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

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

TITLE: Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances

EPA ICR No: 0574.15 OMB Control No.: 2070-0012

1(b) Short Characterization

The Environmental Protection Agency (EPA) administers the New Chemicals Program under section 5 of the Toxic Substances Control Act (TSCA) (see Attachment A). TSCA section 5 requires that any person who proposes to manufacture or import a "new chemical," (i.e., a chemical not listed on the TSCA section 8(b) Inventory), must provide a premanufacture notice (PMN) or an exemption application to EPA at least 90 days prior to commencing manufacture or import of that chemical. Similarly, TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture, import or process a chemical for a use that is determined to be a "significant new use." EPA considers certain genetically engineered microorganisms to be chemical substances for purposes of the notification requirements found in TSCA section 5; the 90-day notice for microorganisms is a Microbial Commercial Activity Notice (MCAN).

Furthermore, TSCA section 5 authorizes EPA to regulate the manufacture, processing, distribution in commerce, use or disposal of new chemical substances. Using the notice information submitted to the Agency, EPA evaluates the health and environmental effects of new chemical substances. On the basis of its review, EPA may take regulatory action with respect to the manufacture or importation of a new chemical substance or with respect to a substance's proposed new use. If EPA takes no action within the 90-day review period for PMNs (30 or 45 days for PMN exemption applications), the submitter is free to manufacture or import the new substance, or to manufacture, import or process the substance for a new use. EPA requires that the submitter inform EPA when non-exempt commercial manufacture, processing or importation of the substance in question actually begins by submitting a Notice of Commencement (see Attachment I).

The Government Paperwork Elimination Act (GPEA, Pub. L. 105-277) requires that, when practicable, federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (October 13, 2005; 70 FR 59848) provides that any requirement in Title 40 of the Code of Federal Regulations to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency publishes a notice that electronic document submission is available for that requirement.

In light of GPEA and CROMERR, EPA published on January 5, 2010, a final rule entitled "TSCA Section 5 Premanufacture and Significant New Use Notification Electronic

Reporting; Revisions to Notification Regulations" (75 FR 773) to amend TSCA section 5 to phase out paper-based submissions and facilitate the introduction and use of electronic reporting. This action enables, and eventually will require, manufacturers, importers and processors of TSCA chemical substances to use the Internet, through EPA's Central Data Exchange (CDX), to submit TSCA section 5 notices to the Agency. These include Premanufacture Notices (PMNs) (40 CFR 720), Significant New Use Notices (SNUNs) (40 CFR 721), Test Market Exemption Applications (TMEAs) (40 CFR 720), Low Volume Exemption notices (LVEs) (40 CFR 723.50), Low Exposure/Low Release Exemption (LoREX) notices (40 CFR 723.50), biotechnology notices for genetically modified microorganisms (40 CFR 725), Notices of Commencement of Manufacture or Import (NOCs) (40 CFR 720.102) and other support documents (e.g., correspondence, amendments and test data); see Attachments C, D, E and F.

The Agency introduced CDX reporting in two phases over a two-year period. From April 6, 2010, (the effective date of the rule) through April 6, 2011, the Agency allowed submissions via CDX, optical disc, and paper. Regardless of the delivery method, EPA required that all submissions be generated with new electronic-PMN "e-PMN" computer software. As of April 6, 2011, paper submissions are no longer accepted for any new notices and support documents (including NOCs). Disc-based submissions (e.g., CDs and data DVDs) for all new notices and support documents will no longer be accepted beyond the second year after the final rule's effective date, April 6, 2012. After this, all submitters will be required to submit electronically via CDX using the e-PMN software. The Agency incorporated this phased approach because it allows submitters to gain experience in using the e-PMN software and the submission delivery system. Note that the final CDX and e-PMN software amendments to the PMN notification requirements in 40 CFR 720 also apply to the SNUN requirements in 40 CFR 721.25(a). See epa.gov/opptintr/newchems/epmn/epmn-index.htm for information on e-PMN reporting and the use of CDX.

This information collection request addresses the TSCA section 5 reporting and recordkeeping requirements associated with the new chemicals review and regulatory program, as briefly outlined above.

2 NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

TSCA section 5(a)(1), 15 U.S.C. 2604, requires manufacturers and importers of new chemical substances to submit to the Administrator of EPA a premanufacture notice (PMN) of intent to manufacture or import a new chemical substance at least 90 days before manufacture or import begins. TSCA section 5(a)(1) also requires notification from any person who proposes to manufacture, import or process a chemical substance for a use that EPA has by rule determined to be a significant new use. The notice must include, insofar as known to or is reasonably ascertainable by the submitter, information described in TSCA section 8(a)(2) (e.g., chemical identity, use and exposure data), plus test data and descriptions of other data related to the effects on health and the environment of the manufacture, processing, use, distribution in commerce and disposal of the new chemical substance. EPA reviews the information to evaluate the health and environmental effects of the new chemical substance. On the basis of the review, EPA can take further regulatory action under TSCA sections 5(e) and 5(f), if warranted. If EPA takes no

action at the end of 90 days, the submitter is free to manufacture or import the new chemical substance.

TSCA section 5, as interpreted in EPA's Microbial Products of Biotechnology; Final Regulation under the Toxic Substances Control Act; final rule published at 62 FR 17910 (April 11, 1997), authorizes EPA to regulate "new" genetically engineered microorganisms. According to the 1997 final rule, "new" microorganisms are those that, through deliberate human intervention, contain genetic material from dissimilar source organisms. For the purposes of this policy, all microorganisms of different genera (intergeneric) are considered "new." Manufacturers and importers of these new microorganisms must submit to EPA a microbial commercial activity notice (MCAN) at least 90 days before manufacturing or import begins. These microorganisms are subject to the same potential regulatory controls as new chemical substances.

TSCA section 5(d)(1)(B) requires notices to include all test data in the submitter's possession or control and TSCA section 5(d)(1)(C) requires submitters to provide other data on environmental or health effects that are known to or reasonably ascertainable by the submitter. These requirements are described in 40 CFR 720.50.

TSCA section 5(e) authorizes EPA to regulate the manufacture, processing, distribution in commerce, use or disposal of a new substance pending development of data sufficient to evaluate the health and environmental effects of the substance. EPA may take action under TSCA section 5(e) if the Agency determines that the information available is insufficient to evaluate the substance and that the substance either (1) may present an unreasonable risk of injury to health or the environment or (2) will be produced in substantial quantities and there may be significant or substantial human or environmental exposure to the chemical. EPA's actions often involve negotiation of a TSCA section 5(e) Consent Order to prohibit or limit activities associated with the new chemical. TSCA section 5(e) Consent Orders typically include exposure or release mitigation, testing, labeling and hazard communication, and record keeping.

Under TSCA section 5(f), EPA may regulate a new chemical substance if there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use or disposal of the new substance will present an unreasonable risk of injury to health or the environment before EPA can promulgate a rule to regulate the chemical under TSCA section 6.

Significant New Use Rules (SNURs) are authorized under TSCA section 5(a)(2). Regulations providing details on EPA's SNUR authority were promulgated at 40 CFR part 721 on July 27, 1989 and at 40 CFR part 725 subparts H-K on April 11, 1997. Because TSCA section 5(e) Consent Orders are only binding on the original PMN submitter that manufactured or imported the substance, EPA may promulgate a SNUR under TSCA section5(a)(2) that mimics the Consent Order to bind all other manufacturers and processors of former new chemicals to the terms and conditions contained in the Consent Order. EPA also uses this authority to take follow up action on new or existing chemicals that may not present an unreasonable risk in their original uses but may present an unreasonable risk should other uses occur that may result in different and/or higher exposures to human beings or the environment. EPA determines that a new use is significant by examining the specific circumstances of each case.

A SNUR allows EPA to receive reporting on such uses, review them and, if necessary, regulate the uses before they occur. Once a use is determined to be a "significant new use," a person must submit a SNUN to EPA at least 90 days before that person may manufacture, process or import a chemical substance for that use. The same reporting requirements that apply to PMNs also apply to SNUNs, and EPA has the same authorities under TSCA section 5(e) and 5(f) to regulate the SNUR chemical during the notice review period.

EPA may also grant certain exemptions from the PMN, SNUN, and MCAN requirements of TSCA section 5, including the following. These exemption rules reduce reporting requirements, thereby providing relief to submitters from the burdens of the full PMN reporting requirements.

(i) Test-Marketing Exemption (TME)

Under TSCA section 5(h)(1), persons may apply for an exemption from the requirements of TSCA section 5 for test-marketing purposes. EPA may grant the exemption if it finds that the test-marketing activities described by the applicant will not present an unreasonable risk of injury to health or the environment. The applicant must provide the information necessary to make this finding and EPA must grant or deny the exemption within 45 days. If EPA grants the exemption, it may impose appropriate restrictions on the test-marketing activities. See 40 CFR 720.38 and 725.370.

(ii) Research and Development Exemption (R&D)

TSCA section 5(h)(3) exempts from PMN reporting small quantities of chemical substances manufactured or imported only for research and development purposes. Persons using this exemption must have their research overseen by a technically qualified individual and must notify any person involved in the research of any risk. See 40 CFR 720.36. Small quantities of genetically modified microorganisms manufactured solely for research and developmental purposes are also exempt when additional criteria are met as described in 40 CFR 725.235, activities conducted inside a structure, and 40 CFR 725.238 and 239, activities conducted outside a structure.

(iii) TSCA Section 5(h)(4) Exemptions

TSCA section 5(h)(4) authorizes EPA to exempt any person from the provisions of TSCA section 5 if EPA determines that the chemical substance will not present an unreasonable risk of injury to health or the environment when manufactured, processed, distributed, used or disposed of under the exemption. To date EPA has promulgated four rules under this section for chemical substances and three exemptions for microbial products of biotechnology:

- Low Volume Exemption (LVE) - This exemption applies to substances manufactured in quantities of 10,000 kilograms or less per year; submitters may request that EPA evaluate their exemption at a lower production volume level, to which the submitter would be legally bound. See 40 CFR 723.50.

- Low Release/Low Exposure (LoREX) - This exemption applies to certain chemical substances that meet strict human exposure and environmental release criteria to

ensure that these substances will not present an unreasonable risk. See 40 CFR 723.50.

- Polymer Exemption - This exemption applies to polymers that comply with certain chemical characterizations and that therefore will not present an unreasonable risk of injury to health or the environment. See 40 CFR 723.250.

- Instant Photographic Film Articles Exemption - This exemption applies to chemical substances used in or for the manufacture or processing of instant photographic and peel-apart film articles. See 40 CFR 723.175.

- TSCA Experimental Release Application (TERA) - This exemption applies to research and development activities that result in intentional environmental releases of microorganisms. EPA may grant the exemption if it finds that the activities described by the applicant will not present an unreasonable risk of injury to health or the environment. The applicant must provide the information necessary to make this finding and EPA must grant or deny the exemption within 60 days. If EPA grants the exemption, it may impose appropriate restrictions on the activities described in the notice. See 40 CFR 725.250.

- Tier I Exemption - This exemption applies to certain microorganisms subject to physical containment and control technologies. EPA has developed specific criteria for the host microorganism, introduced genetic material, and containment technology to ensure that the microorganism will not present an unreasonable risk. See 40 CFR 725.400.

- Tier II Exemption - This exemption applies to the same microorganisms subject to a Tier I exemption without specified physical containment and control technologies. EPA may grant the exemption if it finds that the physical containment and control technologies activities described by the applicant will not present an unreasonable risk of injury to health or the environment. The applicant must provide the information necessary to make this finding and EPA must grant or deny the exemption within 45 days. If EPA grants the exemption, it may impose appropriate restrictions on the activities described in the notice. See 40 CFR 725.428.

Finally, under TSCA section 26(b), EPA requires manufacturers, importers and processors to pay fees for PMNs, MCANs, certain PMN exemption applications and notices, and Significant New Use Notices (SNUNs) submitted under TSCA sections 5(a) and (h) to help defray the cost of administering TSCA. EPA must take into account a submitter's ability to pay the fee and the cost of reviewing the submitted data. TSCA section 26(b) provides for maximum fees of $100 for small business concerns and $2,500 for other PMN submitters. The rule requires a limited amount of additional information to be submitted with the PMN or MCAN form. See 40 CFR 700, Attachment B.

The amended PMN form includes a new User Fee Payment Identity Number field to enable the Agency to match more easily a particular user fee with a particular notice submission. A User Fee Payment Identity Number is required that could be a check number, a wire transfer number, or a "Pay.gov" transaction number used to transmit the user fee.

Copies of TSCA section 5 and of 40 CFR parts 700, 720, 721 (except subpart E), 723 and 725 are available in the public docket established for this ICR under docket identification number and are available for online viewing at www.regulations.gov. (Also see Attachments B, C, D, E and F, respectively.) The regulations may also be viewed online at the National Archives and Records Administration's Electronic CFR Website (http://ecfr.gpoaccess.gov).

2(b) Use/Users of the Data

TSCA gives EPA authority to regulate the manufacture or import of a new chemical substances if EPA determines that: (1) the substance may present an unreasonable risk of injury to health or the environment from its manufacture, processing, distribution in commerce, use or disposal or (2) the substance may be produced in substantial quantities, and that there may be substantial or significant exposure/release. To make a reasoned evaluation of the risk associated with such chemicals, EPA needs data on each chemical's structure and properties, manufacturing process, worker exposure, environmental release, production volume, potential industrial, commercial, and consumer use, and test data related to the substance. EPA needs sufficient information so as to identify substances with analogous chemical structures and properties, with similar manufacturing processes and with similar uses. The Agency reviews available data to evaluate the toxicity of the chemical and the potential risk resulting from human and environmental exposure to the substance. If EPA is considering regulation of the chemical, the Agency also evaluates the benefits of the substance to determine what regulatory action, if any, to take.

On the basis of its initial review, EPA eliminates the vast majority of new chemical substances from further review. EPA may (1) identify a number of chemical substances for more detailed evaluation for which additional exposure or toxicological data may be needed; (2) identify some substances for follow-up reporting on their commercial development; and (3) select a limited number for immediate regulatory action. Through this process EPA minimizes the burden on both the Agency and industry by requiring detailed information only on those substances that may present unreasonable risk or injury to health or the environment or that may be produced in substantial quantities, and may result in substantial or significant exposure/release.

A chemical is considered to be a "new" chemical if it is not listed in the TSCA section 8(b) Inventory of chemicals manufactured or processed in the United States. The Inventory includes both public and confidential information. Chemicals appear in the public portion of the Inventory by name if the company manufacturing the chemical does not claim the name of the chemical to be confidential. Chemicals whose names are claimed confidential are identified in the public portion of the Inventory by an accession number and a generic name. The specific chemical name of a confidential chemical appears only in the confidential portion of the Inventory, which is not available to the public.

A company that intends to manufacture or import a chemical substance that does not appear by a specific name in the public portion of the Inventory may inquire of EPA whether the substance is included in the confidential portion of the Inventory (i.e., to determine whether the substance would be considered new and therefore subject to the TSCA section 5 notice requirements). EPA will respond to such an inquiry only if the Agency determines that the

company has a "bona fide" intent to manufacture or import the substance. Reporting provisions found at 40 CFR 720.25 or 40 CFR 725.15 require additional information from a submitter so as to encourage the submission only of bona fides that reflect serious intent.

EPA requires submitters of PMNs and bona fides to provide a specific chemical identity for the substance for which a notice is made, based on a Chemical Abstracts (CA) Index name or a CA preferred name. This requirement reduces delays caused by incorrect or ambiguous chemical identity, expedites the Agency's ability to perform Inventory searches and saves Agency resources spent on naming submitters' substances.

Since a company's initial intention to manufacture or import a substance or microorganism may change after making a PMN or MCAN submission, EPA requires companies to notify the Agency when manufacture or importation begins by submitting a Notice of Commencement (NOC) (see 40 CFR 720.102 and 725.190). Submitters specify in the NOC whether commencement occurred via manufacture or importation and the address of the site(s) of first manufacture. This information is essential to the Agency as a compliance mechanism. The information requirements for NOC reporting also assist in identifying cases in which submitters have mistakenly reported the wrong case number in the NOC, or erroneously listed a substance that is very different from that which they intended to commence manufacture. In addition, the reporting requirements provide submitters an opportunity to update information that may no longer be correct or appropriate as reported in the notice. Finally, the NOC results in EPA adding that substance to the TSCA Inventory.

EPA requires the use of a specific form (EPA Form No. 7710-56) for NOCs (see Attachment I). The form is not required for microorganisms. The use of a standard form leads to greater efficiency by assisting EPA in readily identifying the type of notice, providing uniformity in recording responses in EPA databases, and providing manufacturers a format to assure that important information is not inadvertently omitted in their submissions. Before EPA required the use of a standard NOC form, a significant number of NOCs created difficulty because they were not recognized by the Agency as a NOC or they contained confusing, missing or unnecessary information. These problems resulted in a waste of time and resources for both submitters and EPA personnel who must prepare or review these notices. The required use of a standard reporting form also reduces EPA processing time for NOCs.

EPA publishes in the Federal Register information summarizing the content of each notice, including the generic name of the chemical substance, the proposed uses and certain test data submitted with the notice, as required by TSCA section 5(d)(2). EPA publishes at the beginning of each month a list of PMN notices and polymer exemption applications that have been received, those that are still under review and those for which the review period has ended. This publication is mandated by TSCA section 5(d)(3). TSCA also requires EPA to publish a notice of receipt of a test-marketing application so that the public may comment, and another notice stating whether the application was granted or denied.

Periodically EPA compiles certain information such as the number of notices submitted and their disposition. This information is presented on EPA's website. See http://www.epa.gov/oppt/newchems/tools/status1.htm and http://www.epa.gov/oppt/ar/.

The recordkeeping requirements for PMNs, MCANs, exemption applications, and

SNURs are necessary for EPA enforcement purposes. As part of its enforcement program, EPA conducts inspections to review the records of TSCA section 5 submitters to ensure that the information submitted in the notice was correct, that the submitter did not begin manufacture, importation or processing before the review period expired, and that, for PMN chemicals or MCAN microorganisms, the notice of commencement was submitted when manufacture or import began. The Agency also inspects manufacturers' or processors' chemical substances subject to SNURs to ensure that they are not doing so in violation of the SNUR. The recordkeeping requirements for exemptions are necessary for enforcement purposes as well. EPA conducts inspections to ensure that the information submitted in the aforementioned applications is true and that the person holding the exemption is complying with any restrictions EPA imposed when it granted the exemption.

Users of these data are EPA employees located primarily in the Office of Pollution Prevention and Toxics (OPPT), within the Office of Chemical Safety and Pollution Prevention (OCSPP), and in the Office of Enforcement and Compliance Assurance (OECA), and Core TSCA Regional Coordinator Inspectors. In particular, staff of the New Chemicals Program of the Chemical Control Division within OPPT use this information to review and evaluate the health and environmental effects of new chemicals and significant new uses of chemicals, and to recommend and implement regulatory actions if warranted. OCSPP employees in the Regional Offices and OECA employees in Headquarters and in the Regions use TSCA section 5 data for compliance monitoring and enforcement purposes.

3 NON-DUPLICATION, CONSULTATIONS AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

EPA is the only federal agency that regularly collects information on new chemical substances used for purely industrial applications. (In instances where chemical substances with industrial applications also have drug or cosmetic uses, the Food and Drug Administration would have concurrent jurisdiction.) Therefore, the information submitters provide in a PMN or MCAN cannot be obtained elsewhere. However, data previously submitted to EPA need not be resubmitted if the following conditions are met: the data were submitted with no claims of confidentiality and the PMN (or other TSCA section 5 notice) identifies the office or person to whom the data were submitted and the date of the submission.

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 September 30, 2011 (76 FR 46794, August 3, 2011). EPA received no comments during the comment period.

3(c) Consultations

For several years EPA has been engaged in a continuing series of joint EPA/industry/public interest group meetings to facilitate the identification and exchange of critical information related to the TSCA New Chemicals Program. These meetings include

numerous "pre-notice" meetings with individual companies, presentations and delivery of training courses at professional meetings (including the annual Global Chems Conference), and active participation in the ORCD Clearing House on New Chemicals.

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

1) Mike Walls, Vice President
Regulatory and Technical Affairs
American Chemistry Council, Inc.
mike_walls@americanchemistry.com

2) Ernie Rosenberg, President and CEO
American Cleaning Institute
erosenberg@cleaninginstitute.org

3) Derek Swick, MPP
Senior Policy Advisor
Regulatory and Scientific Affairs
American Petroleum Institute
swickd@api.org

4) Brigid Klein, Vice President and General Counsel
Consumer Specialty Products Association
bklein@cspa.org

5) John Carroll, Chair
Enzyme Technical Association
Director, Regulatory Affairs
Novozymes North America
john@novozymes.com

6) Lee O. Fuller, Vice President of Government Relations
Independent Petroleum Association of America
lfuller@ipaa.org

7) Jim Cooper, Vice President Petrochemicals
National Petrochemical & Refiners Association
jcooper@npra.org

8) William Carteaux, President
Society of the Plastics Industry, Inc.
wcarteaux@plasticsindustry.org

9)Bill Allmond, Director
Government Relations

Society of Chemical Manufacturers and Affiliates Formerly the Synthetic Organic Chemical Manufacturers Association. (SOCMA)
allmondb@socma.com

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 in Attachment J.

3(d) Effects of Less Frequent Collection

The frequency of the submission of information under TSCA section 5 is not under the Agency's control. Manufacturers of new chemical substances must submit a PMN, SNUN, or MCAN at least 90 days prior to anticipated manufacturing or distribution of the substance for non-exempt commercial use. Submission of information thus is on an as-needed, on-occasion basis, initiated by respondents. Subsequent reporting would only be required if EPA determined that a specific use of a substance constituted a significant new use. Less frequent collection would mean respondents not being required to submit data at all. However, without such data, EPA would be unable to administer the new chemical review requirements found in TSCA and would be unable to carry out its mandate to protect the public from unreasonable risks to health and the environment.

3(e) General Guidelines

This collection of information is consistent with all OMB guidelines under 5 CFR 1320.6 except with respect to the maintenance of records by respondents for more than three years. EPA believes a five-year recordkeeping requirement is needed to carry out an effective program. The five-year recordkeeping requirement is consistent with the five-year statute of limitations under 28 U.S.C. 2462 held applicable to all EPA enforcement actions, including administrative proceedings under TSCA. See 3M Company v. Carol Browner and EPA, 17 F.3d (DC Cir.1994). In addition, a five-year retention period comports with certain recordkeeping requirements imposed by the Occupational Safety and Health Administration and helps to keep these requirements consistent with one another, thereby avoiding different reporting obligations. Therefore, the Agency requires respondents to retain records for more than three years.

3(f) Confidentiality

Much of the required premanufacture information may be considered by the submitter to be a trade secret, proprietary, or "confidential business information" (CBI). However, TSCA mandates that EPA require the submission of such information because it is essential for providing a basis to determine unreasonable risk. EPA cannot draw conclusions or make assumptions concerning toxicological effects and potential risks without examining physicochemical structure, methods of production, byproducts, potential uses, exposure data, etc. The Agency is required by TSCA section 5(d)(2) to publish a Federal Register notice that identifies the chemical substance, lists its uses or intended uses and describes test data. Congress included these provisions to allow active public participation in the review process.

The Agency's policies allow public involvement while preserving confidentiality. TSCA section 14(a) prohibits, except in limited circumstances, the disclosure of trade secret information. TSCA section 14(d) allows disclosure of health and safety studies, including

underlying data, unless these studies disclose confidential process or mixture information. Under 40 CFR 720.85 and 720.87(See also 40 CFR part 2), when the specific chemical identity or use data are claimed confidential, the Agency requires the submitter to provide generic descriptions for inclusion in Federal Register notices and the public file. Additionally, the submitter must provide a "sanitized" copy of all health and environmental effects data, with confidential information deleted, for placement in the public docket. Within the Agency, only personnel with the required clearance may handle CBI.

Based on its experience, EPA expects that most information included in TSCA section 5 notices will be CBI. EPA has developed an elaborate system to prevent unauthorized disclosure of CBI. This system includes procedures for logging material in and out of the Confidential Business Information Center (CBIC) at EPA headquarters and procedures for photocopying and transmitting CBI. These procedures apply to CBI submitted by manufacturers as well as CBI generated by EPA staff in the course of their review. Access to CBI is restricted to persons who need the information for their work. No one is allowed access to CBI without first undergoing instruction on procedures for handling CBI. Special procedures have been instituted to restrict access to computerized CBI. These procedures are detailed in the "TSCA CBI Protection Manual," October 2003. EPA believes these procedures protect confidential information while providing the public with as much information as possible.

Any information being sent via CDX is transmitted using secure technologies to protect CBI. The e-PMN software encrypts PMN submissions using a Federal Information Processing Standards (FIPS) compliant encryption module. The encryption module employs a public key algorithm which converts readable text into encrypted text. This public key is downloaded from CDX to the e-PMN software, and the corresponding private key is sent to EPA's New Chemical System (NCS). The encryption remains while the submission is transmitted via CDX to NCS. The file can be decrypted only with the NCS's private key when it has reached its final destination. The NCS is the only party that possesses the private key, which converts the encrypted text back into readable text.

The same thing will occur for all correspondence going back to the submitter. The NCS and e-PMN software are also provided with a set of public and private keys, so that correspondence containing any potential confidential business information will remain encrypted during transmission via CDX and can be opened only by the submitter within the e-PMN software.

3(g) Sensitive Questions

Information requirements under TSCA section 5 do not include questions of a sensitive nature.

4 THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAIC Codes

This information collection affects companies that manufacture, process or import chemical substances. These companies are typically found in NAIC major groups 325

(Chemical Manufacture) and 324 (Petroleum and Coal Products).

4(b) Information Requested

(i) Data Items - Reporting Requirements

Premanufacture Notices - Premanufacture notices required by TSCA section 5 must include certain information to the extent known to or is reasonably ascertainable by the submitter. This information is defined in TSCA section 8(a)(2) and 40 CFR 720.45. Specific information includes the following:

- Common or trade name, chemical identity and molecular structure of the chemical in question;
- Categories or proposed categories of use of the chemical;
- Estimate of the total amount of such chemical to be manufactured or processed, including the amount to be manufactured or processed for each use category;
- Description of the byproducts resulting from the manufacture, processing, use or disposal of the chemical;
- Estimate of the total number of individuals who will be exposed to the chemical in their places of employment, and the duration of such exposure; and
- Manner or method of the disposal of the chemical.

In addition, the submitter must provide any test data in the submitter's possession that indicate the environmental or health effects of the chemical, and a description of any other data known to the submitter concerning the environmental or health effects of the chemical. The specific information requirements are spelled out in 40 CFR part 720, on the PMN reporting form itself, and in the Instruction Manual (see Attachment H).

To facilitate the review of chemicals, EPA has developed a PMN reporting form (EPA Form 7710-25; see Attachment G). This form is required for reporting new chemicals under TSCA section 5(a)(1) and is also required for submitting Significant New Use Notices (SNUNs). By supplying the information specified in the form, submitters do not incur the burden of providing information unnecessary for EPA's review. Therefore, use of the form lessens the burden on companies by reducing uncertainty, minimizing the need for additional contact with EPA, and allowing companies to establish procedures for meeting reporting requirements.

EPA has limited the level of detail of information required in the PMN form to that necessary for EPA to conduct an initial review of a chemical. However, submitters may include additional or optional information in their notices that they believe EPA should consider in its review. For example, submitters may identify pollution prevention techniques being employed by the submitter that may be relevant to the Agency's risk assessment. EPA encourages submitters to provide information on the benefits of the new substance in comparison to existing chemical substances, information on the substitutes, and any additional information available to

them on waste management techniques.

The existing PMN form is not appropriate for reporting of new microorganisms in MCANs since the form was designed with traditional chemical substances in mind. EPA has developed a "Points to Consider" guidance document to assist submitters in providing to EPA the information necessary for EPA to make assessments of new microorganisms under TSCA section 5 (see http://www.epa.gov/oppt/biotech/pubs/pdf/ptcbio.pdf). The submitter will be able to provide information in a format of his or her own choosing. However, after the effective date of the e-PMN rule (April 6, 2010), submitters of MCANs are required to use the e-PMN software to generate a finalized "header" sheet, called EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*. The form requires contact data, the addition of any attachments, and a signature page.

The amended e-PMN form also includes a new User Fee Payment Identity Number field to enable the Agency to match more easily a particular user fee with a particular notice submission. A User Fee Payment Identity Number will be required and may be a check number, a wire transfer number, or a "Pay.gov" transaction number used to transmit the user fee. This information is presently in the submitter's possession

The second new information element on the amended PMN form is optional and consists simply of the e-mail addresses for the principals listed on the Submitter Identification section of the PMN form. This information will help facilitate electronic communications with the proper point of contact from the submitting entity.

Exemption Applications - Applications for exemptions from premanufacture or microbial commercial activity notice requirements have additional information requirements, as follows:

- Test-Marketing Exemption (TME) (40 CFR 720.38)

  Test-marketing exemption applicants were not required to use the PMN form or any other prescribed reporting form prior to April 6, 2010, the effective date of the e-PMN final rule. Since April 6, 2010, TME submitters have been required to use the e-PMN software to generate finalized submissions either using Form 7710-25 or a cover letter and attached information. The test-marking exemption rule states that applicants should provide the following information: (1) all existing health and environmental effects data on the chemical or a discussion of toxicity based on structure-activity relationships and relevant data on chemical analogues; (2) the maximum quantity of the chemical substance that the applicant will manufacture or import for test-marketing purposes; (3) the maximum number of persons who may be provided the chemical substance during test-marketing; (4) the maximum number of persons who may be exposed to the chemical substance as a result of test-marketing, including information regarding the duration and route of such exposure; and (5) a description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development. The Agency retains the right to declare that an application contains insufficient information to make an evaluation. Any person who receives a test-marketing exemption must retain documentation of any information in the exemption application and documentation of their compliance with any restrictions imposed by EPA when it granted the application. This information must

be retained for five years from the final date of manufacture or import under the exemption.

- Research and Development Exemption (R&D) (40 CFR 720.36)

A manufacturer or importer using this exemption must notify all persons in its employ or to whom it distributes the chemical substance and who are involved in any way in the research, of any risk to health associated with the chemical substance.

- TSCA section 5(h)(4) Exemptions

1. For the low volume exemption (LVE) (40 CFR 723.50(1)), submitters are required to submit their exemption on the PMN form (generated using the e-PMN software) to ensure that the Agency has adequate information to make a determination that these substances will not present an unreasonable risk. Statements describing exposure and release controls, site, and use in an exemption application are legally binding and enforceable.

2. For the low exposure/low release exemption (LoREX) (40 CFR 723.50(2)), submitters are required to submit their exemption on the PMN form (generated using the e-PMN software). The LoREX exemption encourages the use of pollution prevention practices through the development of manufacturing, processing and use techniques that minimize exposure to workers, consumers, the general public and the environment. As with the low volume exemption, site, use, exposure and release controls identified in the notice are binding.

3. The polymer exemption rule (40 CFR 723.250) requires the submission of a post-manufacture report to EPA. A simple one-page annual report is required to be submitted to the Agency no later than January 31 of the year subsequent to initial manufacture under the terms of the exemption. The report must include company identity information including the name and telephone number of a technical contact and the number of exempt substances for which manufacture commenced during the preceding year. These reports are not subject to the electronic reporting requirements of the e-PMN rule.

4. Instant photographic film articles exemption notices (under 40 CFR 723.175) must, at a minimum, identify the manufacturer and the new chemical substance. Applicants must submit an exemption notice when manufacture begins and comply with certain requirements to limit exposure to the chemical. Applicants must retain certain records for 30 years from the final date of manufacture. These exemption notices are not subject to the electronic reporting requirements of the e-PMN rule.

5. A TSCA experimental release application (TERA)(under 40 CFR 725.250) applies to research and development activities that result in intentional environmental releases of microorganisms. Applicants are required to include adequate information in their exemption so that the Agency can make a determination that the microorganism will not present an unreasonable risk. Submitters must follow the conditions described in the TERA as well as any conditions of EPA's TERA approval.

6. Tier I exemption (40 CFR 725.424) - This exemption applies to certain microorganisms subject to physical containment and control technologies. EPA has developed specific criteria for the host microorganism, introduced genetic material, and containment technology to ensure that the microorganism will not present an unreasonable risk. Applicants must notify EPA 10 days before manufacture or import, certifying compliance with the exemption criteria and include the site of manufacture or import.

7. Tier II exemption (40 CFR 725.428) - This exemption applies to the same microorganisms subject to a Tier I exemption, however, the applicant must provide adequate information on its proposed physical containment and control technologies in order for EPA to evaluate the exemption. If EPA grants the exemption, it may impose appropriate restrictions on the activities described in the notice.

After the effective date of the e-PMN rule (April 6, 2010), submitters of biotechnology notices (i.e., MCANs, TERAs, Tier I exemptions, and Tier II exemptions) are required to use the e-PMN software to generate a finalized "header" sheet, called EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*. The form requires contact data, the addition of any attachments, and a signature page.

Notices of Commencement - Under 40 CFR 720.102 and 725.190, EPA requires companies to notify the Agency by submitting a Notice of Commencement (NOC) when non-exempt commercial manufacture or importation of a new chemical begins. Required reporting information includes the following:

- Specific chemical identity of the chemical, and a generic chemical name if the specific name is considered confidential;
- Premanufacture notice number assigned by EPA;
- Date manufacture or importation commenced;
- Address of the site where manufacture commenced;
- Name and address of the submitting company, the name of the authorized official signing the NOC, the name and telephone number of a technical contact person; and
- Clear indication of what information, if any, is to be considered confidential.

For traditional chemicals regulated under 40 CFR part 720, Notices of Commencement must be submitted to EPA using the standard Notice of Commencement form (EPA Form 7710-56). Since the effective date of the e-PMN rule, submitters are required to use the e-PMN software to generate a finalized submission using Form 7710-56. The submitter must provide the NOC to EPA on, or no later than 30 calendar days after, the day manufacture or importation began. The existing NOC form is not appropriate for reporting of new microorganisms since the form was designed with traditional chemical substances in mind. Thus, under 40 CFR 725.190 the submitter may provide information in a format of his or her own choosing when reporting an NOC for a new microorganism.

Bona Fides - To determine whether a chemical substance is on the confidential portion of the TSCA Inventory, submitters of bona fide inquiries under 40 CFR 720.25 are required to provide the specific chemical identity of the substance in question, a signed statement that the submitter intends to manufacture or import that substance, a description of the research and development activity conducted on that substance, a description of the intended use of the substance, infrared spectrum data to identify the substance, the estimated date on which the company intends to submit a PMN, the address of the facility where manufacturing or processing will occur, and a description of the manufacturing process.

To determine whether a microorganism is on the confidential portion of the TSCA Inventory, submitters of bona fide inquiries under 40 CFR 725.15 are required to provide the taxonomic designations, pertinent genotypic and phenotypic information, a signed statement that the submitter intends to manufacture or import that microorganism, a description of the research and development activity conducted on that substance, a description of the intended use of the substance, and an indication of whether a related microorganism was previously reviewed by EPA to the extent known by the submitter. At this time, Bona Fides are not subject to the e-PMN rule electronic reporting requirements.

User Fees - The TSCA section 26(b) rule (at 40 CFR part 700) that requires manufacturers, importers and processors to pay fees for PMNs, MCANs, certain PMN exemption application notices, and SNUNs submitted under TSCA sections 5(a) and (h), requires a limited amount of additional information to be submitted with the section 5 notice. This information includes certification that the firm is a "small business concern," (if applicable) a certification statement that the submitter remitted the appropriate fee, and the placement of corresponding identifying numbers both on the PMN form and the fee remittance.

(ii) Data Items - Recordkeeping Requirements

Under 40 CFR 720.78(a), notice submitters must keep the following data for five years from the date of commencement of manufacture, import, or processing: documentation of information in the notice (e.g., sources of information provided in the notice); production volume for the first three years of production; the date of commencement, plus documentation of this information; and "other data" described in the notice, as required by 40 CFR 720.50(b).

Recordkeeping requirements under SNURs require persons who manufacture or process a substance subject to significant new use reporting to maintain records indicating their compliance with certain methods of manufacture or processing. Some Significant New Use Rules do not require recordkeeping. Rather, recordkeeping requirements apply only to those SNURs for which compliance can only be monitored by recordkeeping or SNUR notice submission under TSCA section 5(a)(2). For example, upon occasion EPA will determine that a specific set of exposure controls will adequately mitigate risks to workers by a specific chemical substance. In such cases EPA may determine, by rule, that the failure to utilize such controls constitutes a significant new use. However, those persons employing the controls identified in the SNUR are not required to report to EPA. In order to demonstrate to EPA inspectors or to purchasers of the chemical substance that they are properly employing worker exposure controls (to avoid SNUR notification requirements), manufacturers or processors will likely maintain some record of their compliance. In instances such as those described above, EPA would request

that records be kept documenting the establishment and implementation of procedures to ensure that employees use applicable personal protective equipment, and that employees are informed of the hazards associated with the chemical substance and are trained in the use of protective equipment. These records aid inspectors in EPA's compliance monitoring program during their visits to plants where substances subject to SNUR requirements are manufactured or processed. EPA does not consider recordkeeping that indicates compliance with a SNUR to be burdensome. Information contained in these records is not submitted to EPA. Therefore, the costs of keeping such records should be minimal.

There are also recordkeeping requirements for persons subject to consent orders containing exposure controls. Depending on the facts of each case, submitters must keep records in connection with the use of the exposure controls including one or more of the following: (1) documentation of manufacture and importation volumes of the PMN substance, with associated dates of manufacture or importation; (2) documentation of the names and addresses of all persons outside the site of manufacture or import to whom the submitter directly sells or transfers the substance, with associated dates of transfer; (3) documentation of the establishment and implementation of personal protective equipment program; (4) documentation of chemical protective clothing imperviousness testing; (5) documentation of the hazard communication program; (6) copies of labels; (7) copies of material safety data sheets; (8) documentation of compliance with industrial, commercial and consumer use limitations; and (9) documentation of compliance with disposal and release to water limitations.

(iii) Respondent Activities

In responding to the reporting and recordkeeping requirements outlined in this document, respondents will engage in the following activities:

- Read regulatory requirements and provisions;
- Determine which provisions are applicable to their activities;
- Gather information necessary to meet the requirements;
- Substantiate any claims of confidential business information;
- Register with CDX
- Use the e-PMN software
- Submit information to EPA, as necessary;
- Comply with any restrictions EPA may impose upon completion of review of their submission; and
- Maintain any necessary records.

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

5(a) Agency Activities

In connection with administering the TSCA section 5 new chemical review and regulatory program, EPA performs the following activities:

- Reviews PMN/MCAN submissions;

- Analyzes submissions for confidentiality and provides appropriate protection for confidential data;
- Files and stores submissions including transfer of data submitted on optical disc to Agency data systems;
- Proposes and implements regulatory action as appropriate;
- Scan paper-based section 5 submissions to create electronic data for inclusion in Agency data systems;
- Acknowledges receipt of submissions and notifies respondents of any submission deficiencies;
- Provides technical assistance to respondents; and
- Conducts site and record inspections and performs related compliance monitoring functions.

5(b) Information Requested

(i) Data items, including record keeping requirements

With the exceptions of the new e-PMN software and the minor revisions to the PMN form that were incorporated into that software, that is, the required User Fee Payment Identity Number, optional E-mail address for Principal Contacts, and software-generated format for Biotech notices (EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*), the data items currently approved under OMB Control Numbers 2070-0012 and 2070-0038 are otherwise unchanged.

(ii) Respondent Activities

Register with EPA's CDX and Complete Electronic Signature Agreement

EPA is providing two different variations of the e-PMNsoftware, one with encryption and one without encryption. The e-PMN software with encryption, available on EPA's CDX website, accommodates electronic submission through CDX. The e-PMN software without encryption is available through EPA's TSCA New Chemicals Program website. Both variations of the e-PMN software are available free of charge as Internet downloads. The e-PMN software without encryption is also available on optical discs provided by the Agency upon request.

To register in CDX, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") downloads two forms: the Electronic Signature Agreement and the Verification of Company Authorizing Official form. Registration enables CDX to perform two important functions: Authentication of identity and verification of authorization. Within the "Electronic Signature Agreement" form, the Authorized Official (AO) agrees to certain CDX security conditions. On the "Verification of Company Authorizing Official" form, the AO designates himself/herself as the AO and attests to the completeness and accuracy of the submitted information.

There is a third form generated by CDX that the AO needs to fill out if the AO wants to authorize other persons to submit support documents on his or her behalf, including a paid employee of the company, an outside consultant for the company, or an authorized representative agent for the company. This form is entitled, "Authorization and Verification for Section 5 Notice Support Submitter by Company Authorizing Official." On this form, the AO designates

various persons to submit support documents on his or her behalf, and attests to the completeness and accuracy of the submitted information. Persons designated by the AO to submit on his or her behalf must also sign this form along with the Electronic Signature Agreement form, in order to be "linked" to the AO by EPA; and therefore, be able to submit support documents via CDX on the AO's behalf.

When these forms are received, EPA activates the submitter's registration in CDX and sends him or her an e-mail notification.

(iii)*Use the e-PMN Software to Prepare TSCA Section 5 Notices*

In all cases, respondents use the e-PMN software to:

- ***generate*** the submission materials for TSCA section 5 notices, including forms (i.e., the PMN form (EPA Form 7710-25), the NOC (EPA Form 7710-56) and the TSCA Biotechnology Notice for Online Submissions (EPA Form 6300-07)) as well as submission materials that do not require a standardized form or format; and,

- ***populate*** the submission materials with the relevant information

There are no required or official forms for certain TSCA section 5 notices, such as LVE modifications, 1LoREX exemption modifications, and TMEAs. For biotechnology notices, no EPA-approved forms exist. To allow for electronic and paper submission of these notices using the e-PMN software, submitters do the following:

(1) For exemption modifications, submitters use the e-PMN form by checking the "modification" box on page 1, filling in contact information on page 3, and including the previous exemption number and chemical identity information. A submitter may send a cover letter with the new revisions to the original exemption notice or the pertinent pages of the e-PMN form.

(2) For a TMEA, the submitter checks the "TMEA" box on page 1 of the e-PMN form, and either fill out the form or attach a cover letter for the body of the submission containing the information required by 40 CFR 720.38.

(3) Biotechnology notices have their own menu option. Instead of selecting "Premanufacture Notice," a submitter selects "Biotech," which prompts the software to present the submitter a header page with choices of biotech notices, and space to fill in contact information. The e-PMN software populates this information in a new form entitled, "TSCA Biotechnology Notice for Online Submissions" (EPA Form 6300-07). The additional information may be submitted as an attachment(s).

Notice Type	**Use of e-PMN Software**
PMN	Form 7710-25 generated and finalized by e-PMN software.
Low Volume Exemption (LVE)	Form 7710-25 generated and finalized by e-PMN software.
Test Market Exemption Application (TMEA)	e-PMN software to generate finalized submission either using 7710-25 or cover letter and attached information.
NOC	e-PMN software to generate finalized submission using Form 7710-56.
Biotechnology Notices	e-PMN software to generate finalized "header" sheet (EPA Form 6300-07, *TSCA Biotechnology Notice for Online Submissions*) with contact data, add attachment with notice information, include signature page.
Modifications to Previous Notices	EPA Form 7710-25 generated and finalized by e-PMN software. Fill in pages 1, 2, and 3 of the Form, plus either applicable pages of Form, cover letter, or attachment.
Support Documents	e-PMN software to generate finalized "header" sheet identifying reason for submission and contact data.

Finalize and Submit

A respondent's activities to finalize and a submit TSCA section 5 notices depend on the chosen submission method. The e-PMN software requires users to complete a finalization process before preparing the information for submission to EPA. During the finalization step, the e-PMN software checks that all legally required information is included and provides warnings for certain kinds of missing, incomplete or incorrect data.

Paper

After the e-PMN finalization step was complete, respondents would print submission materials using the e-PMN software, sign them as required, and deliver the submission to EPA via US Mail or courier.

Optical disc

After the e-PMN finalization step is complete, respondents prepare the data generated by the e-PMN software in XML for transfer to an optical disc. With limited exception, discs will be submitted with an original signed hard copy of page 2 (Certification page) and a hard copy of page 3 (a copy of page 3 is needed for contact information in the event that the disc is not readable). A disc-based TMEA submission only needs to be accompanied by a hard copy of the completed page 3. For biotechnology notices, a signed hard copy of the biotech certification needs to accompany the disc. Discs need to be delivered only by courier service to avoid damage to the disk from the Agency's mail screening equipment.

Using e-PMN Software to Submit Electronically to EPA via CDX

After the e-PMN finalization step is complete, the e-PMN software prompts respondents to log-in to CDX. Respondents simply transmit the information to EPA online by clicking on the

e-PMN software's "send" button.

5(c) Collection Methodology and Management

The electronic Adobe Acrobat version of the PMN form is no longer available to PMN submitters. All PMN forms must be generated using the e-PMN software. The e-PMN software is available as a free internet download. The Agency makes available free optical discs containing the software. The data being transmitted electronically via CDX are encrypted to protect CBI. The software works with Windows, Macs, Linux, and UNIX-based computers, using XML for more efficient data transmittal to Agency data systems that once was performed manually.

The Agency introduced the electronic submission software in two phases. The first year, the Agency allowed the submission of information for notices and support documents via CDX, optical disc, and using paper forms generated with the e-PMN software. All paper submissions were eliminated after April 6, 2011, for all new section 5 notices and support documents whose parent notices were submitted after the new system was implemented (April 6, 2010). Disc submissions generated using the e-PMN software will be eliminated April 6, 2012 (the end of the second year) for all new section 5 notices and support documents whose original notices were submitted after the new system was implemented. After April 6, 2012, only electronic submissions via CDX will be allowed for new section 5 notices and support documents whose related notices were submitted after the new system was implemented. Support documents whose parent notices were submitted before the new system was implemented will still need to be mailed as hard copy to the Agency. NOCs and support documents that are submitted to the Agency for review after implementation of CDX-based submissions, but that are related to section 5 notices that were submitted to the Agency for review before implementation of CDX-based submissions, will still be required to be submitted on paper; however, EPA is planning to revise this requirement in the future and enable submitters to provide them to the Agency electronically. The Agency took this position because although the section 5 notices received after implementation of the new system will be entered into a newly created database, section 5 notices submitted before promulgation of this rule will only exist in the "legacy" database, i.e., the database used prior to promulgation of this rule. This will similarly be the case for SNUNs and related support documents. Support documents that are submitted to the Agency for review after implementation of CDX-based submissions but that are related to SNUNs that were submitted to the Agency for review before implementation of CDX-based submissions will also still have to be submitted by paper. The Agency will prefer to allow everything to be submitted electronically; however, at this time the Agency does not have the resources to enter placeholders for old files in the new system to accommodate support documents and NOCs that will ultimately be submitted to the Agency for section 5 notices and SNUNs submitted prior to the effective date of this rule.

An electronic signature is required for TSCA section 5 notices submitted to the Agency via CDX. Electronic signatures are granted as part of the CDX user-registration process. However, since the Agency has no system for collecting official signatures for forms submitted on an optical disc, such as a CD, original signatures have to accompany the disc and any paper forms submitted during the phase-in period.

The Adobe electronic form that was in use for filling out the PMN form used a "header" page at the beginning of the PMN form. The "header" page asked for certain information for the purpose of adding or spawning additional pages requested by the submitter. In the new e-PMN software, there are header pages for support documents, and attachments that identify submitters and the nature of their communications. These header pages allow the software to identify and store data correctly in the Agency's databases when submitted by paper.

Submitters are required to use the e-PMN software to generate section 5 notices and support documents regardless of whether they are submitted via CDX or delivered on a disc, or were submitted on paper. A notice may have been submitted on paper; however, for the notice to be declared complete, the entire PMN form must have been generated and "finalized" using the software. Disc submissions must be accompanied by an original, signed, hard copy of page 2 of the new e-PMN form (the Certification page), and page 3, (contact information in case the submitted disc is unreadable). All e-PMN software users, regardless of how a document is submitted, need to undergo a "finalization" step in generating a document.

During the "finalization" step, the e-PMN software checks that all legally required information is included, provides warnings where necessary, and saves data in a read-only format acceptable to the Agency. Section 5 notices whose data have not undergone the "finalization" step are declared incomplete. This step is necessary to allow for an accurate and efficient transfer of data from an optical disc or a paper-based form to the EPA data systems. The word, "finalized," is in the file name and the name ends with "_tsca." The "finalized" file (folder) contains the CBI and non-CBI data in XML format that are non-editable. The CBI and non-CBI attachments are also in this folder in their native format. Attachments must be submitted in one of EPA's approved formats for the Agency to be able to open the files.

The biggest difference between the old and new methods of data entry on the e-PMN form is the user interface. Data now are entered through a series of pages or screens on the computer as opposed to being entered on the form itself. Most screens represent a page of the printed e-PMN form. For those submitters who would like to see how their data look on the e-PMN form once filled out, the new software allows the submitter to navigate between the e-PMN form and a PDF version. The PDF or printed version has the look of the original or current paper PMN form; however, submitters should not submit the PDF to the Agency because this submission is in the wrong format and thus would be declared incomplete. Only the "finalized" read-only XML file folder is accepted by the Agency.

The questions and pagination on the new e-PMN form are the same as on the old PMN form, except that fields on the print form have been expanded to make more room for submitter information, which results in the total number of pages being greater. Fields on the new print form have been realigned to make the form easier to scan.

The electronic submission software is changing the way that companies now interact with the Agency with many of its submissions. Electronic communication reduces the reporting burden on industry because it will reduce both the cost and the time required to enter, review, edit and transmit data to the Agency. The electronic submission software improves data quality by facilitating data correction and validation by highlighting fields with omitted data prior to submission. The protection of encrypted TSCA CBI data and the generation of an electronic Copy of Record that is returned to the submitter are other critical advantages of submitting data

electronically through CDX.

All information sent via CDX is transmitted securely to protect CBI. Furthermore, if anything in the submission has been claimed CBI, a sanitized copy of the notice must be provided by the submitter. The new e-PMN software facilitates the creation of this sanitized non-CBI version, eliminating the need for the submitter to do this manually. It also allows submitters to share a draft notice within their company during the creation of a notice and to save a copy of the final file for future use. A "Profiler," available in the software, also allows for certain information to be kept on file by the submitter to avoid re-entering the same information into a new form.

The Agency also benefits from receiving electronic submissions. Data systems that were populated manually are now populated electronically, reducing the potential for human error that exists when data are entered by hand. Agency personnel are also able to communicate more efficiently with submitters electronically, compared to using U.S. mail.

Because companies register with EPA to submit their data electronically to the Agency via CDX, the Agency in turn will be able to communicate electronically with submitters via CDX. Some examples of routine communications from EPA that could go through CDX include the Acknowledgment Letter (acknowledging receipt of a submission), and the Incomplete Letter (stating why a submission has been declared incomplete). Usually, these communications are sent through the mail. An electronic means of communication provides significant time and resource savings for both parties.

Additionally, to aid persons subject to this information collection, OPPT has set up a TSCA Hotline that provides information regarding TSCA regulatory requirements. When TSCA Hotline staff members are unable to answer questions regarding TSCA section 5, the questions are referred to OPPT staff for appropriate resolution.

5(d) Small Entity Flexibility

The reporting and recordkeeping requirements associated with TSCA section 5 are applicable to all affected entities, regardless of size of business. However, EPA provides specialized assistance to respondents, particularly to small entities. TSCA section 26(d) established the TSCA Assistance Office, now known as the Environmental Assistance Division (EAD), to provide technical and other non-financial assistance to manufacturers, importers and processors of chemical substances. This office has established a hotline to assist small businesses complying with TSCA rules. It provides material such as copies of Federal Register notices, advisories, and other information on request. It also publishes the bi-monthly *Chemicals-in-Progress* bulletin that identifies activities in EPA. In addition, "small business concerns" submit a reduced fee of $100 (rather than $2,500) for each TSCA section 5 notice submitted pursuant to the user fee regulation at 40 CFR 700.45(a)(1).

Moreover, EPA has taken certain steps to minimize for all respondents the reporting burden associated with complying with this collection. For example, the information technology used by EPA includes bibliographic data bases that reference scientific literature and data bases containing previously submitted chemical information. These data bases allow EPA to exempt submitters from needlessly providing already-published data or resubmitting previously

submitted information (unless the previously submitted information was claimed confidential).

Also, as discussed above, EPA has issued several TSCA section 5 exemption rules that reduce PMN reporting requirements thereby providing relief to submitters from the burden of responding to the full PMN/MCAN requirements.

Finally, EPA provides the services of pre-notice communications coordinators and other personnel to assist persons in a comprehensive manner for purposes of notice preparation prior to submission. For instance, for new chemical substances a PMN submitter may, upon consultation with the pre-notice communication coordinator, prepare one "consolidated notice" for two or more chemical substances if they are similar in physicochemical structure and use and share common test data or other information. Pre-notice communication coordinators respond to other pre-notice inquiries that may pertain to the full scope of the TSCA section 5 regulations.

5(e) Collection Schedule

Does not apply. Submission of information under this collection is on an as-needed, on-occasion basis, initiated by the respondents.

6 ESTIMATING THE BURDEN AND COST OF THE COLLECTION

The analysis covers submissions of PMNs, SNUNs, MCANs, and associated exemption applications: test-marketing exemption (TME), low volume exemption (LVE), low exposure/low release exemption (LoREX), TSCA Experimental Release Applications (TERAs), and Tier I and II exemption applications. It also covers submission of Bona Fide claims, and the burden associated with implementation of TSCA section 5(e) consent order restrictions. Since the 1995 amendments, polymer exemptions are no longer submitted, and so are not included in this analysis. Since the last renewal of this ICR in 2007, phase-in of the e-PMN rule has begun, reducing the burden hours on submitters.

Burden and cost calculations are based on the assumption that EPA will receive approximately 1,968 TSCA section 5 notices each year, based on the latest estimate of annual notices submitted to EPA, based on the *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule* (2009) (Table 1).

6(a) Estimating Respondent Burden

The burden to respondents includes: (1) reporting burden for submission of PMNs, SNUNs, MCANs, exemption notices, and implementation of TSCA section 5(e) consent order restrictions such as the use of exposure controls and/or performing toxicity testing; and (2) recordkeeping burden associated with notice submissions, consent orders, exposure controls and toxicity testing.

6(b) Burden Associated with Reporting

As shown in Table 1, the total respondent reporting and third-party notification burden associated with this information collection is estimated to total 114,301 hours. This burden

estimate is calculated by multiplying the hours of reporting burden by the number of each type of notice that EPA expects to receive and summing across the notice types.

Number of Notices. The number of notices expected to be submitted annually is estimated according to data provided in the *Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule* (2009).

Prior to the 1995 amendments to the PMN rule, 70% to 80% of all TSCA section 5 notices were full PMN submissions. Since the amendments of 1995, the increase in exemptions has not significantly changed this distribution. EPA expects few persons to submit significant new use notices (SNUNs). The number of SNUNs submitted is a function of the number of chemicals regulated under Significant New Use Rules, which are relatively few. Current data suggest the Agency expects to receive approximately 8 SNUNs annually.

The amendments also placed stricter control on bona fide claims, intended to establish bona fide intent. This was done in response to the steadily increasing number of bona fide notices submitted to EPA. The result of the amendments has been a significant reduction in bona fide submissions. Current EPA data suggest that 116 bona fide notices are expected to be submitted annually.

On average, LVE and LoREX exemptions are expected to account for about 419 notices annually. Further, TME are expected to average 8 applications per year, or less than 1% of all TSCA section 5 notices.

The various exemptions available to submitters since the 1995 amendments have significantly reduced the need for consent order development and post-notice data review. Historical EPA data indicate that such consent orders and post-notice data reviews will amount to roughly 2% of the total TSCA section 5 notices. Based on historical data, EPA estimates 28 cases would be subject to TSCA section 5(e) consent order restrictions burden, with 12 cases requiring test data, and 16 non-testing TSCA section 5(e) cases. Testing is usually contracted out to a laboratory, thus the burden associated with testing requirements represents the time that personnel from the submitting firm would spend overseeing the testing, assumed to be 25% of the lab burden.

The e-PMN rule reduces the burden hours on submitters by eliminating several hours, mainly clerical hours, of the paper submissions. Burden reduction resulted from eliminating the time and expense of preparing and mailing hardcopy notices. Paper submissions of Section 5 notices will no longer be accepted after April 6, 2011, and notices submitted on optical discs will no longer be accepted after April 6, 2012.

Burden hours. Burden hours for each type of notice were estimated in previous analyses, as described below and summarized in Table 1.

- The hours for respondent reporting burden for a full electronic PMN submission is expected to average 92.2 respondent burden hours. This burden applies also to SNUN, LVE, and LoREX submissions since each of these notices requires the submission of a complete PMN form.

- The respondent burden for an MCAN is estimated to average of 288.2 hours.
- The respondent burden for submission of a TME is estimated to average 86.2 hours.
- The respondent burden for submission of a polymer exemption post-manufacture annual report is estimated to average 2 hours.
- The respondent burden for a TERA is estimated to average 507.2 hours.
- The respondent burden for a Tier I or Tier II exemption is estimated to average 110.2 hours.
- The respondent burden for submission of a Notice of Commencement (NOC) is estimated to be 0.6 hours
- Submissions of instant photographic film articles exemption notices are incredibly rare. EPA has not received any such notifications in many years and does not expect to receive any such notices over the next several years. However, for the sake of this analysis, EPA assumes that 1 such exemption will be submitted per year. The minimum amount of information that is required to be contained in this exemption notification is identity of the manufacturer and the new chemical substance. The burden associated with preparing and submitting this type of exemption notification is 0.5 hours.

Table 1. Reporting Burden

Type of Notice	Average Annual Responses[1]	Average Reporting Hours per Response	Average Annual Burden
PMN	720	92.2	66384
SNUN	8	92.2	737.6
MCAN	3	288.2	864.6
Exemptions:			
TME	8	86.2	689.6
LVE/LoREX	419	92.2	38631.8
TERA	2	507.2	1014.4
Tier I and II	3	110.2	330.6
Polymer	175[2]	2	350
Research & Development	200	2.5	500
Instant Photographic Film Articles	1	0.5	0.5
Bona Fide	116	20	2320
5(e) Test	12	151	1812
Non-Testing 5(e) Burden	16	25	400
NOC	443	0.6	265.8

Total Respondent Reporting Burden Hours 114,301

[1]*Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (2009)*
[2]*Although the information requirements of the polymer exemption are expected to apply to 175 new polymers reports per year, EPA only expects to receive 29 post-manufacture annual reports per year*

The total number of estimated annual responses of all types is 2,126.

6(c) Burden Associated with Recordkeeping

The total respondent recordkeeping burden associated with this information collection is an estimated 2,861 hours (Table 2). This burden estimate is calculated by multiplying the estimated recordkeeping burden associated with each type of submission, by the estimated number of submissions for each notice and summing across notice types.

Once a respondent presents information in an initial TSCA section 5 submission, the burden for maintaining or updating these records is minimal. The recordkeeping burden for several TSCA Section 5 submissions have decreased due to the implementation of the e-PMN rule finalized in 2010. EPA assumes an aggregate annualized recordkeeping burden of one hour for each PMN, SNUN, MCAN, exemption submission, or biotech submission under this new rule. This is based on the recordkeeping burden associated with essential technical requirements, such as records that demonstrate that the first commercial batch of chemical manufactured for commercial purposes under the exemption met certain eligibility criteria. The recordkeeping burden for 5(e) testing and non-testing burden are 17.5 and 25 hours, respectively.

The overall respondent recordkeeping burden is displayed below in Table 2.

Table 2. Respondent Recordkeeping Burden

Type of Notice	Average Annual Responses	Hours for Recordkeeping	Average Annual Burden
PMN	720	1	720
SNUN	8	1	8
MCAN	3	1	3
Exemptions:			
TME	8	1	8
LVE/LoREX	419	1	419
TERA	2	1	2
Tier I and II	3	1	3
Polymer	175	4	700
Research & Development	200	0.5	100
Instant Photographic Film Articles	1	0.25	0.25
Bona Fide	116	2	232
5(e) Test	12	17.5	210
Non-Testing 5(e) Burden	16	25	400
NOC	443	0.125	55.375
	Total Respondent Recordkeeping Burden Hours		**2,861**

6(d) Estimating Respondent Cost

Respondents to TSCA section 5 reporting requirements experience costs associated with (1) reporting, (2) recordkeeping, and (3) compliance with exposure controls and testing requirements included in TSCA section 5(e) orders, when EPA takes regulatory action. The respondent costs associated with this information collection are estimated to total $34,417,821 (Table 3).

Respondent costs for all submissions consist of three components: (1) labor costs, calculated by multiplying the estimated burden hours associated with each submission type by the appropriate labor rate; (2) delay costs, estimated as the cost of the delayed receipt of profits by chemical manufactures as a result of the submission review process, and (3) explicit costs, such as user fees or lab testing fees.

In order to estimate total respondent cost associated with TSCA section 5 submissions, an average cost was first calculated for each type of notice. The cost for each notice type was calculated by summing each of the associated cost components, and then multiplying by the expected number of notice submissions. The total industry cost was calculated by summing the costs across notice types. Table 3 outlines the total average cost calculations for the various types of notice submissions and presents the total respondent cost estimate.

Wages and fringe benefits for managerial, professional/technical, clerical and production labor were taken from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation* (ECEC) data, for September 2010, for manufacturing industries.

The cost of fringe benefits such as paid leave and insurance, specific to each labor category, are taken from the same ECEC series. Fringe benefits as a percent of wages are calculated separately for each labor category. For example, for September 2010, the average wage rate for professional/technical labor was $36.57; the average fringe benefit was $18.54. Fringe benefits as a percent of wages were $18.54/$36.57, or approximately 50.7 percent.

An additional loading factor of 17 percent is applied to wages to account for overhead. This approach is used for consistency with Office of Pollution Prevention and Toxics economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* (2002), and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report* (2002). This overhead loading factor is added to the benefits loading factor, and the total is then applied to the base wage to derive the fully loaded wage. For example, the September 2010 fully loaded wage for professional/technical labor is $36.57 × (1+0.506973 + 0.17) = $61.32.

As noted above, delay costs reflect the cost of the delayed receipt of profits by chemical manufactures as a result of the submission review process. Industry delay costs used to calculate the average cost per submission were computed using the midpoint of the low and high delay cost estimates (2003 dollars) as presented in the "Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications" (1994), and inflated to 2010 dollars using the Bureau of Labor Statistics' Producer Price Index data for the Chemical Manufacturing industry.

The explicit costs or fees used to calculate the average cost per submission were taken from the 2007 ICR and have not been adjusted.

The total respondent burden hours and costs is the sum of reporting hours and recordkeeping hours, and the total costs for all expected notice submissions. Total respondent burden hours are 117,162 (114,301 reporting hours + 2,861 recordkeeping hours). As noted above, total respondent costs based on the expected number of TSCA section 5 notice submissions are $34,417,821.

6(e) Estimating Agency Cost

The Agency costs associated with this information collection are estimated to total $6,397,518 (Table 4). Costs to the government include: (1) initial review of PMN substances (after which the majority of cases are dropped from further regulatory review), and (2) comprehensive reviews on a minority of chemicals, during which the Agency conducts a more thorough evaluation of the potential risks associated with manufacturing, processing, use and disposal of PMN substances including, if necessary, taking regulatory action under TSCA sections 5(e) or 5(f).

In order to determine the total cost for the Agency, an average cost was first computed for each type of notice. The Agency cost per notice was computed by multiplying the Agency labor hours for each notice, as reported in various sources, by the current Agency labor cost per hour for a fully loaded GS-13, step 5 employee in the Washington D.C. area, and then adding updated extramural costs for contractor support. The average cost per notice was then multiplied by the expected number of notice submissions and summed across notice types to obtain the total Agency cost.

Agency wage rate data used to calculate labor costs were gathered from the U.S. Office of Personnel Management Salary Table 2010-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 the 2010 loaded wage rate of $161,446 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.

Table 3. Total Respondent Cost Calculation

Type of Notice	Average Annual Responses	Total Burden (reporting + recordkeeping) and Wage Rate by Labor Category				Labor Costs[1]	Delay Costs[2]	Fees[3]	Total Avg. Cost Per Notice[4]	Respondent Cost[6]
		Managerial		Technical						
		Hours	Wage($)	Hours	Wage($)					
PMN	720	18.0	70.16	75.2	61.32	5,874	25,058	2,500	33,432	24,071,144
SNUN	8	18.0	70.16	75.2	61.32	5,874	25,058	2,500	33,432	267,457
MCAN	3	65.0	70.16	224.2	61.32	18,308	25,058	2,500	45,866	137,599
Exemptions:									-	-
TME	8	17.0	70.16	70.2	61.32	5,497	-	-	5,497	43,979
LVE/LoREX	419	18.0	70.16	75.2	61.32	5,874	12,613	-	18,487	7,746,113
TERA	2	129.0	70.16	379.2	61.32	32,303	-	-	32,303	64,606
Tier I and II	3	23.0	70.16	88.2	61.32	7,022	-	-	7,022	21,066
Polymer	175	3.0	70.16	3.0	61.32	394	-	-	394	69,027
Research & Development	200	1.3	70.16	1.75	61.32	195	-	-	195	39,002
Instant Photographic Film Articles	1	0.0	70.16	0.75	61.32	46	-	-	46	46
Bona Fide	116	6.0	70.16	16	61.32	1,402	-	-	1,402	162,641
5(e) Test	12	38.8	70.16	129.75	61.32	10,675	-	132,961[5]	143,636	1,723,632
Non-Testing 5(e) Burden	16	19.5	70.16	30.5	61.32	3,238	-	-	3,238	51,814
NOC	443	0.0	70.16	0.725	61.32	44	-	-	44	19,694

Total Respondent Cost $34,417,821

1 Labor costs are calculated by multiplying burden hours by the wage rate for each labor category and summing across labor categories.
2 Delay costs calculated using the average of low and high estimates from "Regulatory Impact Analysis of Amendments to Regulations for TSCA section 5 Premanufacture Notifications" September 9, 1994 (RIA, 1994), updated to 2010$ using Bureau of Labor Statistics Producer Price Index data for the chemical manufacturing industry. MCANs are assumed to have the same delay costs as PMNs.
3 User fees charged by EPA, except where noted. These were assumed to remain constant since ICR, 2000.
4 Total average cost is the sum of labor costs, delay costs and fees.
5 This figure is for a representative testing regimen consisting of 835.3110 (ready biodegradability), 850.1010, 850.1075, 850.5400 (aquatic base set), and OECD 407 (28-day repeated dose), based on an analysis of average costs for 277 testing cases.
6 While companies incur costs for control equipment, such costs are outside the realm of this ICR.

Table 4. Total Agency Cost Calculation

Type of Notice	Average Annual Responses	Agency Labor Hours[1]	Wage Rate	Labor Costs[2]	Extramural Costs[3]	Total Avg. Cost Per Notice[4]	Agency Cost
PMN	720	53.0	77.62	4,114	987	5,101	3,672,619
SNUN	8	53.0	77.62	4,114	982	5,096	40,767
MCAN	3	886.0	77.62	68,771	-	68,771	206,314
Exemptions:						-	-
TME	8	90.0	77.62	6,986	-	6,986	55,886
LVE/LoREX	419	18.0	77.62	1,397	703	2,100	879,967
TERA	2	1,225.0	77.62	95,085	-	95,085	190,169
Tier I and II	3	155.0	77.62	12,031	-	12,031	36,093
Polymer	175	1.0	77.62	78	-	78	13,584
Research & Development	200	-	77.62	-	-	-	-
Instant Photographic Film Articles	1	1.0	77.62	78	-	78	78
Bona Fide	116	2.0	77.62	155	80	235	27,288
5(e) Test	12	1,245.0	77.62	96,637	-	96,637	1,159,643
Non-Testing 5(e) Burden	16	65.0	77.62	5,045	-	5,045	80,725
NOC	443	1.0	77.62	78	-	78	34,386
						Total Agency Cost	**$ 6,397,518**

[1]*Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule (2009)*

[2] *Labor costs calculated as labor hours multiplied by Agency wage rate. Wage rate based on salary taken from Salary Table 2003-DCB, U.S. Office of Personnel Management.*

[3] *Extramural costs for contractor support. Values taken from RIA, 1994 (except for SNUN value, taken from "Burden Cost Analysis Supporting the Information Collection Request Renewal for TSCA Section 5 Premanufacture Notifications," August 15, 2003) and updated to 2005$ using Bureau of Labor Statistics Producer Price Index data for the chemical manufacturing industry.*

[4] *Agency labor costs plus extramural costs.*

6(f) Reasons for Change in Burden

This request reflects a decrease in the total estimated respondent burden of 350 hours (from 117,512 hours to 117,162 hours) from that currently in the OMB inventory. This decrease represents a re-estimate in the number of annual submissions to reflect EPA's experiences since the most recent ICR. The decrease in the number of annual submissions is largely associated with the finalization of the e-PMN rule in 2010. The decrease is an adjustment.

6(g) Burden Statement

The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0012, is estimated to range between 0.725 hours and 508 hours per response depending upon the type of response. Burden is defined in 5 CFR 1320.3(b). 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-2010-1011. 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 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 Number EPA-HQ-OPPT-2010-1011 and OMB Control Number 2070-0012 in any correspondence.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number **EPA-HQ-OPPT-2010-1011**. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(f) of the supporting statement.

Attachment A: **15 U.S.C. 2604 - Section 5 of the Toxic Substances Control Act.** Also available online at the U.S. House of Representatives' U.S. Code website

Attachment B: **40 CFR part 700 - General**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment C: **40 CFR part 720 - Premanufacture Notification**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment D: **40 CFR part 721 - Significant New Uses Of Chemical Substances**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment E: **40 CFR part 723 - Premanufacture Notification Exemptions**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment F: **40 CFR part 725 - Reporting Requirements And Review Processes For Microorganisms**. Also available online at the National Archives and Records Administration's Electronic CFR Website

Attachment G: **EPA Form 7710-25 - Premanufacture Notice.** Also available online at http://epa.gov/oppt/newchems/pubs/pmnforms.htm

Attachment H: **Instruction Manual for TSCA Section 5 Reporting**. Also available online at http://epa.gov/oppt/newchems/pubs/pmnforms.htm

Attachment I: **EPA Form 7710-56 - Notice of Commencement of Manufacture or Import.** Also available online at http://epa.gov/oppt/newchems/pubs/noc2.pdf

Attachment J: **Copy of Consultations Message Sent by EPA to Potential Respondents**