1 INFORMATION COLLECTION REQUEST (ICR) SUPPORTING STATEMENT

ENVIRONMENTAL PROTECTION AGENCY STRATOSPHERIC OZONE PROTECTION

1. Identification of the Information Collection

a) *Title:* Significant New Alternatives Policy (SNAP) Program (40 CFR part 82, subpart G) (Renewal) (OMB Control Number: 2060-0226) (EPA ICR Number 1596.08).

b) Short Characterization/Abstract

Title VI of the Clean Air Act Amendments of 1990 (the Act) implements the obligation of the United States under the *Montreal Protocol on Substances that Deplete the Ozone Layer* to phase out the use of ozone-depleting substances. Section 612 of Title VI establishes as U.S. policy the requirement that Class I and Class II ozone-depleting substances shall be replaced, to the maximum extent practicable, by chemicals, product substitutes, or alternative manufacturing processes that reduce overall risks to human health and the environment.

EPA developed its Significant New Alternatives Policy (SNAP) program to fulfill the requirements of Section 612. The five major provisions of Section 612 are:

Rulemaking: Section 612(c) requires EPA to enact rules making it unlawful to replace any Class I or II substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where an alternative has been identified that (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

<u>Listing of Unacceptable/Acceptable Substitutes</u>: Section 612(c) also requires EPA to publish a list of the substitutes prohibited for specific uses. EPA must publish a corresponding list of acceptable alternatives for specific uses as well.

<u>Petition Process</u>: Section 612(d) grants the right for any person to petition EPA to add or delete a substance from the lists published in accordance with Section 612(c). EPA has 90 days to grant or deny a petition.

<u>90-day notification</u>: Section 612(e) authorizes EPA to require any person who produces a chemical substitute for a Class I substance to notify EPA not less than 90 days before the new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a Class I substance. The producer must also provide EPA with all unpublished health and safety studies on such substitutes.

<u>Clearinghouse</u>: Section 612(b)(4) requires EPA to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use Class I and II substances.

EPA issued regulations on March 18, 1994, in 59 FR 13043, which are codified at 40 Code of

Federal Regulations (CFR) Part 82, Subpart G (Section 82.170 et seq.), establishing the SNAP program. EPA's major activities in the SNAP program are to review proposed substitutes based on the risk-assessment criteria and the procedures set forth in the regulations, and to publish (and update) lists of acceptable and unacceptable substitutes by end use categories.

The information required for collection under the SNAP regulations is described below in Section 4 of this statement, and is currently approved by OMB for use through June 30, 2011. EPA is in the process of publishing a notice of intention to renew this information collection request. This notice of intention will be published in the Federal Register.

The previous ICR of 2007 had the following Terms of Clearance:

"The collection is approved for 3 years. OMB notes that the recordkeeping requirement does not stem from the requirements of the SNAP program but from the enforcement requirements as stated in the supporting statement. If the agency revises the enforcement requirements, then the recordkeeping requirement should be updated accordingly. "

EPA is not revising enforcement requirements at this time.

2. Need for and Use of the Collection

a) Authority for the Collection

Information required to be collected under the SNAP program is intended to fulfill the general mandate in Section 612(c) of identifying acceptable substitutes that can serve as replacements for ozone-depleting substances being phased out under the Act, as well as unacceptable substances which may not be used as replacements for ozone-depleting substances being phased out under the Act. Section 612 (42 U.S.C. 7671k) is attached as Appendix B, and EPA's implementing regulations (40 CFR Part 82, Subpart G, Sect. 82.170 et seq.) are attached as Appendix C.

b) Use/Users of the Data

EPA's Stratospheric Protection Division (SPD) uses the information submitted to evaluate the health and environmental effects of proposed alternatives for industrial and commercial uses that have historically used Class I and Class II ozone-depleting substances.

3. Non-duplication, Consultations, and Other Collection Criteria

a) Non-duplication

The specific information requested by this notice is not currently collected by EPA or any other government agency. According to the United Nations Environment Programme (UNEP) report, *Environmental Effects of Ozone Depletion and its Interactions with Climate Change: 2010 Assessment*, EPA's SNAP program is the only national program in the world designed to evaluate alternatives to ozone-depleting substances, and as such, represents the most comprehensive and accessible resource for information on alternatives.

Use of the Toxic Substances Control Act (TSCA) SNAP Addendum form (described in section 4(b) of this statement) will ensure that companies participating in the TSCA Pre-Manufacture

Notice (PMN) program will not duplicate their data in reporting to the SNAP program.

b) Public Notice Required Prior to ICR Submission to OMB

In compliance with the 1995 Paperwork Reduction Act (PRA), EPA sought public comments for a 60-day period prior to submitting the ICR renewal package to OMB. These comments, which are used partly to determine realistic burden estimates for respondents, must be considered when completing the Supporting Statement that is submitted to OMB.

The announcement of a public comment period for this renewal ICR was published in the Federal Register on January 31, 2011 (76 FR 5366). EPA sought public comments, pursuant to 5 CFR 1320.8(d), on the previous burden estimates being sought by the Agency. EPA received no comments.

c) Consultations

In developing the regulations under the Act, EPA established an advisory committee for issues relating to stratospheric ozone. The Stratospheric Ozone Protection Advisory Committee (STOPAC) membership included representatives from affected industries, environmental interest groups, and academics in related fields. Within the STOPAC, subcommittees were formed to look at more detailed issues. The subcommittee on the SNAP program met several times to discuss possible substitutes for ozone-depleting substances, guiding principles for SNAP evaluations, and strategies to obtain information about substitutes from industry. This consultation was invaluable in developing the SNAP Information Notice form (described below in section 4(b).) EPA also received comments on its proposed SNAP regulations, which identified the information to be collected through the SNAP program, and these comments were also helpful in developing the SNAP Information Notice form.

In preparing to renew this information collection request, EPA consulted with fewer than nine actual or potential respondents to discuss estimated burden hours and costs associated with this information collection request. The respondents with whom EPA consulted are from various industries, companies, and organizations that have recently reported to the SNAP program. They include: Katarzyna Bober of Honeywell at 973-455-4420; Kelley Kline of General Electric at 502-452-7603; and Nesa Dunn of Global Safety Labs at 918-551-5514.

d) Effects of Less Frequent Collection

The SNAP program has minimized the number of reporting and recordkeeping requirements as much as possible by requiring only a one-time application, and a one-time recordkeeping of documents submitted to EPA.

e) General Guidelines

This rule does not exceed any of the guidelines, except for records retention for more than 3 years. Retention periods for the two SNAP recordkeeping requirements (described below in section 4(b) of this statement) are not specified in Title VI of the Act or in the SNAP regulations, but EPA requires retention of these records for five years for enforcement purposes, pursuant to statutory authority under 28 U.S.C. Section 2462, the applicable statute of limitations. Sec. 2462 states:

Except as otherwise provided by Act of Congress, an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued if, within the same period, the offender or the property is found within the United States in order that proper service may be made thereon.

f) Confidentiality

Measures to protect confidentiality of information collected under the SNAP program are based on EPA's confidentiality regulations (40 CFR 2.201 et seq., or Subpart B.) SNAP regulations (at 40 CFR 82.182) describe these measures, which are also mentioned on the front page of each of the SNAP forms. Each form mentions basic information about asserting confidentiality claims, and also instructs the submitter to read the Instruction Manual, which contains more detailed discussion of the procedures for confidentiality claims. (See pages 7-9 of the Instruction Manual, which, as described in section 4(b), is attached as Appendix F). These procedures are described briefly below.

Submitters may designate all or portions of their forms or petitions as confidential. EPA requires the submitters to substantiate their claim of confidentiality. The submitter is advised that, under Section 114(c) of the Act, emissions data may not be claimed as confidential. The submitter is also advised that there are further instances, described in the provisions of 40 CFR Part 2, Subpart B, in which confidential assertions may be reopened or denied even when confidentiality claims are initially received. The submitter will be contacted as part of such an evaluation process. If required substantiation is not provided along with the submission of information claimed as confidential, EPA may make the information available to the public without further notice. The submitter must provide one copy of the submission which contains no information claimed as confidential. The non-confidential submission will be put in the public docket.

If toxicity or health and safety studies are listed as confidential, this information cannot be maintained as confidential where such data are also submitted under TSCA or the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to the extent that confidential treatment is prohibited under those statutes. However, information in a toxicity study that is not health and safety data and is not relevant to the effects of a substance on human health and the environment, <u>e.g.</u>, discussion of process information, or proprietary blends, can be maintained as confidential subject to 40 CFR Part 2, Subpart B.

Information submitted as part of a joint submission to either SNAP/TSCA or SNAP/FIFRA must adhere to the security provisions of the program offices implementing these statutes. For such submissions, the SNAP handling of such notices will follow the security provisions under these statutes.

g) Sensitive Questions

This section does not apply because the SNAP regulations and the associated information collection request do not seek information of a sensitive nature.

4. The Respondents and the Information Requested

a) Respondents

Respondents for reporting requirements, as well as for the recordkeeping requirement for the exemption for small volume use, include manufacturers, importers, formulators and processors of substitutes for ozone-depleting substances. Principally, these respondents are in the following major categories of industry groups, by Standard Industry Code (SIC) and North American Industry Classification System (NAICS):

Manufacturers, Chemicals and Allied Products

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Industry	SIC	NAICS
Plastics materials and synthetics	282	325211
Soap, cleaners, and toilet	284	325611
goods		
Paints and allied products	285	32551
Industrial organic chemicals	286	325191
Miscellaneous chemical	289	325998
products		

Manufacturers, Rubber and Misc. Plastics Products

Industry	SIC	NAICS
Plastics foam products	3086	<u>32615</u>

Wholesale Trade- Nondurable Goods

Wholesale Hade Wohadrable Goods						
Industry	SIC	NAICS				
Chemicals and allied products	516	42261				
Miscellaneous nondurable	519	42299				
products						

Respondents for the recordkeeping requirement for substitutes acceptable subject to use conditions or narrowed use limits include end users of the substitutes in the following industrial sectors:

Construction- Special Trade Contractors

Industry	SIC	NAICS
Plumbing, heating, and air-	171	<u>23511</u>
conditioning		

Manufacturing- Industrial Machinery & Equipment

Industry	SIC	NAICS
Computer and office	357	334111, 333313
equipment		
Refrigeration and service	358	333415
machinery		

Manufacturing- Electronic & Other Electric Equipment

Industry	SIC	NAICS
Electric distribution equipment	361	335311
Electric industrial apparatus	362	335312
Communications equipment	366	33421
Electronic components and	367	334411
accessories		

Manufacturing- Transportation Equipment

Industry	SIC	NAICS
Automobile manufacturing	371	336111
Aircraft and parts	372	336412
Ship and boat building and	373	336611
repairing		

Manufacturing- Instruments & Related Products

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Industry	SIC	NAICS			
Search and navigation equipment	381	334511			
Medical instruments and supplies	384	339112			
Ophthalmic goods	385	339115			

Services

Industry	SIC	NAICS
Services to buildings	734	56179
Computer and data	737	541511
processing services		
Refrigeration service and	7623	811412, 81131
repair		

b) Information Requested

i) Data Items (including recordkeeping requirements):

To simplify and expedite the submission and review of SNAP notices, EPA has developed the following forms and an instruction manual:

- SNAP Information Notice (Appendix D)
- TSCA/SNAP Addendum (Appendix E)
- Instructions for the SNAP Program Information Notice and TSCA/SNAP Addendum (Appendix F)

The SNAP Information Notice is the form used in most submissions to give notice of a respondent's plans to introduce a proposed substitute into the marketplace. The TSCA/SNAP Addendum is an abbreviated SNAP form for submissions in situations where there is joint statutory review between the TSCA PMN program and the SNAP program. The full SNAP Information Notice should be used in the case of a joint review with the FIFRA. A petition

should include the same information that is requested in the SNAP Information Notice. No additional information is required for a petition. The instruction manual provides further information for a respondent preparing any of these submissions.

The forms were developed to minimize the reporting burden for the submitter; however, their use is optional. Respondents with more efficient means of submitting the information are encouraged to use them. EPA has based the estimated respondent burden and cost on the use of the recommended forms; to the extent a respondent uses more efficient means to submit the data, the estimates contained in this analysis may overestimate the respondent burden and cost.

1. <u>SNAP Information Notice/ Petition Data Items:</u> Reference: Sections 82.176(a), 82.178, 82.180(a)(5), 82.184(c)

The information requested on the SNAP Information Notice includes the following data items:

Name and description of the substitute. To the extent possible, the substitute should be identified by its (1) commercial name, (2) chemical name, (3) trade name(s), (4) generic name, (5) identification numbers (e.g., CAS registry, NIOSH RTECS, EPA hazardous waste, OHMTADS, DOT/UN/NA/IMCO shipping, HSDB, NCI), (6) chemical formula, and (7) chemical structure.

<u>Physical and chemical information</u>. Key properties that should be included to characterize the substitute are: molecular weight; physical state; melting point; boiling point; density; odor threshold; solubility; partition coefficients (Log Kow, Log Koc); and vapor pressure.

<u>Substitute applications</u>. Identification of the applications in which the substitutes are likely to be used is required. It is essential to provide a complete list of potential uses as the substitute listing required by section 612(c) is specific to application.

<u>Process description</u>. For each application identified, EPA is requesting available descriptive data on processing, including in-place pollution controls. Such information will be helpful in characterizing workplace and environmental releases and exposures.

Ozone depletion potential. The predicted ozone depletion potential (ODP) of substitute chemicals is requested. The submitter should also provide sufficient supporting documentation-- either a citation or the background information used to develop the ODP. For purposes of calculating ODP, EPA recommends the methodology used in the most recent *Scientific Assessment of Ozone Depletion,* which was prepared for the United Nations Environment Programme.

Global warming potential. EPA requests readily available data on the global warming potential (GWP) and atmospheric lifetime of the substitute in its particular application (e.g., as a refrigerant, foam blowing agent, etc.) EPA requests that all GWPs be referenced to CO₂ using the methodology recommended by the most recent assessment report from the Intergovernmental Panel for Climate Change (IPCC). To the extent that data is available, EPA also considers indirect effects. Indirect effects explicitly consider the impact on global warming arising from changes in energy consumption associated with the use of a substitute (e.g., an alternative refrigerant). This latter measure can be identified as changes in energy efficiency or demand relative to the substitute being replaced.

<u>Toxicity data</u>. Information on toxicity from acute and chronic exposure to a substitute chemical, its impurities, and its degradation products on any organism (e.g., humans, mammals, fish, wildlife, and plants) is required. For mammals, EPA requests a minimum submission of the following tests to characterize substitute risks: a range-finding study, and a 28-day subchronic repeated dose study in an appropriate rodent species. For substitutes that are being evaluated as fire suppressants, refrigerants, or aerosols, a cardiotoxicity study, usually performed on a dog, may be required. Additional mammalian toxicity tests will be identified based on the substitute and application being evaluated. To sufficiently characterize aquatic toxicity concerns, both acute and chronic toxicity test results for a variety of species is required. EPA requires a minimum data set as described in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses," which is available through the National Technical Information Service (#PB 85-227049). Other relevant information and data summaries, such as the Material Safety Data Sheets, should also be submitted. Submission of the actual toxicity studies is most beneficial; however, it is not necessary to submit these reports if they have been supplied to EPA as part of other regulatory submissions. To assist in locating these studies, the submitter must provide a sufficiently clear citation to ensure that these studies can be located by EPA in a timely fashion. EPA requires that submitters providing information on new chemicals for joint review under TSCA and SNAP adhere to the TSCA minimum testing requirements described in TSCA section 5.

<u>Environmental Fate and Transport</u>. Where available, information must be submitted on the environmental fate and transport of substitutes. Such data shall include information on bioaccumulation, biodegradation, adsorption, volatility, transformation, and other data necessary to characterize movement and reaction of substitutes in the environment.

<u>Flammability</u>. Data on the flammability of a substitute chemical or mixture are required. Specifically, data on flash point and flammability limits are needed, as well as information on the procedures used for determining the flammability limits. For substitutes that will be used in consumer applications, documentation of testing results conducted by independent laboratories (e.g., Underwriters Laboratories) should be submitted where appropriate. Detail on any suggested abatement techniques to minimize the risks associated with the use of flammable substances or blends should also be provided. EPA recognizes that many promising alternatives may be considered marginally flammable, but can be used safely and effectively. The information requested on this topic will help EPA make a balanced decision regarding the use of a flammable alternative.

Exposure data. The submitter should provide extant modeling or monitoring data on exposures associated with the manufacture, formulation, transport, and use of a substitute. Descriptive process information for each substitute application, as requested above, will be used to develop exposure estimates where measured exposure data are not readily available. Depending on the application, exposure profiles will be needed for workers, consumers, and the general population.

Environmental release data. Available data on emissions from the substitute application and equipment, as well as pollutant releases or discharge to all environmental media (ambient air, surface water, hazardous/solid waste), are needed to complete the risk characterization. Submitters should provide information on release locations, if known. Any information on pollution controls used or that could be used in association with the substitute (e.g., emissions reduction technologies, wastewater treatment, and treatment of hazardous waste) and the costs of such technology are also requested.

Replacement ratio for a chemical substitute. EPA is requesting information on the replacement ratio for a chemical substitute versus the Class I or II substances being replaced. For example, in the case of a degreasing agent, how much more or less of the substitute chemical is needed? This will have an impact on the estimated incremental cost and environmental effects associated with use of the substitute.

Required changes in technology. Detail on the changes in technology needed to use the alternative is requested. Such information should include a description of whether the substitute can be used in existing equipment—with or without some retrofit—or in new equipment. Data on the cost (capital and operating) and estimated life of the technology modifications should also be submitted. These economic data are essential to understanding the near-term potential of using an alternative.

Cost of substitute. EPA is requesting data on the expected average cost of the alternative. The cost of the substitute can be expressed, for example, in terms of \$/pound (for a chemical substitute) or as incremental capital and operating costs associated with a retrofit or new equipment. In addition, information is needed on the expected equipment lifetime for an alternative technology. Other critical cost considerations should be identified, as appropriate. For example, it is important to understand the incremental costs associated with losses or gains in energy efficiency associated with use of a substitute relative to current experience.

<u>Availability of substitute</u>. EPA needs to understand the extent to which a substitute is already commercially available or the expected date at which it may become available. The timing of availability is an important factor in assessing the overall health and environmental impacts of the substitute.

Anticipated market share. Data on the anticipated near-term and long-term (over the next five years) nationwide substitute sales (not just those of the submitter) is requested. This information can be presented in several ways, for example: a percentage of existing nationwide use of Class I or Class II chemicals in a particular application; number of units/products to be produced; or pounds of substitute sold. This information is required to assess the potential impacts related to total consumption and environmental releases.

Applicable regulations under other environmental statutes. The submitter is requested to provide information on whether the substitute(s) are regulated under other statutory authorities, in particular the Clean Water Act, Safe Drinking Water Act, the Resource Conservation and Recovery Act, FIFRA, TSCA, and other titles under the CAA. EPA will evaluate substitutes under the SNAP program subject to these existing regulatory constraints.

Information already submitted to EPA. Individuals may have already submitted information being requested in the SNAP program notice to EPA as part of past regulatory and information-gathering activities. If such a situation exists, and to minimize reporting burden, the submitter should provide the following information to help locate the data already maintained at EPA: type of information submitted; the date of submission; the name of the EPA office to which the data were sent; description of the regulatory program; and a document-control number, if assigned (e.g., a PMN number). If the submitter cannot provide references to data sent previously to EPA, he or she should include all requested information in the SNAP notice.

Information already available in the literature. If any of the data needed to complete the SNAP program notice are available in the literature, the submitter should provide EPA with references for such information. Failure to provide EPA with sufficient citation, however, will delay review of the notice. Additionally, submitters are encouraged to provide copies of any literature to expedite review, particularly if the citation is from a source not readily available to EPA researchers. Any references from sources in foreign languages should be translated.

Additional information. If critical new information becomes available during the review period that may influence EPA's evaluation of a substitute, the submitter must notify EPA of the existence of such information within 10 days of learning of such data. The submitter must also inform EPA of new studies underway, even if the results will not be available within the review period.

2. <u>TSCA/SNAP Addendum Form Data Items</u>: Reference: Sections 82.176(a), 82.178, 82.180(a)(5)

EPA has identified only a few additional data elements, beyond those already required by the Premanufacture Notice (PMN) program that would need to be included for review under the SNAP program. For this reason, the added burden to respondent from the SNAP program, above that already required by the PMN program, is very small.

The additional data elements in the TSCA/SNAP Addendum include:

- The ozone-depletion potential,
- The global-warming potential,
- Explicit quantification of the cost of using the substitute and information on when the substitute is expected to be available (including the chemical replacement data, chemical cost data, incremental equipment expenditures needed to use the substitute, and information on the cost implications resulting from changes in energy consumption), and
- Documentation of testing results regarding the flammability of substitutes that will be used in consumer applications.

If critical new information becomes available during the review period that may influence EPA's evaluation of a substitute, the submitter must notify EPA of the existence of such information within 10 days of learning of such data. The submitter must also inform EPA of new studies underway, even if the results will not be available within the review period.

3. Notification for Test Marketing Activity Data Items Reference: Section 82.176(b)(5)

Uses of substitutes for the sole purpose of test marketing are exempt from requirements for submitting a SNAP Information Notice or equivalent until 90 days prior to the introduction of such substitutes for full-scale commercial sale in interstate commerce. Persons taking advantage of this exemption are, however, required to notify EPA in writing that they are conducting test marketing 30 days prior to the commencement of such marketing. Notification shall include the following data items:

- Name of the substitute
- Volume used in the test marketing
- Intended sector and end uses

- Expected duration of the test marketing period
- 4. Recordkeeping for Substitutes Acceptable Subject to Use Conditions or Subject to Narrowed Use Limits Data Items Reference: Section 82.180(b)(2) and (b)(3)

If a substitute is listed by EPA, in a decision on a SNAP information notice, TSCA/SNAP addendum, or petition, as acceptable subject to narrowed use limits, end users intending to use the substitute must determine that other alternatives are not technically feasible. For some substitutes listed as acceptable subject to use conditions, the end user needs to perform an assessment that other alternatives are not technically feasible due to safety, performance, or technical reasons. Such end users must document the results of their evaluation and retain the results on file for the purpose of demonstrating compliance. This documentation shall include the following data items:

- Descriptions of substitutes examined and rejected
- Processes or products in which the substitute is needed
- Reason for rejection of other alternatives, <u>e.g.</u>, performance, technical or safety standards
- The anticipated date other substitutes will be available and projected time for switching to other available substitutes.

Respondents are required to maintain these records for five years. See section 3(d) of this statement for the justification for this length of time.

In addition, some substitutes subject to use conditions may have specific recordkeeping requirements imposed through a use condition (e.g., requirement to keep records of failure mode and effects analysis when introducing certain automotive refrigerants, consistent with requirements of industry standards). Respondents are required to maintain these records for three years.

5. Recordkeeping for Small Volume Use Exemption Data Items Reference: Section 82.176(b) (3)

Within the eight principal SNAP sectors, persons introducing a substitute whose expected volume of use amounts to less than 10,000 pounds per year within a SNAP sector are exempt from notification requirements. Persons taking advantage of this exemption for small uses must maintain documentation for each substitute describing how the substitute meets this small use definition. This documentation must include the following data item:

- Annual production and sales information by sector

Respondents are required to maintain these records for five years. See section 3(d) of this statement for the justification for this length of time.

ii) Respondent Activities

There are five types of respondent reporting and recordkeeping activities required pursuant to Section 612 of the Act and the SNAP regulations promulgated thereunder, 40 CFR Sections 82.170-82.184:

Reporting: SNAP Information Notice/ Petition

This includes the following types of activities:

- Pre-submittal contact with EPA.
- Prepare and submit notice or petition to EPA.
- Respond to EPA requests for additional information and/or notify EPA of additional information as it becomes available.

Reporting: TSCA/SNAP Addendum

This includes the following types of activities:

- Pre-submittal contact with EPA.
- Prepare and submit form to EPA.
- Respond to EPA requests for additional information and/or notify EPA of additional information as it becomes available.

Reporting: Notification for Test Marketing Activity

- Compile information, and prepare and submit letter to EPA with the information.

Recordkeeping: Substitutes Acceptable Subject to Use Conditions or Narrowed Use Limits

- Assess other acceptable alternative substitutes.
- Compile and prepare record of assessment or other records as required by use conditions.

Recordkeeping: Small Volume Uses

- Assess sector sales.
- Compile and prepare record of sector sales.

5. <u>The Information Collected - Agency Activities, Collection Methodology and Information Management.</u>

a) Agency Activities

EPA activities associated with reviewing SNAP submissions consist of the following:

<u>Pre-submittal contact with respondent</u>

- Send forms and guidance document to potential respondents.
- Answer questions regarding the completion of SNAP program forms and the need to submit a SNAP notice.

Review and communication regarding submission

- Assign tracking number to SNAP notice or petition.
- Review SNAP notice or petition for sufficiency of information provided, send letter of receipt, and notify submitter if additional information is required.
- Review requests for confidentiality and provide appropriate protection.
- Review SNAP notice or petition, and notify submitter of decision.
- Review TSCA/SNAP Addendum in detail, coordinate with TSCA office, and notify submitter of decision.
- Prepare and evaluate EPA-initiated changes to the SNAP determinations.

Administrative operations

- Maintain administrative tracking system for all submissions.
- Maintain technical clearinghouse to help users identify acceptable substitutes that are listed under SNAP.
- Prepare and publish in the <u>Federal Register</u> periodic notices and rulemakings to inform the public of any changes to the SNAP lists and of all pending determinations.

b) Collection Methodology and Management

EPA collects information through respondents' submission of a SNAP Information Notice, a TSCA/SNAP Addendum, or a petition. In each case, the collection methodology is the same. EPA has 90 days from receipt of a complete submission to respond to the filing, and EPA must publish its decisions in these submissions in its periodic <u>Federal Register</u> notices and rulemakings.

Initially, EPA reviews each submission for completeness within 15 days of receipt of the submission. If information is incomplete, the submitter will be contacted for this information. Thus, the 15 day completeness review period begins on the date EPA receives a submission, and it ends 15 days after the date of receipt.

The 90-day review period will not commence until EPA judges the submission complete, although manufacturers of a new substitute may introduce the substitute into interstate commerce 90 days after EPA receives a submission if EPA has not already rendered an unacceptability determination. Once the 90-day review period has begun, EPA may determine that additional data are necessary, or the submitter may notify EPA of additional information which has become available and may influence EPA's evaluation of the proposed substitute. In either case, EPA may contact the submitter to explore extending or suspending the review period, depending on the type of data and the stage of review. Thus, the 90-day review period begins on the date a complete submission is received by EPA, and it ends 90 days thereafter, unless EPA and the submitter have agreed to another date.

EPA will check data quality of each submission by its review of the data in each submission. EPA will use its existing systems for telephones and computers to process each submission. The public can get access to non-confidential data in each submission by visiting the public docket maintained in Washington, DC or by checking the online version of the docket at www.regulations.gov, docket number EPA-HQ-OAR-2004-0077.

There is a means for filing electronic SNAP submissions with EPA. To help respondents reduce

the burden of gathering information to prepare a SNAP submission, EPA has established an electronic clearinghouse of useful information about the SNAP program, including updated lists of acceptable and unacceptable substitutes. In addition, the online docket provides examples of submissions of various types.

c) Small Entity Flexibility

Submission of a notice to EPA 90 days before introducing a new substitute into commerce is required by statute, regardless of the size of the submitter. The information requested in the SNAP program is necessary for EPA to evaluate the proposed substitute chemicals which will be listed as acceptable or unacceptable, depending on the evaluations. The SNAP program has directed the burden on manufacturers and formulators, rather than the end user, which greatly reduces the potential burden on small entities.

Additionally, SNAP reporting requirements provide an exemption for persons introducing a substitute whose expected volume of use amounts to less than 10,000 pounds per year within a SNAP industrial sector. This exemption reduces the potential burden on small entities, although such persons are subject to a recordkeeping requirement documenting their qualification for this exemption.

d) Collection Schedule

The SNAP regulations were promulgated March 18, 1994, and collection of information as required therein commenced on that date. EPA accepts and reviews SNAP submissions as respondents provide them to EPA. Information in the public docket on these submissions has been available since submissions have been received.

6. Estimating the Burden and Cost of Collection

a) Estimating Respondent Burden

b) Estimating Respondent Costs

The following tables (6A/B-1 through 6A/B-5) present estimates of annual respondent burden hours and costs for each of the respondent activities described in section 4(b)(ii), with explanations of the assumptions made in each table. All cost values are in 2010 dollars and reflect inflation since the previous ICR. Labor costs are from the Bureau of Labor Statistics.

Exhibit 6A/B-1: SNAP Information Notice/Petition: Annual Respondent Burden and Cost (1)

The following table shows estimates of respondent burden hours and costs for the first set of activities listed above in section 4(b)(ii). In making these estimates, relied on its experience in sixteen years of implementing the SNAP program and its consultations with respondents, and made the following assumptions:

- The number of inquiries about filing a SNAP Information Notice or petition is 14 per year, of which 50% submit the filing. The number of CBI requests is 67% of the 7 submittals. The number of filings for which additional information is required is 67% of the 7 submittals.
- Labor cost of \$68 represents an average hourly rate of pay, including overhead and benefits,

for a private company for labor that would be classified as "technical" time for the bulk of the effort and "clerical" time for a small part of the effort.

- Estimated start-up cost is based on the cost of required toxicological data which, in 25% of SNAP filings, is a one-time event incurred for the sole purpose of fulfilling SNAP requirements. EPA estimates the cost of such data ranges from \$30,000 to \$350,000, with more than half of respondents incurring such costs in an amount equal to or less than \$75,000. EPA multiplied a weighted average of these costs (\$133,610) by 0.25 to get an estimated average start-up cost of \$33,402 which represents the cost distributed among all respondents. EPA calculated the annualized cost per respondent by using 20 years as the useful life of the chemical for which data was collected and 7% as the discount value.
- There is no annual operating and maintenance cost associated with this reporting requirement.

Table 6A/B-1: SNAP INFORMATION NOTICE / PETITION

Table DAVE-1. SINAP	IIVI OIV		VIVOTIC	LIFETITION				
	(A) Hours/ Year Resp.	(B) Labor Cost (@ \$68/ hr) per Resp. per Year	(C) Annua- lized Start-up Cost per Resp.	(D) No. of Resp.	(E)Total Hrs/Year (All Resp.) (A*D)	(F) Total Annualized Cost per Year (All Resp.) (C*D)	(G) Total Labor Cost per Year (All Resp.) (B*D)	(H) Total Cost per Year (All Resp.) (F+G)
a) Pre-submittal contact with EPA								
Obtain form and guidance document from EPA	0.75	\$51	\$0	7	5.25	\$0	\$357	\$357
Review form and guidance document from EPA	3	\$204		7	21		\$1,428	\$1,428
Identify chemical and applications	9	\$612	\$0	7	63	\$0	\$4,284	\$4,284
b) Prepare and submit form to EPA								\$0
Collect data for form	75	\$5,100	\$3,153	7	525	\$22,071	\$35,700	\$57,771
Prepare notification form	12	\$816	\$0	7	84	\$0	\$5,712	\$5,712
Prepare non-confidential version of form if CBI is declared	3	\$204	\$0	5	15	\$0	\$1,020	\$1,020
c) Respond to EPA requests for add'I information and/or notify EPA of add'I. info.								
Communicate with EPA	7	\$476	\$0	5	35	\$0	\$2,380	\$2,380
Collect data	58	\$3,944	\$0	5	290	\$0	\$19,720	\$19,720
Prepare data to send to EPA	3	\$204	\$0	5	15	\$0	\$1,020	\$1,020
Subtotals	170.75	\$11,611	\$3,153	varies but 7 is most	1,053.3	\$22,071	\$71,621	\$93,692

Exhibit 6A/B-2: TSCA/SNAP ADDENDUM: Annual Respondent Burden and Cost (2)

The following table shows estimates of respondent burden hours and costs for the second set of activities listed above in section 4(b)(ii). In making these estimates, EPA relied on its experience in sixteen years of implementing the SNAP program and its consultations with respondents, and made the following assumptions:

- Three inquiries per year come in regarding a TSCA/SNAP Addendum. EPA receives three submittals per year. Three CBI claims come from those 3 submittals. Additional information is usually required from the submitter.
- Labor cost of \$68 represents an average hourly rate of pay, including overhead and benefits, for a private company for labor that would be classified as "technical" time for the bulk of the effort and "clerical" time for a small part of the effort.
- -There is no start-up or operating and maintenance cost associated with the TSCA/SNAP Addendum.

Table 6A/B-2: TSCA/SNAP Addendum

		(B)			
	(A) Hours/ Year Resp.	Labor Cost (@ \$68/ hr) per Resp. per Year	(C) No. of Resp.	(D)Total Hrs/Year (All Resp.) (A*C)	(E) Total Labor Cost per Year (All Resp.) (B*C)
a) Pre-submittal contact with EPA					
Obtain form and guidance document from EPA	0.5	\$34	3	1.5	\$102
Review form and guidance document from EPA	3	\$204	3	9	\$612
Identify chemical and applications	0.5	\$34	3	1.5	\$102
b) Prepare and submit form to EPA					
Collect data for form	20	\$1,360	3	60	\$4,080
Prepare notification form	5	\$340	3	15	\$1,020
Prepare non-confidential version of form if CBI is declared	2	\$136	3	6	\$408
c) Respond to EPA requests for add'l information and/or notify EPA of add'l. info.					
Communicate with EPA	1	\$68	3	3	\$204
Collect data	3	\$204	3	9	\$612
Prepare data to send to EPA	1	\$68	3	3	\$204
Subtotals	36	\$2,448	3	108.0	\$7,344

Exhibit 6A/B-3: Notification for Test Marketing Activity: Annual Respondent Burden and Cost (3)

The following table shows estimates of respondent burden hours and costs for the third set of activities listed above in section 4(b)(ii). In making these estimates, EPA relied on its experience in sixteen years of implementing the SNAP program and its consultations with respondents, and made the following assumptions:

- The number of notifications for test marketing activity is one per year, and the number of hours per notification is two.
- Labor cost of \$68 represents an average hourly rate of pay, including overhead and benefits, for a private company for labor that would be classified as "technical" time for the bulk of the effort and "clerical" time for a small part of the effort.
- There is no start-up or operating and maintenance cost associated with the notification.

Table 6A/B-3: Notification for Test Marketing Activity

Table 67 VB 6. Notification for rest Marketing Activity							
	(A) Hours/ Year Resp.	(B) Labor Cost (@ \$68/ hr) per Resp. per Year	(C) No. of Resp.	(D)Total Hrs/Year (All Resp.) (A*C)	(E) Total Labor Cost per Year (All Resp.) (B*C)		
a) Compile information and prepare letter	2	\$136	1	2	\$136		
Subtotal	2	\$136	1	2	\$136		

Exhibit 6A/B-4: Recordkeeping for Substitutes Acceptable Subject to Use Conditions or Narrowed Used Limits: Annual Respondent Burden and Cost (4)

The following table shows estimates of respondent burden hours and costs for the fourth set of activities listed above in section 4(b)(ii). In making these estimates, EPA relied on its experience in sixteen years of implementing the SNAP program and its consultations with respondents, and made the following assumptions:

- The number of recordkeeping collections is 200 per year. Each collection is a one-time occurrence. Users of restricted alternatives may periodically reevaluate alternatives available.
- Labor cost of \$68 represents an average hourly rate of pay, including overhead and benefits, for a private company for labor that would be classified as "technical" time for the bulk of the effort and "clerical" time for a small part of the effort.
- There is no start-up cost associated with the recordkeeping collection.
- Annual operating and maintenance cost represents an estimate of cost of storage space for keeping the records.

Table 6A/B-4: Recordkeeping For Substitutes Acceptable Subject to Use Conditions or Narrowed Used Limits

Narrowed Osed Limits									
	(A) Hours/ Year Resp.	(B) Labor Cost (@ \$68/ hr) per Resp. per Year	(C) Annua- lized O&M Cost per Resp.	(D) No. of Resp.	(E)Total Hrs/Year (All Resp.) (A*D)	(F) Total Annualized Cost per Year (All Resp.) (C*D)	(G) Total Labor Cost per Year (All Resp.) (B*D)	(H) Total Cost per Year (All Resp.) (F+G)	
a) Assessment of other acceptable alternatives b) Compile information	25	\$1,700	\$0	200	5,000	\$0	\$340,000	\$340,000	
and prepare recordkeeping Subtotal	2 27	\$136 \$1,836	\$1 \$1	200	400 5,400	\$200 \$200	\$27,200 \$367,200	\$27,400 \$367,400	

Exhibit 6A/B-5: Recordkeeping for Small Volume Uses: Annual Respondent Burden and Cost (5)

The following table shows estimates of respondent burden hours and costs for the fifth set of activities listed above in section 4(b)(ii). In making these estimates, EPA relied on its experience in sixteen years of implementing the SNAP program and its consultations with respondents, and made the following assumptions:

- The number of recordkeeping collections is 10 per year, and each collection is a one-time occurrence.
- Labor cost of \$68 represents an average hourly rate of pay, including overhead and benefits, for a private company for labor that would be classified as "technical" time for the bulk of the effort and "clerical" time for a small part of the effort.
- There is no start-up cost associated with the recordkeeping collection.
- Annual operating and maintenance cost represents an estimate of cost of storage space, filing materials and other associated, non-labor costs for keeping the records.

Table 6A/B-5: Recordkeeping for Small Volume Uses: Annual Respondent Burden and Cost

	(A) Hours/ Year Resp.	(B) Labor Cost (@ \$68/ hr) per Resp. per Year	(C) Annua- lized O&M Cost per Resp.	(D) No. of Resp.	(E)Total Hrs/Year (All Resp.) (A*D)	(F) Total Annualized Cost per Year (All Resp.) (C*D)	(G) Total Labor Cost per Year (All Resp.) (B*D)	(H) Total Cost per Year (All Resp.) (F+G)
a) Assessment of sector sales								
	10	\$680	\$0	10	100	\$0	\$6,800	\$6,800
b) Compile information and prepare recordkeeping	2	\$136	\$1	10	20	\$10	\$1,360	\$1,370
Subtotal	12	\$816	\$1	10	120	\$10	\$8,160	\$8,170

c) Estimating Agency Burden and Costs

Exhibit 6C-1: Annual Agency Burden and Costs

The following table shows estimates of EPA burden hours and costs (including the cost of contractor services) for the activities listed in section 5 above. In making these estimates, EPA made the following assumptions:

- The number of occurrences is based on the number of inquiries and submittals by respondents estimated above in tables 6A-1 and 6A-2.
- The number of EPA-initiated changes in SNAP determinations is estimated to be two per year.
- The number of hours per detailed review of a TSCA/SNAP Addendum assumes 60 hours per form.
- Labor cost is based on the annual 2010 salary for a GS 12/ Step 2 employee (\$77,368), which is divided by 2,080 hours, the number of hours in a federal work year (resulting in an hourly rate of \$37.20), then multiplied by 1.6, the standard government benefits multiplication factor (resulting in a final hourly rate of \$59.52).
- The cost of contractor services in the two circumstances noted in the chart is based on a percentage of the total annual cost to SPD of the contractor's charges under the respective 2010 contracts. The percentage in each case represents an estimate of the time spent by the contractor on SNAP issues as distinguished from other SPD issues not related to SNAP. The hourly rate noted in each case represents the average rate charged per hour under these contracts.
- Total Agency costs have decreased. This is primarily due to a substantial decrease in the cost of contractor services for administrative support of the SNAP program. EPA staff complete an increasing proportion of clearinghouse maintenance and updates, rather than using contractor services.

Table 6C1: EPA burden hours and costs

	No. of Occur- rences	No. of Hours per Occur- rence	Total no. of Hours per Year	Labor Cost (@ \$59.52/hr) per Year	Cost of Contract Services per Year	Total Cost per Year
1) Pre-submittal contact w/ respondent						
Send forms/ guidance to potential submitters	14	0.1	1.4	\$83.33	n/a	\$83
Answer questions re potential submissions	14	3	42	\$2,499.84	n/a	\$2,500
Review & communication re submission						
Assign tracking number to submission	7	0.5	3.5	\$208.32	n/a	\$208
Review submission, send receipt, notify if add'l info required	7	2	14	\$833.28	n/a	\$833
Review CBI requests and protect as appropriate	5	4	20	\$1,190.40	n/a	\$1,190
Review submission in detail and notify submitter of decision	7	120	840	\$49,996.80	n/a	\$49.997
Contractor assistance in reviewing submissions (@ \$132/per hr)	n/a	n/a	2325	ф49,990.00 n/a	\$306,900	\$306,900
Review TSCA/SNAP Addendum in detail and notify submitter of						
decision	3	60	180	\$10,713.60	n/a	\$10,714
Prepare and evaluate EPA-initiated changes to determinations	2	40	80	\$4,761.60	n/a	\$4,762
3) Administrative operations						
Maintain system of tracking submissions	on- going	120	120	\$7,142.40	n/a	\$7,142
Maintain clearinghouse to help users	on- going	150	150	\$8,928.00	n/a	\$8,928
Contractor assistance for clearinghouse(@ \$99/per hr)	n/a	n/a	25	n/a	\$2,475	\$2,475
Prepare FR notices and rule-makings re changes to SNAP lists	5	80	400	\$23,808.00	n/a	\$23,808
Totals	varies	varies	4200.9	\$250,037.57	\$309,375	\$419,541

section 6(a) and (b) for these estimates.

e) Bottom Line Burden Hours and Cost Tables

Exhibit 6E-1: Information Collection Activity: Total Estimated Respondent Burden and Cost Summary

Table 6E1: Total Estimated Respondent Burden and Cost Summary

Table OLI. Totali	_Stirriate	u respo	ident bu	iden and eo	ot Julillio	u y		
	No. of Resp- ondent s per year	No. of Activities per year	Total Hours per Year	Total Labor Cost per Year @\$68	Total Annua- lized Start-up Costs	Total Annua- lized O&M Costs	Total Annua- lized Costs	Total Costs
SNAP Information Notice/ Petition	7	7	1,053	\$71,621	\$22,071	\$0	\$22,071	\$93,692
TSCA/SNAP Addendum	3	3	108.0	\$7,344	\$0	\$0	\$0	\$7,344
Notification for test marketing activity	1	1	2	\$136	\$0	\$0	\$0	\$136
Recordkeeping for Substitutes Acceptable Subject to Use Conditions or Limits	200	200	5,400	\$367,200	\$0	\$200	\$200	\$367,400
Recordkeeping for Small Volume Uses	10	10	120	\$8,160	\$0	\$10	\$10	\$8,170
Totals	221	221	6,683	\$454,461	\$22,071	\$210	\$22,281	\$476,742

Exhibit 6E-2: Total Estimated Agency Burden and Cost Summary

Table 6E2: Total Estimated Agency Burden and Cost Summary

	No. of Respondents	No. of Activities	Total Hours per Year	Total Govt Labor Hours per Year	Total Annual Govt Labor Cost @\$59.52	Cost of Contract Services per Year	Total Cost per Year
Pre-submittal contact with respondents	14	14	43.4	43.4	\$2,583	\$ -	\$2,583
Review and communicate re submission	7	7	3,463	1,138	\$67,704	\$306,900	\$374,604
Administrative operations	varies	varies	695	670	\$39,878	\$2,475	\$42,353
Totals	varies	varies	4,200.9	1,851	\$110,166	\$309,375	\$419,541

f) Reasons for Change in Burden

The total number of respondent burden hours requested annually (Exhibit 6E-1) for this

information collection has decreased from 8,204 hours in 2007 to 6,683 hours in 2010. The SNAP burden hours have been decreasing since 2000, starting at 10,363 hours and decreasing to 8,972 hours in 2004, 8,204 hours in 2007, and 6,683 hours in 2010. This is due to changes in EPA's estimates of the burden hours and number of respondents fulfilling reporting and recordkeeping requirements.

The development of new substitutes caused the number of persons filing a SNAP Information Notice or TSCA/SNAP Addendum to increase slightly, but also resulted in fewer respondents keeping records for alternatives that are subject to use conditions or narrowed use limits. In addition, respondents filing a SNAP Information Notice reported a decrease in total annual burden of hours when collecting data to complete the form and when responding to requests for additional information. This decrease may be attributable to increased respondent familiarity with EPA's forms, more examples in the public record for respondents to research and use in preparing responses, and general increased availability of computer software and information via the Internet.

g) Burden Statement

Exhibits 6A/B-1 through 6A/B-5 present the average annual respondent burden for each person subject to SNAP reporting and recordkeeping requirements. For persons filing a SNAP Information Notice or petition, the reporting burden is estimated to average 171 hours per year. For persons filing a TSCA/SNAP Addendum, the reporting burden is estimated to average 36 hours per year. For persons filing a notification of test marketing activity, the reporting burden is estimated to average 2 hours per year. For persons keeping records of use of a substitute subject to use conditions or narrowed use limits, the recordkeeping burden is estimated to average 27 hours per year. For persons keeping records of a small volume use, the recordkeeping burden is estimated to average 12 hours per year.

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. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying 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 numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

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-OAR-2004-0077, which is available for online viewing at www.regulations.gov, or in person viewing at the OAR Docket in the EPA Docket Center (EPA/DC), EPA West, 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 Reading Room is (202)566-1744, and the telephone number for OAR Docket is (202)566-1742. An electronic version of the public docket is available at www.regulations.gov. This site can be used 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. When 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, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OAR-2004-0077 and OMB Control Number 2060-0226 in any correspondence.

Appendices

- A- Draft FR notice announcing request for ICR renewal
- B- Text of Section 612 of the Clean Air Act as amended in 1990
- C- Text of SNAP Regulations, 40 CFR Part 82, Subpart G
- D- SNAP Information Notice (EPA Form 1265-07)
- E- TSCA/SNAP Addendum (EPA Form 1265-07)
- F- Instructions for the SNAP Program Information Notice and TSCA/SNAP Addendum (EPA Form 1265-93(1)