|---|---|
| Create and gather information | | 1.50 | | 1.50 | $88.26 |
| Review and report information | 0.50 | | | 0.50 | $35.02 |
| Recordkeeping | | | 0.25 | 0.25 | $ 7.12 |
| Subtotal | 0.50 | 1.50 | 0.25 | **2.25** | **$130.40** |

## 6(c). Estimating Agency Burden and Cost

Costs associated with this collection include the printing and distributing of reporting forms, providing reporting assistance, reviewing and processing of the report forms and entry of data into the Inventory databases. The time to review a correction request by an EPA employee is estimated from experience at two hours. Hourly costs for technical support personnel are based upon the salary for a GS-12, step 1 employee of $35.03. The hourly rates were taken from the U.S. Office of Personnel Management's 2009 General Schedule for workers with the Washington, D.C. locality payment. These hourly estimates were then multiplied by 1.6 to account for benefits (EPA Instructions for Preparing Information Collection Requests, 1992). Thus the hourly cost estimate adjusted for benefits is $56.05 for technical workers. Assuming the receipt of nine reports, the cost for EPA review is $504.45. Processing of the forms and entry of the data into EPA computer systems is estimated at $271.50 per form (based on contractor's fee and estimate of 0.5 hours non-exempt time and 1.5 hours of exempt time), for a total of $2,443.50. The total Agency cost would be $2,947.95. The total Agency burden in reviewing and processing the forms, based on two hours of review and two hours of processing time, would be 36 hours.

## 6(d). Bottom Line Burden Hours and Cost

<u>Respondent Burden</u>

The simple collection (see Table 2)
Burden: 2.25 hours/report x 9 reports = 20 hours
Costs: $130.40/report x 9 reports = $1,173.60

Agency Burden

The total Agency burden is estimated to be 36 hours.
The total Agency cost is estimated to be $2,947.95

**6(e). Reasons for Change in Burden**

This request reflects no change in the total estimated respondent burden from that currently in the OMB inventory.

**6(f). Burden Statement**

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0145, is estimated to be 2.25 hours per response. Burden is defined in 5 CFR 1320.3(b). An Agency may not conduct or sponsor such a request and a person or facility is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

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 public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2010-0497. The docket is available for public viewing at the Pollution Prevention and Toxics Docket in the EPA Docket Center (EPA/DC). The EPA/DC Public Reading Room is located in the EPA West Building, Room 3334, 1301 Constitution Ave., N.W., Washington, DC. The EPA/DC 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 EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. An electronic version of the public docket is available through the Federal Docket Management System (FDMS) at *http://www.regulations.gov*. Use FDMS to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "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-2010-0497 and OMB control number 2070-0145 in any correspondence.