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: 0574.13 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). 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) 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 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, 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.

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.

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. EPA 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.

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.

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.

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.

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. 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 chemical substances that may present an unreasonable risk of injury to health or the environment from their manufacture, processing, distribution in commerce, use or disposal. 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.

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 Notice of Commencement results in EPA adding that substance to the TSCA Inventory.

EPA requires the use of a specific form (EPA Form No. 7710-56) for Notices of Commencement of chemical substances. 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.

To facilitate EPA's ability to regulate new substances efficiently and expeditiously, EPA

considers essential the capability to promulgate Significant New Use Rules (SNURs) for new chemical substances without first issuing a TSCA section 5(e) consent order for the substance. Since the reporting requirements and provisions of a non-section 5(e) SNUR apply also to the original PMN submitter, only one EPA action is required instead of two; fewer EPA resources are necessary and efficiency is gained as a non-section 5(e) SNUR is more efficient than a combination of consent order and SNUR to regulate new chemical substances.

EPA publishes in the Federal Register information summarizing the content of each notice, including the generic class 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 may be published in various EPA documents or other publications, e.g., Chemicals-in-Progress Bulletin, support documents for TSCA section 5 rulemakings.

The recordkeeping requirements for PMNs, MCANs, 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 Prevention, Pesticides and Toxic Substances (OPPTS), 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. OPPTS 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 July 9, 2007 (72 FR 26353, May 9, 2007). EPA received one non-substantive comment during the comment period. The comment is included as Attachment I to this Supporting Statement.

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 or to arrange for the generation of data that otherwise are not available to the PMN program. These meetings have involved issues of hazard assessment (health and environmental), exposure analysis (occupational, environmental, consumer) and economics. 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 seven parties via email. The individuals contacted were:

Kathleen Roberts
American Chemistry Council
Kathleen_Roberts@americanchemistry.com

David L. Schutt
American Chemical Society
d_schutt@acs.org

Derek Swick
American Petroleum Institute
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Brent Erickson
Biotechnology Industry Organization
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D. Douglas Fratz
Consumer Specialty Products Association
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Harry Gregori
Forum on State and Tribal Toxics Action
Harry.Gregori@envirsol.com

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

EPA received no responses to its solicitation for consultations. A copy of EPA's consultation e-mail to the above potential respondents is included below as 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 typically 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. 3M Company v. Carol Browner and EPA, 17F.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.

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 indicates 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.

To facilitate the review of chemicals, EPA has developed a PMN reporting form (EPA Form 7710-25, copy attached). 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. The submitter will be able to provide information in a format of his or her own choosing.

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 are not currently required to use the PMN form or any other prescribed reporting form. However, 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 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. The low exposure/low release exemption (LoREX) (40 CFR 723.50(2)) 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.

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.

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.

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 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). 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.

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;
- 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;
- Proposes and implements regulatory action as appropriate; and
- Conducts site and record inspections and performs related compliance monitoring functions.

5(b) Collection Methodology and Management

EPA encourages but does not require the submission of premanufacture notices and other submissions by electronic means (see 40 CFR 720.40). EPA believes electronic submission potentially reduces the reporting burden on industry, because it is intended to reduce both the cost and the time required to enter, review, edit and transmit the data. Electronic submission may also improve data quality because it facilitates correcting incorrect data or adding omitted data.

An electronic, Adobe Acrobat version of the existing, approved PMN form is available to respondents that allows them to complete and save the form electronically, then print it and mail it to EPA as hard copy as they have always done. About 15-20% of TSCA section 5 notices are submitted on this form. This was the first phase of an e-PMN project that is to be followed with submitters being able to submit the form electronically via diskettes with a hard copy signature page.

The Agency is currently developing a data entry tool using technology that will allow pure electronic submittal of TSCA section 5 data. This technology will work with DOS- as well as UNIX-based computers and uses XML technology for more efficient data transmittal. This approach will be designed so that data can be submitted using portable media, such as a CD ROM. However the proposed solution can easily be scaled to enable eventual submission of data over the Internet. The Agency contemplates in time receiving electronic TSCA section 5 notices via the Internet once security issues have been resolved and industry=s preferences have been determined. No matter what electronic media the Agency decides upon, however, paper submissions will always be accepted.

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(c) 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(d) 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.

Burden and cost calculations are based on the assumption that EPA will receive approximately 1,455 TSCA section 5 notices each year, based on the average number of notices received for years 2003, 2004, and 2005 (see Table 1). Amendments to the PMN rule in 1995 eliminated the PMN requirement for eligible polymers, broadened the low volume exemption, and introduced the low release/low exposure exemption. The overall effect of these amendments has been a significant decline in the submission of notices in general and of full PMNs in particular, from 2,645 in FY 1994, to 772 in FY 2005.

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 3rd-party notification burden associated with this information collection is estimated to total 143,450 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 by averaging the number of each type of submissions received over the past three years (2003, 2004, and 2005), according to data provided in the *OPPT New Chemicals Annual Report* (2006).

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 7 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 suggests that 133 bona fide notices are expected to be submitted annually.

On average, LVE and LoREX exemptions are expected to account for about 470 notices annually. Further, TME are expected to average 5 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 29 cases would be subject to TSCA section 5(e) consent order restrictions burden, with 13 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.

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 PMN submission is estimated to range between 95 and 114 hours, with an average respondent burden of 105 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 range between 71 and 533 hours, with an average of 302 hours.

- The respondent burden for submission of a TME is estimated to average 98 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 range between 91 and 950 hours, with an average of 521 hours.

- The respondent burden for a Tier I or Tier II exemption is estimated to range between 13 and 215 hours, with an average of 114 hours.

- The respondent burden for submission of a Notice of Commencement (NOC) is estimated to be 0.5 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.

EPA expects that the electronic reporting process that is currently under development will reduce burden associated with reporting for all notification types. Burden reduction will result from eliminating the time and expense of preparing and mailing hardcopy notices. However, because the timeframe for release of the electronic reporting tool is not yet known and the complete details of the electronic submission option are not yet determined, the cost savings from this option are not quantified here. To the extent that submitters will be able to use an electronic submission tool, costs both to submitters (reporting burden) and to the Agency (time required to manual processing of data) may be over-reported in this analysis.

Table 1

Reporting Burden

Type of Notice	Avg. Annual Responses[1]	Average Reporting Hours per Response	Avg. Annual Burden
PMN	805	105	84,525
SNUN	7	105	735
MCAN	3	302	906
Exemptions:			
TME	5	98	490
LVE/LoREX	470	105	49,350
TERA	2	521	1,042
Tier I and II	2	114	228
Polymer	175[2]	2	350
Research & Development	200	2.5	500
Instant Photographic Film Articles	0	0.5	0
Bona Fide	133	20	2,660
5(e) Test	13	155	2,015
Non-Testing 5(e) Burden	16	25	400
NOC	497	0.5	249
Total Respondent Reporting Burden Hours			**143,450**

[1]Average Annual Responses computed as the average of the number of notices filed over 2003, 2004, and 2005 based on OPPT New Chemicals Annual Report, 2006.

[2]Although the information requirements of the polymer exemption are expected to apply to 175 new polymers per year, EPA only expects to receive 29 post-manufacture annual reports per year. However, since the information requirements apply to all 175 new polymers, we've assumed that 175 reports would be submitted for the sake of uniformity throughout this analysis. This will result in an overestimate of the burden.

6(c) Burden Associated with Recordkeeping

As shown in Table 2, the total respondent recordkeeping burden associated with this information collection is estimated to equal 4,633 hours. 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 Agency assumes an aggregate annualized recordkeeping burden of two hours for each PMN, SNUN, MCAN, or exemption submission, or biotech submission. 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 35 and 25 hours, respectively.

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

Table 2

Respondent Recordkeeping Burden

Type of Notice	Avg. Annual Responses[1]	Hours for Recordkeeping	Avg. Annual Burden
PMN	805	2	1,610
SNUN	7	2	14
MCAN	3	2	6
Exemptions:			
TME	5	2	10
LVE/LoREX	470	2	940
TERA	2	2	4
Tier I and II	2	2	4
Polymer	175[2]	4	700
Research & Development	200	0.5	100
Instant Photographic Film Articles	0	0.25	0
Bona Fide	133	2	266
5(e) Test	13	35	455
Non-Testing 5(e) Burden	16	25	400
NOC	497	0.25	124
Total Respondent Recordkeeping Burden Hours			**4,633**

[1]Average Annual Responses computed as the average number of notices filed over 2003, 2004, and 2005 based on OPPT New Chemicals Annual Report, 2006.

[2]Although the information requirements of the polymer exemption are expected to apply to 175 new polymers per year, EPA only expects to receive 29 post-manufacture annual reports per year

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 $34,394,474, as presented in Table 3 below.

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 below 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 December 2005, 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 December 2005, the average wage rate for professional/technical labor was $31.02; the average fringe benefit was $16.73. Fringe benefits as a percent of wages were $16.73/$31.02, or approximately 53.9 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 December 2005 fully loaded wage for professional/technical labor is $31.02 × (1+0.539329 + 0.17) = $53.02.

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 2005 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 2000 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 148,083 (143,450 reporting hours + 4,633 recordkeeping hours). As noted above, total respondent costs based on the expected number of TSCA section 5 notice submissions are $34,394,474.

6(e) Estimating Agency Cost

The Agency costs associated with this information collection are estimated to total $7,619,502 as presented in Table 4 below. 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 through 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 2006-DCB, for a GS-13, step 5 employee in the Washington, D.C. area. A loading factor of 1.6 was applied to the base rate to arrive at the 2006 loaded wage rate of $140,262 per year. The hourly wage rate was computed by dividing the loaded wage by 2,080 hours, the hours associated with a full time employee. This loaded hourly wage was used in calculations of Agency cost.

Table 3
Total Respondent Cost Calculation

Notice	Average Annual Number of Responses	Total Burden (reporting + recordkeeping) and Wage Rate by Labor Category						Labor Costs[1]	Delay Costs[2]	Fees[3]	Total Avg. Costs Per Notice[4]	Total Respondent Cost
		Managerial		Technical		Clerical						
		Hrs	Wage($)	Hrs	Wage($)	Hrs	Wage($)					
PMN	805	18	63.61	75	53.02	14	$26.37	5,491	22,215	2,500	30,206	24,315,830
SNUN	7	18	63.61	75	53.02	14	$26.37	5,491	22,215	2,500	30,206	211,442
MCAN	3	65	63.61	224	53.02	15	$26.37	16,407	22,215	2,500	41,122	123,366
Exemptions:												
TME	5	17	63.61	70	53.02	13	$26.37	5,136	0	0	5,136	25,680
LVE/LoREX	470	18	63.61	75	53.02	14	$26.37	5,491	11,182	0	16,673	7,836,310
TERA	2	129	63.61	380	53.02	15	$26.37	28,749	0	0	28,749	57,498
Tier I and II	2	23	63.61	88	53.02	5	$26.37	6,261	0	0	6,261	12,522
Polymer	175	1	63.61	3	53.02	2	$26.37	286	0	0	286	50,050
Instant Photographic Film Articles	1	0	63.61	0.5	53.02	0.25	$26.37	33	0	0	33	33
R&D	200	0	63.61	2.5	53.02	0.5	$26.37	146	0	0	146	29,147
Bona Fide	133	5	63.61	12	53.02	5	$26.37	1,086	0	0	1,086	144,457
5(e) Test	13	38	63.61	130	53.02	22	$26.37	9,890	0	108,108[5]	117,998	1,533,973
Non-Testing 5(e) Burden	16	10	63.61	25	53.02	15	$26.37	2,357	0	0	2,357	37,714
NOCs	497	0	63.61	0.5	53.02	0.25	26.37	33	0	0	33	16,452
Total Respondent Costs												**$34,394,474**

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 2005$ 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 costs 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 Number of Responses	Agency Labor Hours	Wage Rate	Labor Costs[6]	Extramural Costs[7]	Total Avg. Costs[8]	Total Agency Costs
PMN	805	64 [1]	67.43	4,316	949	5,265	4,643,730
SNUN	7	64 [1]	67.43	4,316	944	5,260	36,820
MCAN	3	1,067 [2]	67.43	71,952	0	71,952	215,856
Exemptions:							
TME	5	109 [3]	67.43	7,350	0	7,350	36,750
LVE/LoREX	470	22 [1]	67.43	1,484	676	2,160	1,015,200
TERA	2	1,476 [2]	67.43	99,532	0	99,532	199,065
Tier I and II	2	187 [2]	67.43	12,610	0	12,610	25,220
Polymer	29	1	67.43	67	0	67	67
Instant Photographic Film Articles	1	1	67.43	67	0	67	67
R&D (3rd-party notification)	200	0	0	0	0	0	0
Bona Fide	133	2 [1]	67.43	135	77	211	28,121
5(e) Test	13	1,500 [4]	67.43	101,151	0	101,151	1,314,960
Non-Testing 5(e) Burden	16	65 [5]	67.43	4,383	0	4,383	70,131
NOCs	497	1	67.43	67	0	67	33,515
Total Agency Cost							$7,619,502

[1] *"Regulatory Impact Analysis of Amendments to Regulations for TSCA Section 5 Premanufacture Notifications" September 9, 1994 (RIA, 1994).*
[2] *"Regulatory Impact Analysis of Regulations on Microbial Products of Biotechnology" January 21, 1997 (RIA, 1997).*
[3] *ICR, 2000.*
[4] *Estimated to be similar to TERA review.*
[5] *Estimated to be similar to PMN / SNUN review.*
[6] *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.*
[7] *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.*
[8] *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 15,708 hours (from 163,791 hours to 148,083 hours rounded) 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 submissions per year is largely associated with the polymer and other exemptions implemented under the 1995 amendments. 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 average 97.8 hours per response for reporting, and to require 2.5 hours per response for recordkeeping, or an average of 100.3 hours overall per response. According to the Paperwork Reduction Act, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2007-0094, which is available for online viewing at www.regulations.gov, or in person 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. You may submit comments regarding 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.

Submit your comments, referencing Docket ID No. EPA-HQ-OPPT-2007-0094 and OMB Control No. 2070-0012, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and

Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

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-2007-0094**. 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 at online at the US House of Representatives' US 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: **Public Comment Submitted in Response to Proposed ICR Renewal.**

Attachment J: **ICR Consultation Solicitation**