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.: 1741.05 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 below), 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. Copies of the relevant sections of TSCA and of the Code of Federal Regulations are attached below (see Attachments 1 and 2, respectively).

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 fully to 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 he/she manufactures or imports is correctly identified on the Inventory, so that he/she 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 November 20, 2007 (72 FR 54034, September 21, 2007). EPA received no comments during the comment period.

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 and based on OPPTS Regulatory Coordination Staff guidance, EPA submitted questions to eight parties via email. The individuals contacted were:

Kathleen Roberts American Chemistry Kathleen_Roberts@americanchemistry.com

James Cooper Synthetic Organic Chemical Manufacturers Association (SOCMA) cooperj@socma.com

Dr. Susan Hearn Dow Chemical Company shearn@dow.com

Jessine Monaghan GE Plastics jessine.monaghan@ge.com

Derek Swick American Petroleum Institute swickd@api.org

Dr. Richard Denison Environmental Defense rdenison@environmentaldefense.org

D. Douglas Fratz Consumer Specialty Products Association dfratz@cspa.org

Jennifer Sass, Ph.D. Natural Resources Defense Council jsass@nrdc.org

EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above nine potential respondents is included below as Attachment 5.

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

(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.

(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 online 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 the 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 27 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

Worksheet 1 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.

The assumptions for wages and fringe benefits for managerial, professional/technical and clerical employee categories are based on information published by the Bureau of Labor Statistics (BLS), specifically *Employer Costs for Employee Compensation* (ECEC) data, for December 2005 for manufacturing industries.

	Managerial @ \$63.61	Technical @ \$53.02	Clerical @\$26.37	Total Hours	Total Costs
Create and gather information		1.50		1.50	\$79.53
Review and report information	0.50			0.50	\$31.81
Recordkeeping			0.25	0.25	\$ 6.59
Subtotal	0.50	1.50	0.25	2.25	\$117.93

WORKSHEET 1: ANNUAL RESPONDENT BURDEN/COST ESTIMATES Burden Hours and Costs per Respondent by Employee Category

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. Assuming salary and benefits costs of \$67.43 per hour (based on salary scales for a GS-13, step 5 employee) and the receipt of approximately nine reports, the cost for EPA review is \$1,215.54. 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 \$3,659.04. The total burden found in reviewing and processing the forms, based on two hours of review and two hours of processing time, would be 36 hours.

Agency wage rate data used to calculate labor costs were gathered from the U.S. Office of Personnel Management Salary Table 2006-DCB, for a GS-13, step 5 employee in the Washington, D.C. area. A loading factor of 1.6 was applied to the base rate to arrive at a 2006 loaded wage rate of \$140,262 per year. The hourly wage rate was computed by dividing the loaded wage by 2,080 hours, the hours associated with a full-time employee. This loaded hourly wage was used in calculations of Agency cost.

6(d) Bottom Line Burden Hours and Cost

(i) Respondent Burden

The simple collection (see Worksheet 1) Burden: 2.25 hours/report x 9 reports = 20 hours Costs: \$117.93/report x 9 reports = \$1,061.37

(ii) Agency Burden

The total Agency burden is estimated to be 36 hours. The total Agency cost is estimated to be \$3,659.04.

- (iii) The complex collection Not applicable.
- (iv) Variations in the annual bottom line Not applicable.

6(e) Reasons for Change in Burden

This request reflects no net 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 hour 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, 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-2007-0272. 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., NW., 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 <u>www.regulations.gov</u>. 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-2007-0272 and OMB control number 2070-0145 in any correspondence.

ATTACHMENTS:

[NOTE: Unless otherwise noted, an electronic version of the listed attachment appears in the electronic file for the ICR, following the main text of the Supporting Statement. Electronic copies are also available in the docket identified above at www.regulations.gov.]

Attachment 1 - Toxic Substances Control Act (TSCA), Section 8 (15 USC 2607)

Attachment 2 - 40 CFR 710, Inventory Reporting Regulations

Attachment 3 – Inventory Correction Guidelines (45 FR 50544, July 29, 1980) (See discussion in Unit C.). [A copy of this document is available as a separate document in the docket for this ICR at <u>www.regulations.gov</u> (see Docket ID # EPA-HQ-OPPT-2007-0272).]

Attachment 4 - Inventory Correction Form (EPA Form 7710-3C). [A copy of this form is available as a separate document in the docket for this ICR at <u>www.regulations.gov</u> (see Docket ID # EPA-HQ-OPPT-2007-0272). The form can also be accessed electronically through the IUR Reporting Web site at <u>http://www.epa.gov/oppt/iur/</u>.]

Attachment 5 - Copy of EPA's Consultations Message to Potential Respondents

Attachment 6 - Public Notice Required Prior to ICR Submission to OMB (72 FR 54034, September 21, 2007). [A copy of this FR Notice is available as a separate document in the docket for this ICR at <u>www.regulations.gov</u> (see Docket ID # EPA-HQ-OPPT-2007-0272). You can also access an electronic copy at

http://www.epa.gov/fedrgstr/EPA-TOX/2007/September/Day-21/t18684.pdf.]

ATTACHMENT 1

Toxic Substances Control Act

Section 8

15 USC 2607

[Available electronically in this file – text follows.]

Sec. 2607. (TSCA §8) Reporting and retention of information

(a) Reports

(1) The Administrator shall promulgate rules under which -

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process -

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product, shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this chapter. The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this chapter. For purposes of the compilation of the list of chemical substances required under subsection (b) of this section, the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after January 1, 1977.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure. (G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method. To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3) (A)

(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b) of this section.

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture -

(I) subject to a rule proposed or promulgated under section 2603, 2604(b)(4), or 2605 of this title, or an order in effect under section 2604(e) of this title, or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 2604 or 2606 of this title, to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(b) Inventory

(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 2604 of this title or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1) of this section. In the case of a chemical substance for which a notice is submitted in accordance with section 2604 of this title, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after January 1, 1977. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this chapter, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) Records

Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) Health and safety studies

The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator -

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this chapter; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) Notice to Administrator of substantial risks

Any person who manufactures, processes, or distributes in commerce as chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) "Manufacture" and "process" defined

For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

ATTACHMENT 2

40 CFR 710

Inventory Reporting Regulations

[Available electronically in this file – text follows.]

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY

PART 710--INVENTORY REPORTING REGULATIONS

Sec. 710.1 Scope and compliance.

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

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

Note: As a matter of traditional Agency policy, EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.

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

[42 FR 64572, Dec. 23, 1977, as amended at 45 FR 18375, Mar. 21, 1980; 60 FR 31921, June 19, 1995]

Sec. 710.2 Definitions.

In addition to the definitions in Sec. 704.3 in this chapter, the following definitions also apply to this part:

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

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

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

(d) Act means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

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

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

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

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

(1) Any mixture,

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

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

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

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

(6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(i) Commerce means trade, traffic, transportation, or other commerce: (1) Between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce described in paragraph (i)(1) of this section.

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

(k) EPA means the U.S. Environmental Protection Agency.

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

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

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

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

(n) Intermediate means any chemical substance:

(1) Which is intentionally removed from the equipment in which it is manufactured, and (2) which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).

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

(o) Manufacture means to produce or manufacture in the United States or import into the customs territory of the United States.

(p) Manufacture or import "for commercial purposes" means to manufacture or import:

(1) For distribution in commerce, including for test marketing purposes, or

(2) For use by the manufacturer, including for use as an intermediate.

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

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

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

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

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

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

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

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

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

(x) Small manufacturer or importer means a manufacturer or importer whose total annual sales are less than \$5,000,000, based upon the manufacturer's or importer's latest complete fiscal year as of January 1, 1978, except that no manufacturer or importer is a "small manufacturer or importer" with respect to any chemical substance which such person manufactured at one site or imported in quantities greater than 100,000 pounds during calendar year 1977. In the case of a

company which is owned or controlled by another company, total annual sales shall be based on the total annual sales of the owned or controlled company, the parent company, and all companies owned or controlled by the parent company taken together.

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

(y) Small quantities for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product (hereinafter sometimes shortened to small quantities for research and development) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that (1) are no greater than reasonably necessary for such purposes and (2) after the publication of the revised inventory, are used by, or directly under the supervision of, a technically qualified individual(s).

Note: Any chemical substances manufactured, imported or processed in quantities less than 1,000 pounds annually shall be presumed to be manufactured, imported or processed for research and development purposes.

No person may report for the inventory any chemical substance in such quantities unless that person can certify that the substance was not manufactured, imported, or processed solely in small quantities for research and development, as defined in this section.

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

(aa) Technically qualified individual means a person: (1) Who because of his education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his supervision, (2) who is responsible for enforcing appropriated methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in paragraph (aa)(3) of this section may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (aa)(1) of this section.

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

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

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

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

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

[42 FR 64572, Dec. 23, 1977, as amended at 60 FR 31921, June 19, 1995]

Sec. 710.4 Scope of the inventory.

(a) Chemical substances subject to these regulations. Only chemical substances which are manufactured, imported, or processed ``for a commercial purpose," as defined in Sec. 710.2, are subject to these regulations.

(b) Naturally occurring chemical substances automatically included. Any chemical substance which is naturally occurring and:

(1) Which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or

(2) Which is extracted from air by any means, shall automatically be included in the inventory under the category ``Naturally Occurring Chemical Substances." Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

(c) Substances excluded by definition or section 8(b) of TSCA. The following substances are excluded from the inventory:

(1) Any substance which is not considered a "chemical substance" as provided in subsection 3(2)(B) of the Act and in the definition of "chemical substance" in Sec. 710.2(h);

(2) Any mixture as defined in Sec. 710.2(q);

Note: A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term ``mixture'' includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.

(3) Any chemical substance which is manufactured, imported, or processed solely in small quantities for research and development, as defined in Sec. 710.2(y); and

(4) Any chemical substance not manufactured, processed or imported for a commercial purpose since January 1, 1975.

(d) Chemical substances excluded from the inventory. The following chemical substances are excluded from the inventory. Although they are considered to be manufactured or processed for a commercial purpose for the purpose of section 8 of the Act, they are not manufactured or processed for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they may be a part.

Note: In addition, chemical substances excluded here will not be subject to premanufacture notification under section 5 of the Act.

(1) Any impurity.

(2) Any byproduct which has no commercial purpose.

Note: A byproduct which has commercial value only to municipal or private organizations who (i) burn it as a fuel, (ii) dispose of it as a waste, including in a landfill or for enriching soil,

or (iii) extract component chemical substances which have commercial value, may be reported for the inventory, but will not be subject to premanufacturing notification under section 5 of the Act if not included.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleansers or other housekeeping products, fuels and fuel additives, water softening and treatment agents, photographic, films, batteries, matches, and safety flares, and which is not itself manufactured for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints; or other chemical substances formed during manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that may occur as described elsewhere in this Sec. 710.4(d).

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or de-foamer, dispersant, precipitation inhibitor, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended or (ii) a chemical substance, solely intended to impart a specific physicochemical characteristic, functions as intended.

(8) Chemical substances which are not intentionally removed from the equipment in which they were manufactured.

Note: See note to definition of "intermediate" at Sec. 710.2(n) for explanation of "equipment in which it was manufactured."

[42 FR 64572, Dec. 23, 1977]

Sec. 710.25 Chemical substances for which information must be reported.

Any chemical substance which is in the Master Inventory File at the beginning of a reporting period described in Sec. 710.33, unless the chemical substance is specifically excluded by Sec. 710.26.

[51 FR 21447, June 12, 1986]

Sec. 710.26 Chemical substances for which information is not required.

The following categories of chemical substances are excluded from the reporting requirements of this subpart. However, a chemical substance described in paragraphs (a), (b), or (c) of this section is not excluded from the reporting requirements of this subpart if that substance is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Act, or is

the subject of an order issued under section 5(e) or 5(f) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act.

(a) Inorganic chemical substances. Any chemical substance which does not contain carbon or contains carbon only in the form of carbonato [=CO<INF>3</INF>], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups.

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

(2) Any chemical substance which is identified in the 1985 edition of the Inventory or the Master Inventory File as siloxane and silicone, silsesquioxane, a protein (albumin, casein, gelatin, gluten, hemoglobin), an enzyme, a polysaccharide (starch, cellulose, gum), rubber, or lignin. This exclusion, however, does not apply to a chemical substance which has been hydrolyzed, depolymerized, or chemically modified to the extent that the final product is no longer polymeric in structure.

(c) Microorganisms. Any combination of chemical substances that is a living organism, such as bacteria, eimeria, fungi and yeasts. Any chemical substance produced from such a living organism is reportable unless otherwise excluded.

(d) Naturally occurring chemical substances. Any naturally occurring chemical substance, as described in Sec. 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the substance in question. Some chemical substances can be manufactured both as described in Sec. 710.4(b) and by means other than those described in Sec. 710.4(b). If a person described in Sec. 710.28 manufactures a chemical substance by means other than those described in Sec. 710.4(b), the person must report regardless of whether the substance also could have been produced as described in Sec. 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in Sec. 710.4(b) is reportable unless otherwise excluded.

[51 FR 21447, June 12, 1986]

Sec. 710.28 Persons who must report.

Except as provided in Secs. 710.29 and 710.30, the following persons are subject to the requirements of this subpart. Persons must determine whether they must report under this Sec. 710.28 for each chemical substance that they manufacture at an individual site.

(a) Persons subject to initial reportinq. Any person who manufactured for commercial purposes 10,000 pounds (4,540 kilograms) or more of a chemical substance described in Sec. 710.25 at any single site owned or controlled by that person at any time during the person's latest complete corporate fiscal year before August 25, 1986.

(b) Persons subject to recurring reporting. Any person who manufactured for commercial purposes 10,000 pounds (4,540 kilograms) or more of a chemical substance described in Sec. 710.25 at any single site owned or controlled by that person at any time during the person's latest complete corporate fiscal year before August 25, 1990, or before August 25 at four-year intervals thereafter.

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

[51 FR 21447, June 12, 1986]

Sec. 710.29 Persons not subject to this subpart.

A person described in Sec. 710.2 8 is not subject to the requirements of this subpart if that person qualifies as a small manufacturer as that term is defined in Sec. 704.3 of this chapter. Notwithstanding this exclusion, a person who qualifies as a small manufacturer is subject to this subpart with respect to any chemical substance that is the subject of a rule proposed or promulgated under section 4, 5(b)(4), or 6 of the Act, or is the subject of an order in effect under section 5(e) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act.

[51 FR 21447, June 12, 1986]

Sec. 710.30 Activities for which reporting is not required.

A person described in Sec. 710.28 is not subject to the requirements of this subpart with respect to any chemical substance described in Sec. 710.25 that the person manufactured or imported under the following circumstances:

(a) The person manufactured or imported the chemical substance described in Sec. 710.25 solely in small quantities for research and development,

(b) The person imported the chemical substance described in Sec. 710.25 as part of an article,

(c) The person manufactured the chemical substance described in Sec. 710.25 in a manner described in Sec. 720.30(g) or (h) of this chapter.

[51 FR 21447, June 12, 1986]

Sec. 710.32 Reporting information to EPA.

Any person who must report under this part must submit the information prescribed in this section for each chemical substance described in Sec. 710.25 that the person manufactured for commercial purposes in an amount of 10,000 pounds (4,540 kilograms) or more at a single site during a corporate fiscal year described in Sec. 710.28. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.). A respondent to this subpart must report information in writing or by magnetic media as prescribed in this section, to the extent that such information is known to or reasonably ascertainable by that person. A respondent to this subpart must report information that applies to the specific corporate fiscal year for which the person is required to report.

(a) Reporting in writing. Any person who chooses to report information to EPA in writing must do so by completing the reporting form available from EPA at the address set forth in Sec. 710.39(b). The form must include all information prescribed in paragraph (c) of this section. Persons reporting in writing must submit a separate form for each site for which the person is required to report.

(b) Reporting by magnetic media. Any person who chooses to report information to EPA by means of magnetic media must submit the information prescribed in paragraph (c) of this section. Magnetic media submitted in response to this subpart must meet EPA specifications, as described in the instruction booklet available from EPA at the address set forth in Sec. 710.39(b).

(c) Information to be reported. Persons reporting information under this subpart must report the following:

(1) The name, company, address, city, State, Zip code, and telephone number of a person who will serve as technical contact for the respondent company, and will be able to answer questions about the information submitted by the company to EPA. Persons reporting by means of magnetic media must submit this information on the reporting form available from EPA at the address set forth in Sec. 710.39.

(2) A certification statement signed and dated by an authorized official of the respondent company. Persons reporting by means of magnetic media must submit this information on the reporting form available from EPA at the address set forth in Sec. 710.39.

(3) The specific chemical name and Chemical Abstracts Service (CAS) Registry Number of each chemical substance for which reporting is required under this subpart. A respondent to this subpart may use other chemical identification numbers in lieu of CAS Registry Numbers when a CAS Registry Number is not known to the respondent as provided in the instruction booklet identified in Sec. 710.39(b), including EPA-designated Accession Numbers for confidential substances, EPA-assigned numbers for bona fide or Premanufacture Notification submissions, or Test Market Exemption Applications, or original Inventory form numbers.

(4) The name, street address, city, State, and Zip code of each site at which 10,000 pounds (4,540 kilograms) or more of a chemical substance for which reporting is required under this subpart is manufactured or imported. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.) A respondent to this subpart must include the appropriate Dun and Bradstreet Number for each plant site reported.

(5) A statement for each substance for which information is being submitted indicating whether the substance is manufactured in the United States or imported into the United States.

(6) A statement for each substance for which information is being submitted indicating whether the substance is site-limited.

(7) The total volume (in pounds) of each subject chemical substance manufactured or imported at each site. This amount must be reported to two significant figures of accuracy provided that the reported figures are within plus-minus10 percent of the actual volume.

[55 FR 39587, Sept. 27, 1990, as amended at 60 FR 31921, June 19, 1995]

Sec. 710.33 When to report.

All information reported to EPA in response to the requirements of this subpart must be submitted during an applicable reporting period. The following reporting periods are prescribed for this subpart.

(a) Initial reporting period. The first reporting period is from August 25, 1986 to December 23, 1986. Any person described in Sec. 710.28(a) must report during this period for each chemical substance described in Sec. 710.25 that the person manufactured during the corporate fiscal year described in Sec. 710.28(a).

(b) Recurring reporting periods. The first recurring reporting period is from August 25, 1990 to December 23, 1990. Subsequent reporting periods, except as provided in paragraph (c) of this section, are from August 25 to December 23 at 4-year intervals thereafter. Any person described in Sec. 710.28(b) must report during the appropriate reporting period for each chemical substance described in Sec. 710.25 that the person manufactured during the applicable corporate fiscal year

described in Sec. 710.28(b).

(c) Reporting in 1998. The 1998 reporting period is from August 25, 1998 until January 31, 1999. Any person described in Sec. 710.28(b) must report during this reporting period for each chemical substance described in Sec. 710.25 that the person manufactured during the applicable corporate fiscal year described in Sec. 710.28(b). This reporting period is applicable to 1998 reporting only.

[51 FR 21447, June 12, 1986: 51 FR 22521, June 20, 1986, as amended at 63 FR 71600, Dec. 29, 1998]

Sec. 710.35 Duplicative reporting.

(a) With regard to section 8(a) rules. Any person subject to the requirements of this part who previously has complied with reporting requirements of a rule under section 8(a) of the Act by submitting the information described in Sec. 710.32 for a chemical substance described in Sec. 710.25 to EPA, and has done so within one year of the start of a reporting period described in Sec. 710.33, is not required to report again on the manufacture of that substance at that site during that reporting 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 Sec. 710.25. 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 Secs. 710.2(l) and 704.3 of this chapter, they may determine among themselves who should submit the required report; if no report is submitted as required under this part, EPA will hold each such person liable for failure to report.

[51 FR 21447, June 12, 1986, as amended at 60 FR 31921, June 19, 1995]

Sec. 710.37 Recordkeeping requirements.

Each person who is subject to the reporting requirements of this part must maintain records that document any information reported to EPA. For substances that are manufactured or imported at less than 10,000 pounds annually, volume records must be maintained as evidence to support a decision not to submit a report. Records relevant to reporting during a reporting period

described in Sec. 710.33 must be retained for a period of four years beginning with the effective date of that reporting period.

[51 FR 21447, June 12, 1986, as amended at 58 FR 34204, June 23, 1993; 60 FR 31921, June 19, 1995]

Sec. 710.38 Confidentiality.

(a) Any person submitting information under this part may assert a business confidentiality claim for the information. The procedures for asserting confidentiality claims are described in the instruction booklet identified in Sec. 710.39. Information claimed as confidential in accordance with this section and those instructions will be treated and disclosed in accordance with the procedures in part 2 of this chapter.

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

(c) To assert a claim of confidentiality for the chemical identity of a specific chemical substance, the person must take the following steps:

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

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

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

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

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

(v) Is the fact that the chemical substance is being manufactured or 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 you taken to prevent undesired disclosure of the fact that this chemical substance is being manufactured or imported for a commercial purpose?

(vii) To what extent has the fact that this chemical substance is manufactured or 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 in any form, as product, effluent, emission, etc.? If so, what measures have you taken to guard against discovery of its identity?

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

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

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

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

(d) If no claim of confidentiality accompanies information at the time it is submitted to EPA under this part or if substantiation required under paragraph (c) of this section is not submitted with the reporting form, EPA may make the information available to the public without further notice to the submitter.

[51 FR 21447, June 12, 1986, as amended at 55 FR 39588, Sept. 27, 1990; 60 FR 31921, June 19, 1995]

Sec. 710.39 How do I submit the required information for the 1998 reporting cycle?

(a) Use the proper EPA form. You must use the EPA form identified as "Form U" to submit written information in response to the requirements of this subpart. Copies of the Form U are available from EPA at the address set forth in paragraph (c) of this section, from the EPA Internet Home Page at http://www.epa.gov/opptintr/iur98, or via Fax-on-Demand by using a faxphone to call (202) 401-0527 and selecting item 5119.

(b) Follow the reporting instructions. You should follow the detailed instructions for completing the reporting form and preparing a magnetic media report, which are given in the EPA publication entitled "Instructions for Reporting for Partial Updating of the TSCA Chemical Inventory Data Base," via the Internet or the TSCA Hotline.

(c) Obtain the reporting package and copies of the form. EPA is mailing the reporting package to those companies that reported in 1994. Failure to receive a reporting package does not obviate or otherwise affect the requirement to submit a timely report. If you did not receive a reporting package, but are required to report, you may obtain a copy of the reporting package and the reporting form from EPA by submitting a request for this information as follows:

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

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

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

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

[63 FR 45953, Aug. 28, 1998]

ATTACHMENT 3

Inventory Correction Guidelines

45 FR 50544, July 29, 1980 (See discussion in Unit C.)

[A copy of this document is available as a separate document in the docket for this ICR at <u>www.regulations.gov</u> (see Docket ID # EPA-HQ-OPPT-2007-0272).]

ATTACHMENT 4

Inventory Correction Form EPA Form 7710-3C

[A copy of this form is available as a separate document in the docket for this ICR at <u>www.regulations.gov</u> (see Docket ID # EPA-HQ-OPPT-2007-0272). The form can also be accessed electronically through the IUR Reporting Web site at <u>http://www.epa.gov/oppt/iur/</u>.]

ATTACHMENT 5

Copy of EPA's Consultations Message to Potential Respondents

[Available electronically in this file – text follows.]

From:	Ron Carlson/DC/USEPA/US
To:	[addressees]
Subject:	Request for assistance; renewal of "Correction of Misreported Chemical
	Substances" ICR
Date:	11/14/07

Dear [name of addressee],

On September 21, 2007, EPA published a Notice in the <u>Federal Register</u> (72 FR 54034) titled **Agency Information Collection Activities; Proposed Collection; Comment Request; Correction of Misreported Chemical Substances on the TSCA Inventory; EPA ICR No. 1741.05, OMB Control No. 2070-0145.** This Notice refers to EPA's intention to request renewed Office of Management and Budget (OMB) clearance of an information collection involving the submission of information to EPA to correct misreported entries in the Inventory of Chemical Substances in Commerce as initially established in 1979 under section 8(b) of the Toxic Substances Control Act (TSCA).

In addition to public notice and comment requirement that the above Notice initiates, OMB regulations at 5 CFR 1320.8(d)(1)) require agencies to consult with potential respondents and data users about specific aspects of an information collection request (ICR) before submitting it to OMB for review and approval, regardless, in the case of ICR renewals, of whether changes have or have not been made to the collection activity.

As part of this required consultation, I am contacting you to solicit your input. I will also note that, if you take this opportunity to provide input, your name, affiliation, e-mail address, phone number and any information you provide (e.g., copies of e-mails) will be incorporated and attached to the ICR supporting statement, which will be a public document. In addition, the OMB Desk Examiner for the ICR in question may contact you to verify the accuracy of any comments EPA identifies in the ICR.

EPA solicits your input on the following questions:

Are the data EPA seeks under this ICR available from any public source, or already collected by another EPA office or by another agency? If so, where can the data be found?

Is it clear what is required for data submission? If not, are there any suggestions for clarifying instructions?

Would you be interested in an electronic/data submission option? What type of alternative would you be most likely to utilize – web form, diskette, CD-ROM?

For electronic submission, how should signature requirements be handled – Private Key Infrastructure, PINS and passwords, signed paper cover sheet? How does TSCA CBI affect your choice or use of an electronic medium? Would you be more inclined to

submit TSCA CBI on diskette than on paper and what benefits would you realize (e.g., burden reduction, greater efficiency in compiling information, etc).

Do you agree with EPA's estimated burden and costs (the ICR addresses only the costs associated with paperwork)? Are the Bureau of Labor Statistics (BLS) labor rates accurate? If you have any reason to consider the BLS labor rates inaccurate or inappropriate as used by EPA, explain your rationale.

You can access the <u>Federal Register</u> Notice, the ICR supporting document, and any public comments received to date at: <u>http://www.regulations.gov/fdmspublic/component/main</u>

- select the Search for Dockets link at the top of the page
- select Environmental Protection Agency in the Agency drop-down menu
- enter EPA-HQ-OPPT-2007-0272 in the Docket ID field
- scroll down to Submit
- then click on the Docket ID in the search results for a listing of the documents within the docket

Your response will be greatly appreciated. If you have any comments in answer to the above questions, or with respect to any other part of the information collection, please respond by return e-mail by November 30, 2007. EPA will consider those responses, as well as any public comment received in response to the <u>Federal Register</u> Notice identified above, in preparing a final document for OMB review.

Thank you for your assistance.

Sincerely yours,

Ron Carlson, Environmental Protection Specialist Information Management Division/Office of Pollution Prevention and Toxics/Office of Prevention, Pesticides and Toxic Substances Environmental Protection Agency Washington, DC 20460 202-564-8631

ATTACHMENT 6

Public Notice Required Prior to ICR Submission to OMB (72 FR 54034, September 21, 2007)

[A copy of this FR Notice is available as a separate document in the docket for this ICR at <u>www.regulations.gov</u> (see Docket ID # EPA-HQ-OPPT-2007-0272). You can also access an electronic copy at <u>http://www.epa.gov/fedrgstr/EPA-TOX/2007/September/Day-21/t18684.pdf</u>.]