U.S. ENVIRONMENTAL PROTECTION AGENCY INSTRUCTIONS FOR THE SIGNIFICANT NEW ALTERNATIVES POLICY (SNAP) PROGRAM INFORMATION NOTICE AND TSCA/SNAP ADDENDUM September, 2011

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The U.S. Environmental Protection Agency (EPA) has prepared this instruction manual to help you in submitting information on alternatives to ozone-depleting chemicals to the Significant New Alternatives Policy (SNAP) program. This manual provides instructions on submitting the SNAP Information Notice and TSCA/SNAP Addendum forms, asserting confidentiality claims, and submitting test data and optional information. However, please note that in the event of any discrepancies between this document and the Code of Federal Regulations (CFR), the CFR requirements are legally binding and take precedence.

TABLE OF CONTENTS

1.	INTRODUCT	TION TO THE SNAP PROGRAM	2
	A.	What is the purpose of the SNAP Program?	2
	B.	Do I need to submit information to the SNAP Program?	2
	C.	When can I qualify for an exemption from submitting information to SNAP?	3
	D.	Who must submit to the SNAP Program?	
2.	INTRODUCT	ION TO THE SNAP SUBMISSION FORMS	
	A.	Which form do I submit—the SNAP Information Notice form or the TSCA/SNAP Addendum	n form?
	B.	When do I need to submit to the SNAP Program?	
	C.	Is there a fee for submitting to the SNAP Program?	
	D.	How should I fill out the SNAP Information Notice form?	
3.	CONFIDENT	IALITY CLAIMS	6
	A.	Can EPA keep confidential the information in my SNAP submission?	6
	B.	How do I make a claim of Confidential Business Information?	6
	C.	What do I need to provide to EPA to substantiate my CBI claim?	
	D.	What kinds of data am I not allowed to claim as confidential?	7
	E.	Does anyone besides EPA staff see my SNAP submission?	8
	F.	Does EPA ever reconsider which data are confidential?	8
4.	BEGINNING	THE SNAP INFORMATION NOTICE	8
	A.	Should I mark my form as a manufacturer's submission or as a petition?	8
	B.	What are the types of petitions allowed under the SNAP Program?	8
	C.	What are reasons for submitting a petition?	9
	D.	What do I need to include in my petition?	9
	E.	What does EPA consider when reviewing my petition?	
	F.	What kinds of test data and effects data do I need to provide to EPA?	9
5.	STEP-BY-ST	EP INSTRUCTIONS FOR COMPLETING THE SNAP INFORMATION NOTICE	10
	Part I –	INTRODUCTION AND GENERAL INFORMATION	10
		Part I, Initial Information (Page 1 and Page 2)	
		Part I, Section A - Submitter Identification (Page 3)	10
		Part I, Section B - Alternative Identification (Page 4)	11
	Part II -	ALTERNATIVE-SPECIFIC INFORMATION	
		Part II, Section A - Physical and Chemical Properties (Page 6)	13
		Part II, Section B - Atmospheric Information (Page 7)	
		Part II, Section C - Other Statutes (Page 8)	15
		Part II, Section D - Cost and Availability of the Alternative (Page 9)	
	PART I	II - RELEASE AND EXPOSURE DATA	
		Part III, Section A - Toxicity and Hazard Information (Page 10)	
		Part III, Section B - Environmental Release and Disposal at Manufacture (Page 10)	
		Part III, Section C - Occupational Exposure at Manufacture (Page 11)	
		Part III, Section D - Environmental Release and Disposal in End-use (Page 11)	
		Part III, Section E - Occupational Exposure at End-use (Page 12)	
		Part III, Section F - Consumer Exposure (Page 12)	18

	Part III, Section G - General Population Exposure - OPTIONAL (Page 13)	18
Par	t IV - LIST OF ATTACHMENTS (Page 14)	19
	t V - CERTIFICATION (Page 15)	
	EVIEW WITH OTHER ÈPĂ OFFICES	
A.	What is the relationship between the SNAP Program and the New Chemicals (Pre-Manu	ufacture
	Notice) Program?	
B.	What forms should I submit to the SNAP program and to the New Chemicals program?.	
C.	When should I submit to the SNAP program if I am also submitting a PMN?	
D.	Do both the SNAP program and the New Chemicals program have a 90 day review?	
E.	How does EPA treat confidentiality during co-review of a chemical under the SNAP programmer.	
	under the New Chemicals program?	
F.	What is the relationship between the SNAP Program and review of antimicrobials under	
		20
G.	What form do I submit to SNAP for a sterilant?	20
7. CONSUI	LTATION WITH EPA CONCERNING THE SNAP INFORMATION NOTICE	20
A.	Where do I get more information about submitting to the SNAP program?	20
B.	How will EPA interact with me after I submit to the SNAP program?	
APPENDIX	A: LIST OF END-USES WITHIN SECTORS INCLUDED IN THE SNAP PROGRAM	
	B: SECTOR-SPECIFIC DATA REQUIREMENTS	

1. INTRODUCTION TO THE SNAP PROGRAM

A. What is the purpose of the SNAP Program?

The Significant New Alternatives Policy (SNAP) program is designed to:

- \$ Identify and evaluate substitutes for end-uses that have historically used ozone-depleting substances (ODSs)
- \$ Look at overall risk to human health and the environment of both existing and new substitutes
- \$ Publish lists of acceptable and unacceptable substitutes by end-use
- \$ Promote the use of acceptable substitutes for ozone-depleting substances
- \$ Provide the public with information about the environmental and health impacts of substitutes for ozone-depleting substances

To arrive at determinations on the acceptability of substitutes, the Agency performs a cross-media analysis of risks to human health and the environment from the use of various substitutes in different industrial and consumer uses that have historically used ODS.

For additional information on the SNAP program and a copy of the existing listing decisions, please see the SNAP Program web site at http://www.epa.gov/ozone/snap/index.html or call the Stratospheric Ozone Hotline at (800) 296-1996.

For the purposes of this document, EPA is using the word "substitute" as a synonym for "alternative".

B. Do I need to submit information to the SNAP Program?

You may need to submit information to EPA's Significant New Alternatives Policy (SNAP) program if you are introducing a substance, process, or product for sale, import, export or use in one of the following industrial sectors:

- s refrigeration and air-conditioning
- \$ foam blowing
- \$ solvent cleaning
- \$ fire suppression and explosion protection
- \$ tobacco expansion
- \$ adhesives, coatings and inks
- \$ aerosols
- sterilants

In certain cases, you may be exempt from the requirement to submit information under the SNAP program.

C. When can I qualify for an exemption from submitting information to SNAP?

Below are a number of exemptions from the general requirement to submit information to the SNAP Program. (40 CFR 82.176(b))

1. Substitutes Already Listed Under SNAP in the Same End Use

You do not need to submit to SNAP if someone else has already submitted the same substance, process, or product for the same end use and it has already been listed as acceptable (see Appendix A for the list of end uses by industrial sector). To find out if someone else has already submitted, first check the SNAP listings online or in the docket.

2. Small Sectors

The major industrial use sectors included under SNAP are those that historically used ODS: refrigeration and air-conditioning; foam blowing; fire suppression and explosion protection; solvent cleaning; adhesives, coatings, and inks; aerosols; sterilization; and tobacco expansion. If your product is not or will not be used under one of these sectors, you do not need to submit under SNAP.

3. Small Volume Use within SNAP Sectors

Producers of substitutes produced in annual quantities of 10,000 lbs per year or less for a sector do not need to notify EPA of their activities under SNAP. Note that this applies to total use within the industrial sector and not just to the individual producer. EPA encourages producers to maintain documentation describing the basis for their view that any substitute being used meets this small use definition. This documentation could be necessary in the event the Agency receives a petition to evaluate such substitutes. Documentation should take the form of production volume and sales information.

4. Formulation Changes

In general, formulation changes that accommodate introduction of a substitute do not require submitting to SNAP. Such changes may be necessary, for example, when a new foam blowing agent necessitates the replacement of the catalyst formerly used with the ozone-depleting blowing agent. However, if a SNAP submitter has reason to believe such changes will significantly influence the environmental and human health risk characteristics associated with the use of any substitute, you should share this concern with the Agency. EPA may also review any changes in formulation in connection with review of substitute compounds where the Agency has reason to believe the formulation change may affect the risk profile of a substitute. Further, formulation changes in a substitute do require submission to SNAP (e.g., a refrigerant blend with a new formulation).

5. Test Marketing

You do not need to send in a SNAP Information Notice form or TSCA/SNAP Addendum form if use of alternatives is for the sole purpose of test marketing. Once you decide to sell an alternative as a class I or class II substitute, you must provide the Agency with notification at least 90 days prior to commercialization. Producers of new chemicals must still abide by the provisions of section 5(h)(1) of TSCA, which authorizes EPA to grant exemptions from TSCA-reporting requirements, provided that test marketing will not present an unreasonable risk to human health or the environment.

If you plan to take advantage of this exemption, you must send a test marketing notification to EPA at least 30 days before you start test marketing. Your notification must include:

- the name of the substitute,
- the volume you intend to test market,
- the industrial sector and end use(s) for the test market, and
- the expected duration of the test market period,

Send your test marketing notification to the same address as for the SNAP Information Notice form.

6. Research & Development

Substitutes manufactured or imported solely for research and development are exempt from reporting requirements under the SNAP Program. For new chemicals, the provisions of Section 720.36 of EPA's TSCA Premanufacture Notice (PMN) rule (40 CFR Part 720) are in effect for chemicals produced solely for research and development.

7. Substitutes Used as Feedstock

Substitutes that could replace ozone-depleting chemicals which are used solely as intermediates in the production of other chemicals are exempt from reporting to the SNAP program.

D. Who must submit to the SNAP Program?

Manufacturers, formulators, and end-users may need to submit under the SNAP program.

1. Designated Submitters

Anyone who produces a substitute for a class I or class II ozone-depleting substance must provide the Agency with that person's unpublished health and safety studies on the substitute. The producer of the substitute must also notify the Agency at least 90 days before introducing the substitute or a product using the substitute into interstate commerce for significant new use as an alternative.

The Agency recognizes that a substitute can potentially pass through numerous steps prior to its introduction into interstate commerce. Therefore, we consider responsibility for notification under SNAP to rest with the person who produces the substitute in its final form for interstate commerce for purchase by an end-user. Therefore, the designated submitter could potentially be a manufacturer, formulator, or an end-user.

a. Manufacturers

Manufacturers producing a substitute (a chemical, alternative process or technology) in its final form for direct commercial sale to the end-user are required to notify the Agency about the existence of that substitute. For instance, if a chemical manufacturer intends to market a chemical as a substitute foam blowing agent to companies that manufacture insulation products, the chemical manufacturer would be required to notify the Agency about the existence of the substitute. If the substitute is a new chemical not already on the TSCA Inventory, it must also undergo review under EPA's New Chemicals (Pre-Manufacture Notice) program. For more information on this simultaneous review process, see Section 6 of this document.

b. Formulators

A formulator is engaged in the preparation or formulation of a substitute, after chemical manufacture of the substitute or its components, for distribution or use in commerce. Formulators usually only sell substitutes based on existing chemicals, since they do not ordinarily possess chemical manufacturing capabilities. Chemicals used in such substitutes are frequently in common use and have already been approved for general use through other chemical review programs such as TSCA or FIFRA.

However, formulators can be considered directly responsible for production of the substitute for an enduse. For example, by offering a specific solvent formulation for an industrial cleaning process, formulators would be subject to reporting requirements under SNAP. In such cases, the formulator is best suited to present information on how substitutes based on existing chemicals are or could be used. In cases where the manufacturer of a chemical is also the formulator of a blend, the manufacturer is responsible for meeting reporting requirements on the substitute.

c. End-users

End-users of substitutes are not obligated to meet SNAP reporting requirements, except in rare cases where the end-user is also the substitute producer and will be the first to introduce it into commerce. While the Agency expects that this situation will occur infrequently, several companies have developed substitutes for their own use and subsequently have notified EPA of their intent to offer those substitutes for commercial sale.

2. INTRODUCTION TO THE SNAP SUBMISSION FORMS

A. Which form do I submit—the SNAP Information Notice form or the TSCA/SNAP Addendum form?

Use the <u>SNAP Information Notice form</u> ("SNAP application") if you are applying to use an existing substance that is already being produced and sold or imported into the U.S., or if you are applying for a new technology or process. Most SNAP submitters use this form.

Use the <u>TSCA/SNAP Addendum form</u> only if you have already prepared a Pre-Manufacture Notice (PMN) to send to EPA for a new chemical. You will include the PMN form as an attachment to the TSCA/SNAP Addendum form.

If you are not sure if the chemical you intend to use is considered to be an existing chemical, consult with EPA's New Chemicals Program (TSCA Hotline at 202-554-1404). Existing chemicals are listed on the TSCA Inventory. You can find more information on <u>EPA's New Chemicals Program web site</u>.

B. When do I need to submit to the SNAP Program?

You must submit a SNAP notice at least 90 days before you begin sale of a new substitute for an ozone-depleting substance. A petition may be submitted any time adequate data exists for EPA consideration.

C. Is there a fee for submitting to the SNAP Program?

No. There is no application fee for submitting information to the SNAP program.

D. How should I fill out the SNAP Information Notice form?

You must file a separate notice for each substitute you submit for evaluation. However, a single alternative may be submitted for multiple end-uses simultaneously provided that the appropriate information is submitted for each specific end-use. See Appendix A for a list of sector end-uses included under SNAP. If you submit a substitute for review under more than one sector, you may wish to complete a separate notice for each sector. Please check the type of notice submitted on page 1 of the form. If this notice is being submitted as part of a petition to the Agency, indicate the type of petition. See Section 4 for an explanation of the different types of petitions.

Checklist for Completing the SNAP Information Notice form

- ✓ Please type the SNAP form or print legibly in black ink.
- ✓ All information must be in English.
- ✓ Provide all information requested on the notice form to the extent that you know or can reasonably ascertain it. If you do not know or cannot reasonably ascertain the information, enter "unknown" (for not known). However, if you cannot answer a question that is needed for evaluation of the substitute within a given sector (see Appendix B), review of the substitute may be delayed.
- ✓ You may attach continuation sheets to any subsection or item on the form.
- ✓ You may photocopy the notice form or sections of the form, or download extra copies, as needed.
- ✓ Send your completed submission notice to the SNAP Document Control Officer (6205J), whose address appears on page 1 of the form.
- ✓ For paper submissions, you must submit three copies of the submission to EPA. If information is claimed as confidential, it must be removed from one of the copies, which will be placed in the public docket; the other two copies must include all confidential material. If you do not claim any information as confidential, all copies must be identical.

✓ For CD-ROM submissions, if information is claimed as confidential, it must be removed from one of the files on the CD-ROM, which will be placed in the public docket; the other file must include the confidential material. (See below for further guidance on handling of confidential information under SNAP.)

3. CONFIDENTIALITY CLAIMS

A. Can EPA keep confidential the information in my SNAP submission?

EPA will keep information confidential provided that you make a claim of confidential business information at the time you submit and that you provide reasons for that claim. As described below, you may not claim certain types of information as confidential business information.

B. How do I make a claim of Confidential Business Information?

If you submit information for which you request Confidential Business Information (CBI) status, you must make a claim of confidentiality at the time of submission. If you do not assert a claim of confidentiality at the time of submission, EPA may disclose the information to the public without further notice to you. Information which is publicly available (e.g., in journals, trade magazines, product literature, etc.) cannot be claimed as CBI. Requesting CBI status for such public information could delay EPA's review. EPA will treat all claims of confidentiality consistent with 40 CFR Part 2, Subpart B.

To claim information as CBI, circle or bracket the <u>specific</u> information you claim as confidential and check the box at the bottom of the page. Then provide reasons why you are claiming this information as confidential on an attachment to the notice. For example, if you submit a study which describes a physical or chemical property and it is only that property which you wish to claim as confidential, bracket only that property. Do not simply mark "Confidential" on the page which contains that property. EPA requires substantiation of all CBI claims under SNAP or a submission will be considered incomplete.

If you claim the identity or formulation of a substitute as confidential, you must provide a generic description of this information. Section 5 of this document gives guidance on developing generic names.

For paper submissions, only two of the three copies of your submission should include CBI material. To ensure that no confidential information is disclosed to the public, you must delete all CBI from a third "sanitized" public copy, including attachments, which will become part of the public docket. The following special preparation is required for the sanitized copy:

- \$ Remove from the body of the submission any information you claim as confidential. Replace with generic information if it is available.
- \$ Mark the sanitized copy plainly on both its cover and its title page with the phrase "Public Docket Material -- contains no information claimed as confidential."

For CD-ROM submissions, one file on the CD-ROM should include CBI material and one should be sanitized. Prepare the CBI and sanitized files in the same way as described above for paper submissions. When you are ready to save the files to the CD-ROM, ensure that the file with the CBI material is clearly identified by the words "contains CBI" in the file name.

If you claim CBI but do not provide the sanitized copy with your submission, EPA will consider your submission incomplete. This may delay or prevent publishing an acceptability determination on your product. EPA recognizes that substantial portions of submissions may be omitted from the public docket copy. However, all CBI claims must be substantiated to warrant restricting access to such information.

C. What do I need to provide to EPA to substantiate my CBI claim?

EPA requires substantiation of all confidentiality claims at the time of submission. In making these claims, the following applies:

- \$ The specific information to which the claim applies must be clearly marked as subject to a claim of confidentiality;
- A `Supplemental Statement of Data Confidentiality Claims' must be submitted, identifying each section claimed confidential and describing in detail the basis for the claim (see below for specific points that should be addressed);
- \$ The `Supplemental Statement of Data Confidentiality Claims' must be signed and dated and must include the typed name and title of the official who signed it.

If you do not provide the required substantiation when submitting information claimed as confidential, EPA may make the complete submitted information available to the public without further notice.

Supplemental Statement of Data Confidentiality Claims

For any portion of a submission that you claim as confidential, the following information must be included in a Supplementary Statement of Data Confidentiality Claims:

- s Identify specifically by page and line number(s) each portion of the document for which you claim confidentiality.
- \$ Give the reasons why the cited passage qualifies for confidential treatment.
- \$ Indicate the length of time until a specific date or event, or permanently for which the information should be treated as confidential.
- \$ Identify the measures you have taken to guard against undesired disclosure of this information.
- \$ Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with these disclosures.
- \$ Enclose copies of any determinations of confidentiality previously made by EPA, other Federal agencies, or courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

D. What kinds of data am I not allowed to claim as confidential?

Publicly available information may not be claimed as confidential.

Under section 114(c) of the Clean Air Act, emissions data may not be claimed as confidential.

Toxicity or health and safety studies, to the extent that confidential treatment is prohibited under the Toxic Substances Control Act (TSCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), cannot be held confidential. However, other information can be maintained as confidential subject to the provisions of 40 CFR, Part 2, Subpart B, so long as it is: a) information other than emissions data, b) not health and safety data, and c) not data on the effects of a substance on human health and the environment. The Agency requests that you do not identify the following information as confidential: all information concerning the objectives, methodology, results, or significance of any toxicity test or experiment performed on or with a substitute or its degradation products; any information concerning the effects of the substitute on any organism (e.g., fish, wildlife, humans and other mammals) or the environment (e.g., studies related to persistence, translocation, and fate); emissions data; and pharmacokinetics/metabolism studies. Examples of information that may be claimed as confidential include discussion of process information, composition of proprietary blends, identity of the submitter or the substitute, and cost and availability of the substitute.

E. Does anyone besides EPA staff see my SNAP submission?

Before issuing a decision, EPA posts the public version of your SNAP submission in our public docket. The SNAP docket is docket number EPA-HQ-OAR-2003-0118, available online at www.regulations.gov.

Information submitted as CBI may be accessed by companies designated as Authorized Representatives of the United States Environmental Protection Agency (EPA) under an EPA contract for the purpose of assisting EPA in the development and implementation of national regulations for the protection of stratospheric ozone, including the development of the SNAP program. These Authorized Representatives may have access to any information received by the Stratospheric Protection Division within EPA's Office of Atmospheric Programs for use in reviewing the need for possible control of any substance, practice, process or activity that may reasonably be anticipated to affect stratospheric ozone. In general, this information will pertain to the feasibility, costs, and environmental and health impacts of using substitutes for class I and class II substances. Access to such information is necessary to ensure that these companies can complete the work required by the contract.

Authorized Representatives of EPA are subject to the provisions of 42 U.S.C. 7414(c) respecting confidential business information as implemented by 40 CFR 2.301(h).

F. Does EPA ever reconsider which data are confidential?

EPA may reconsider confidentiality assertions even when confidentiality claims are received. This could occur, for example, if EPA receives a Freedom of Information Act (FOIA) request on a particular substitute. These circumstances and others are described in 40 CFR Part 2, Subpart B. You will be contacted if EPA reconsiders the confidential status of your data or if we receive a FOIA request that includes your confidential data. In such a case, EPA would typically ask for additional information to support whether the data should remain confidential.

4. BEGINNING THE SNAP INFORMATION NOTICE

A. Should I mark my form as a manufacturer's submission or as a petition?

If you are providing information on a new substitute that you produce, formulate, use, or distribute, you should check the box for a manufacturer's submission.

Petitions may be submitted by anyone. The petition provision serves two principal needs. The first is to give the public a way to appeal existing Agency determinations under the SNAP program. The second is to provide a way for individuals and organizations to bring to the Agency's attention new information on substitutes that could affect existing listing determinations or result in new ones.

If you file a petition for EPA to review a substitute that has not previously been reviewed, you will provide the same information as for a manufacturer's submission. There are other types of petitions that do not require submitting the SNAP Information Notice form.

B. What are the types of petitions allowed under the SNAP Program?

Five types of petitions exist (see 40 CFR 82.184):

- (1) Petitions to add a substitute not previously reviewed under the SNAP program to the acceptable list:
- (2) Petitions to add a substitute not previously reviewed under the SNAP program to the unacceptable list;
- (3) Petitions to move a substitute from the acceptable list to the unacceptable list or to move a substitute from the unacceptable list to the acceptable list:
- (4) Petitions to add or delete use restrictions on an acceptability listing, and

(5) Petitions to grandfather general use of a substitute found "unacceptable" or "acceptable subject to narrowed use limits" in specified applications within an end-use.

C. What are reasons for submitting a petition?

A petitioner may submit a petition for several reasons, including:

- Availability of new information on substitutes or end-uses not covered in the existing SNAP determinations;
- \$ Requests to extend the effective date for prohibitions on uses of an unacceptable substitute;
- New technologies or practices that reduce exposure to a substitute previously unacceptable under SNAP due to toxicity or flammability concerns.

All of the above are examples of valid justifications for submitting a petition. Other bases for petitioning the Agency may exist as well, and all petitions with adequate supporting data will receive consideration under the SNAP program.

D. What do I need to include in my petition?

Petition types (1) and (2) must contain the information requested in the SNAP Information Notice. Information requirements for such petitions and for manufacturers' submissions are the same. For petition types (3) and (4), which request a reexamination of a substitute previously reviewed under the SNAP program, the submitter may reference the prior submission rather than submit duplicate information. In this case, the petitioner should specifically indicate any new or additional data and submit complete test reports.

For petition type (5), EPA must consider a specific test to determine whether grandfathering should be allowed for specified applications within an end use. This test involves balancing the results of four analyses, including whether the new rule represents an abrupt departure from previously established practice, the extent to which a party relied on the previous rule, the degree of burden which application of the new rule would impose on the party, and the statutory interest in applying the new rule immediately. Thus, petition type (5) requires information about the current level of use of the substitute and other information to allow EPA to conduct these analyses.

For all petitions, the Agency also requires the following information:

- \$ Action requested: A brief statement describing the type of petition; and
- \$ Rationale: A brief summary of the basis for the petition and the data that support the petition.

E. What does EPA consider when reviewing my petition?

EPA will only review and grant or deny petitions based on the sector and end-use identified in the petition. For example, the fact that a substitute is placed on the list of unacceptable substitutes for a particular end-use in the solvents cleaning sector does not mean the substitute is unacceptable for any specific end-use as a refrigerant. A similar caveat applies for petitions on end-uses within a sector. If a substitute, for instance, is found acceptable for a specific end-use within a sector, it will not automatically be deemed acceptable for any other end-use in that sector or in other sectors.

F. What kinds of test data and effects data do I need to provide to EPA?

You are required to provide test data on the health and environmental effects of alternatives, including data on physical/chemical properties, in your possession or control, and a description of any other health and environmental effects data on the substance known to or reasonably ascertainable by you. The Agency

considers data in the possession or in control of either a parent company or an affiliated subsidiary located outside the U.S. to be data that should be known to or reasonably ascertainable by a submitter.

Complete test data, not summaries of data, must be submitted if they do not appear in the published literature. Incomplete reports (e.g., from ongoing studies) are exempt from full reporting. However, you must describe the nature and objective of any incomplete study, report, or test; the name and address of any laboratory developing the data; progress to date, type of data collected; significant preliminary results; and an anticipated completion date. If significant preliminary results or final results are obtained prior to the completion of the notice review period or any other additional information significant to the review of the notice becomes available to you, you must submit this information within 10 days of receipt. If information becomes available during the last 5 days of the review period, you should <u>immediately</u> inform EPA by telephone. Data must be submitted in English.

Lists of the test data you must submit for each sector are provided in Appendix B at the end of this manual. For additional information on health and safety studies and on submitting test data, see '82.172 and 82.178 of the SNAP Rule and Section 5 of these instructions.

5. STEP-BY-STEP INSTRUCTIONS FOR COMPLETING THE SNAP INFORMATION NOTICE

Part I - INTRODUCTION AND GENERAL INFORMATION

You must complete all of Part I for your submission to be accepted for review under SNAP. See below for sector-specific data requirements.

Part I, Initial Information (Page 1 and Page 2)

Please select the appropriate box on page 1 indicating the type of notice (manufacturer submission or petition, see Section 4.A-C above) and check the boxes on page 2 indicating the sector(s) for which you are submitting information on the substitute and the types of test data included in your submission. Attach all test data to the notice form and reference them by page number in Part IV-List of Attachments (pg. 14).

Part I, Section A - Submitter Identification (Page 3)

- 1a. Person submitting notice Enter information for the official who signs the certification on page 15.
- b. Agent Complete only if you authorize an agent to assist you in preparing this notice. The agent must also sign the certification as noted above.
- c. Joint Submitter Identify the joint submitter, if any, who is authorized by the primary submitter to provide some of the information required in the notice. A submission will not be considered complete until EPA receives all information. If information from multiple parties will not be sent together, mark each set clearly with the same alternative identification information.
 - If you authorize another person (e.g., a foreign manufacturer or supplier) to provide information directly to EPA, indicate which information will be supplied by the other person. Identify that person by name, company, and address in a continuation sheet. Such a letter in support of your notice should be provided by the other person on company letterhead. An example of where this option could apply would be in situations where alternative formulation information is held confidentially by a foreign manufacturer. A notice will be considered incomplete until this information is provided. Whenever possible, use the same alternative identification information (e.g., generic name) to link this information to your submission.
- 2. Technical Contact Identify a person who can provide EPA with additional technical information on the substitute during the review period. The technical contact identified should be located within the U.S. and be available to be reached by telephone during normal business hours.

3. Provide information on any prior communication with EPA regarding this submission. Provide the EPA staff person's name, the date, and the form of communication (e.g., letter or phone). Mark the box labeled "Mark (X) if None" if no prior communication has occurred.

Part I, Section B - Alternative Identification (Page 4)

EPA must receive a complete and unambiguous identification of the new substitute. If the alternative is not adequately identified, we will consider the submission incomplete. If you are an importer of an alternative and do not know the chemical identity of a substitute because it is confidential, you must contact the manufacturer or supplier and have the specific chemical identity provided directly to EPA. In this way, manufacturers can protect confidential business information. This information may be provided in a letter on company letterhead from the supplier or in a joint submission, referencing the earlier submission.

- Commercial/Trade Name(s) of the Alternative Indicate the name(s) under which the alternative is marketed.
- 2. Name of Chemical, Process, or Alternative Technology Enter the specific name of the chemical substance, the Chemical Abstracts Service (CAS) registry number, and the molecular formula of the alternative. In describing chemical substances, EPA prefers that International Union of Pure and Applied Chemistry (IUPAC) nomenclature be used for identification purposes. If the substitute is a blend of chemicals, you must provide the exact composition and/or the range of percent composition of all components (where appropriate) of a substitute. In addition to active ingredients, you must also list other chemical substances in blends, such as solvents, inhibitors, etc., that may also be present in the alternative.

For agents where the discharged agent is different from the original formulation, such as pyrotechnically generated aerosol fire suppressants, include composition information for both the original formulation and for the gaseous and/or particulate constituents of the discharged agent.

For alternative technologies and/or processes, provide a detailed description and diagram of the technology or process and information on any chemical constituents.

Also, if you have applied for or hold a patent on the substitute, provide the patent name, number (if available), and information on topics covered in the patent.

Sector-Specific Data Requirements

Solvents; Aerosols; Adhesives, Coatings, & Inks: Give the function of each constituent as well as the percent composition. For example, in an aerosol product, such a list may include:

HFC-134a (propellant) dimethyl ether (propellant) methanol (solvent)

silicone (active ingredient)

3. Generic name - If the identity of a substitute is claimed as confidential or if the formulation or process is such that it cannot be identified by its individual chemical components, you must provide a generic name that is only as generic as necessary to protect the confidential identity. The name should reveal the chemical identity or alternative process description to the maximum extent possible. The generic name may be published in the Federal Register notice announcing EPA's acceptability determination of your alternative. If the name seems more generic than necessary, EPA will contact you and assist you in developing an adequate name.

The generic name should provide sufficient information for the public by indicating the classes of chemicals which the alternative contains without revealing specific information about the product's composition. For example, it may be necessary to reveal that a refrigerant blend contains an HCFC in order to allow users or importers to comply with regulations issued under sections 604or 608 of the CAA.

When reviewing the SNAP lists for the solvents, aerosols, and adhesives, coatings and inks sectors you will notice that many of the listings are grouped into general classes of substitutes. If your substitute is

already included under one of these classifications, you need to submit information to EPA for review under SNAP <u>only</u> if your substitute contains a new chemical which is subject to review under the PMN program.

4. Specific End-use - Identify the specific end-uses in which the alternative is to be used. Be sure to provide a broad description (e.g. terpene-based semi-aqueous solvent cleaner of metal parts as an alternative for methyl chloroform, or HFC refrigerant as an alternative for CFC-12 centrifugal chillers.)

Specify the ozone-depleting substance (ODS) being replaced, and include an estimate of the quantity of alternative (lbs.) needed to replace the ODS for each end-use. This is known as the replacement ratio. For example, if 100 pounds of a new refrigerant will replace 150 pounds of CFC-12, the replacement ratio is 1:1.5.

See Appendix A for a list of end-uses included under SNAP. If you are proposing a new end-use, please indicate why the substitute does not fit into an existing one.

Sector-Specific Data Requirements

Refrigerants: Indicate whether the alternative is a candidate for use in retrofits of existing equipment, for use in new equipment only, or both. If the alternative can be used both as a retrofit and in new equipment, these uses should be treated as separate end-uses throughout the notice. If the substitute is a chemical replacement, provide the size of the average charge used in each end-use. Describe the technology or the industry standard that will be used to recover the substitute.

Foams: If the alternative blowing agent can be used in several different types of foam, treat each enduse separately throughout the notice.

Fire Suppression: Provide information on the weight and storage volume equivalence replacement ratio for the substitute versus the ODS being replaced, using the method described in Appendix B.

Tobacco Expansion: Specify the base replacement ratio values on the amount of new expansion agent consumed per unit mass of tobacco compared to the amount of CFC-11 consumed per unit mass.

- 5. Impurities Identify by name, weight percent, and CAS number (where available) each impurity that you reasonably anticipate will be present in the alternative as manufactured for commercial purposes. An impurity is any chemical substance that is unintentionally present in the alternative. List all impurities, regardless of weight percent. If the substance contains some unidentified impurities, also enter "unidentified". Do not include substances that are mixed with the new substance after manufacture of the primary ingredients. If there are no impurities, enter "None."
- 6. Byproducts Describe any byproducts or degradation products that you reasonably anticipate will result from the manufacture, processing, use, or disposal of the alternative both at sites you control and in enduse. Identify these byproducts or degradation products by specific name or class or range of structures (e.g., HF or other acid gases formed from the combustion of halocarbon compounds), CAS Registry number (where available), and the estimated amount formed. Also indicate where the byproduct or degradation product is formed (e.g., during manufacture, during end-use, following disposal).

Sector-Specific Data Requirements

Foams: Provide information on the catalyst used in manufacture and an analysis of breakdown products under different external conditions, such as temperature, during use.

Fire Suppression: Provide information on the degradation products of the alternative following discharge in a fire situation. Explain the conditions used in determining these products, such as the flame temperature, time required to extinguish the fire, amount of O₂ present, and the combustible material.

Part II - ALTERNATIVE-SPECIFIC INFORMATION

EPA requires certain information on all substitutes. However, the data that are required may vary by sector. See Appendix B for more information on sector-specific requirements.

Part II, Section A - Physical and Chemical Properties (Page 6)

Include all data on the physical or chemical properties of the alternative that are reasonably available to you. Those properties included in this section are illustrative and are not an exhaustive list of potential data. See Appendix B for sector-specific data needs within this section.

If you are extracting this information from a public reference source (e.g., CRC Handbook of Chemistry and Physics, Merck Index), please indicate the reference in Question 27, "Other". If you have performed chemical analysis and testing on the substitute to derive the properties, attach copies of all test reports and specify the protocol used.

- 1-27. Complete the form as appropriate for the specific substitute. Many physical characteristics will apply to more than one sector; see Appendix B to these instructions for detail by sector. For flammable substances or mixtures, be sure to fill in items 22-26.
- 28. Provide all test data regarding flammability of the substitute, including the procedures used for determining flammability and any other information on flammability concerns. If a substitute is flammable under the conditions expected in the proposed end-use, describe any abatement techniques being used to minimize the risks associated with use of a flammable substance (e.g., equipment design modifications or alternate labeling). EPA recognizes that many flammable alternatives may be promising.

If an alternative is flammable (this applies to both blends and pure materials), you must analyze the risk of fire resulting from the use of the substitute in each proposed end-use. This assessment should include, but not be limited to, a description of typical scenarios in which the substitute is used, potential leak scenarios, sources of ignition, and probabilities of ignition. It should also assess the likelihood of injury within each scenario. Significant differences exist both in the design and in the ambient conditions for various end-uses. Thus, risk assessments are extremely sensitive to end-use. Low risk in one end-use does not, in general, imply low risk in another end-use.

Sector-Specific Data Requirements

Refrigerant alternatives: Information on the flammability of a blend as well as its individual constituents must be provided. Flammability testing should include the lower flammability limit (LFL) and upper flammability limit (UFL) for the blend as well as its constituents. Testing of all blends should identify the compositions for which the blend itself is flammable. Blends that contain flammable components should be tested during leaks in system components containing two phases to identify limits of fractionation. Worst-case of formulation for flammability (WCF) and worst-case of fractionation for flammability (WCFF) compositions must be reported and analyzed under normal operation. For flammable substitutes, also submit documentation of testing safety results conducted by independent laboratories. Include both evaporator and condenser temperature and pressure conditions. Provide a flammability risk assessment and a fault-tree analysis that analyzes the probability of failures that might lead to a fire or explosion. You can find samples of fault tree analyses for motor vehicle air conditioning and for household refrigerators and freezers. See Appendix B for suggested tests and examples of potential scenarios to be examined in a risk assessment.

Foam blowing agents. If you are submitting for a flammable substitute for use in spray foams, provide a training program to address flammability risks.

Sterilants: If the substitute is a blend with ethylene oxide (EtO), include information on the critical flammability ratios.

Aerosols: If the product contains an immiscible component, address the potential flammability of the product that could be expelled if the entire mixture is not shaken immediately before each use.

Part II, Section B - Atmospheric Information (Page 7)

1. Provide information on the predicted 100-year ozone depletion potential (ODP) of the alternative relative to CFC-11, if known. If the substitute is a blend, provide the ODPs of the individual constituents. You should also provide supporting documentation indicating how and by whom this value was calculated. This information may be provided as a citation from the published literature or by providing the background information used to develop the ODP.

For purposes of calculating ODP, EPA recommends the methodology used in the <u>Scientific Assessment of Ozone Depletion</u> prepared for the United Nations Environment Programme (UNEP) by the World Meteorological Organization (WMO). The ODP refers to the amount of ozone destroyed by a gas over its entire atmospheric lifetime (e.g. at a steady state) relative to that due to emissions of the same mass of CFC-11. It is defined in modeling calculations as follows:

$$ODP_x = \frac{Global \, \Delta \, O_3 \, caused \, by \, x}{Global \, \Delta \, O_3 \, caused \, by \, CFC - 11}$$

Calculations should reflect ground level emissions. For aircraft applications, be sure to also consider emissions at the appropriate altitude.

You should also include any other related data available to you, such as information on the substitute's atmospheric lifetime and chlorine or bromine loading potential. See the <u>2010 WMO Scientific</u>

Assessment of Ozone Depletion for additional information on calculating ODPs and related information.

2. Provide information on the 100-year global warming potentials (GWPs) of a substitute relative to CO₂, as well as atmospheric lifetime of a substitute. If they are available, you may also provide the 20- and 500-year GWPs, and the GWP relative to CFC-11, known as the halocarbon GWP (HGWP). If the substitute is a blend, provide the GWPs of the individual constituents and an estimate of the blend at its nominal composition.

Provide GWPs as listed in the most recent <u>assessment reports from the Intergovernmental Panel for Climate Change</u> (IPCC AR4). Alternate sources may include the <u>2010 WMO Scientific Assessment of Ozone Depletion</u> or the peer-reviewed literature. IPCC defines GWP of the emissions of a greenhouse gas as the time integrated commitment to climate forcing from the instantaneous release of 1kg of a trace gas expresses relative to that from 1 kg of CO₂.

$$GWP = \frac{\int_{0}^{n} a_{i} c_{i} dt}{\int_{0}^{n} a_{CO_{2}} c_{CO_{2}} dt}$$

where

a_i = the instantaneous radiative forcing due to a unit increase in the concentration of trace gas, i

c_i = the concentration of trace gas, i, remaining at time, t, after its release, and

n = the number of years over which the calculation is performed.

Corresponding values for CO₂ are in the denominator.

Provide GWPs using a 100-year time integration; GWPs using other time horizons may also be provided. For GWP values that do not come from AR4 or WMO 2010, you should also include the data used to calculate these potentials such as atmospheric lifetime, infrared adsorption spectrum, and infrared absorption capacity. Reference the source of this information.

To the extent that data is available, EPA considers total global warming impacts (both direct and indirect effects) of a substitute for each end use. GWPs provide a measure of direct effects, i.e., they refer to the direct contribution to global warming from use of the substitute due to its radiative forcing. Indirect effects are contributions to global warming resulting from changes in energy consumption and corresponding changes in emissions of CO₂ and other trace gases. If known, provide information on the energy efficiency of the substitute relative to that of the substance being replaced and results of any testing or modeling done on the substitute. See Appendix B for a list of applicable tests. Data on energy efficiency is particularly of interest for alternative refrigerants and foam blowing agents.

If the alternative is captured as a byproduct of another manufacturing or industrial process, indicate the source of the alternative. This information is important in assessing the effects of the new use of the substitute versus those effects occurring strictly because of the release of a byproduct.

Part II, Section C - Other Statutes (Page 8)

Please provide all information that is reasonably available regarding regulation of a substitute under other regulatory authorities. The Agency will evaluate substitutes under the SNAP program subject to existing regulatory constraints. This information allows EPA to coordinate regulatory efforts within EPA and among other authorities.

- 1. Environmental Statutes Provide information on whether the manufacture, use, or disposal of a substitute is regulated under any other environmental statutes such as:
 - \$ Titles of the Clean Air Act (CAA) other than Title VI
 - \$ the Clean Water Act (CWA)
 - \$ the Safe Drinking Water Act
 - \$ the Resource Conservation and Recovery Act (RCRA)
 - \$ the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - \$ the Toxic Substances Control Act (TSCA)
 - \$ the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)
 - \$ the Emergency Planning and Community Right-to Know Act (EPCRA or SARA Title III)
 - \$ state and local laws

List any concentration-based or other numerical standards to which the substitute is subject under the above statutes or regulations.

For example, many alternative solvents are considered to be volatile organic compounds (VOCs) and are subject to emission restrictions under Title III of the CAA. If you know your alternative is either regulated or exempt as a VOC or Hazardous Air Pollutant (HAP), please indicate this.

- 2. Other Statutes Indicate whether occupational, consumer, or general population exposure to the substitute is regulated under other statutory authorities concerned with health and safety issues, such as those implemented by:
 - \$ the Food and Drug Administration (FDA)
 - \$ the Occupational Safety and Health Administration (OSHA)
 - \$ the Department of Transportation (DOT)
 - \$ and state and local laws.

Also include information on any other standard-setting bodies who will be evaluating the substitute, such as the National Fire Protection Association (NFPA), Underwriters Laboratories (UL), or the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE). List any concentration-based or other numerical standards (e.g., permissible exposure limit (PEL), short-term exposure limit (STEL), ASHRAE safety classification) to which the substitute is subject under these statutes or organizations.

Part II, Section D - Cost and Availability of the Alternative (Page 9)

- 1. Estimate the cost per pound (\$/lb) of the chemical substitute or, where appropriate, indicate the cost per unit volume or per packaging unit (e.g., aerosol spray can). If the cost is not per pound of material, specify the units. For alternative processes and technologies, describe the equipment costs and other costs such as those associated with installing the new substitute. Costs may be either commercial or consumer, as long as you provide information on the basis for your cost estimate.
- 2. Provide information on the levels of production and market penetration that you expect for the substitute. Include values for total production in lbs/yr both at the start of production and in the future (e.g., 3 years from now), the number of years you anticipate until the substitute reaches its maximum market penetration, and the total production level that you anticipate for the substitute when it reaches the point of market saturation. Finally, if possible, estimate the percentage of the market held by the ODS being replaced that will be captured by this substitute. If the substitute is not currently available, indicate when you anticipate it will enter the marketplace.

If you are submitting the substitute for several end-uses, you must provide this information for each end-use.

3. Describe any new equipment and how the substitute or alternative technology is used. If retrofitting of existing equipment is possible, detail changes in technologies needed to use the substitute. Also provide information on materials compatibility and attach any available test results. Provide specific information on each different end-use, including cost of equipment, equipment lifetime, changes in labor, and changes in energy costs. For example, if the substitute is an alternative refrigerant that may be used both as a retrofit in existing equipment or used in new equipment for chillers, information on the equipment changes should be provided for both retrofit and new equipment scenarios. This cost information may be provided as a range where equipment may be optimized to different levels of energy efficiency.

All claims that an agent is a "drop-in" for the ODS it is replacing must be substantiated, and qualified by a description of any necessary technical changes to existing equipment.

PART III - RELEASE AND EXPOSURE DATA

The following sections describe the types of human health and safety and environmental exposure data used to evaluate substitutes under the SNAP program. For existing chemicals, specific data requirements may depend on what types of data are already available. Attach all complete test reports that are reasonably available to you. Also indicate all concentration-based exposure limits that have been set for the substitute, such as PELs, occupational exposure limits (OELs), or acceptable exposure limits (AELs) set by the manufacturer. You may submit references to studies that have already been submitted to the SNAP program. If you have done a literature search on the alternative or its constituents, please include it as well.

Decisions on data requirements will be determined by the exposure patterns of the sector(s) in which the substitute is to be used. For example, substitutes used only in settings which would generally preclude all but acute exposures (such as in fire extinguishing) may not require chronic toxicity data. For other sectors, such as solvent cleaning, where aqueous cleaners are used, additional tests related to impacts on aquatic life may be necessary depending on the means of discharge and disposal of the substitute.

If the substitute is a blend containing constituents not previously reviewed under SNAP for any end-use, additional data other than those specified below may be required.

Part III, Section A - Toxicity and Hazard Information (Page 10)

1. For chemical alternatives and for chemicals used with alternative processes, summarize information on the acute and chronic toxicity of the substitute and/or of its constituent chemicals on any organism (e.g. humans, other mammals, fish, wildlife, plants, etc.). 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. In addition to those data mentioned specifically below, attach **all** supporting information such as test reports, if available. In addition, attach a copy of any hazard warning statement, label, material safety data sheet (MSDS) or other information that will be provided to any person who is reasonably likely to be exposed. Include any data on toxicity of impurities and degradation products if known.

Sector-Specific Data Requirements

Refrigerants: A cardiosensitization study, usually measuring cardiotoxic effects in the dog, may be required. This requirement also applies to blends of chemicals which have already been tested individually. Blends can exhibit unpredictable cardiotoxicity levels, and testing is necessary.

Foams: A study on the degradation products of the foam under different external conditions, including the catalyst used during manufacture and the temperature during use is required. EPA's assessment of potential hazards for insulation foam suggests that breakdown/degradation products of foam during use may be significant, and thus information on such processes is required.

Solvents: To characterize aquatic toxicity, both acute and chronic toxicity data for a variety of species may be required. The Agency requires a minimum aquatic data set to be submitted 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). If other regulatory limits such as effluent guidelines exist, these values may be used in lieu of compiling toxicity data.

Fire Suppression: See the document "A Guide to Completing a Risk Screen: Collection and Use of Risk Screen Data – Fire Suppression Sector." A cardiosensitization study, usually measuring cardiotoxic effects in the dog, may be required. For specialized halon use, such as in airline cabins, information on central nervous system (CNS) depression may also be required. An exposure assessment, such as personal monitoring testing, for evaluation of alternative streaming agents may also be required.

For powdered aerosol fire suppressants, provide results of testing for ocular and dermal irritation.

Aerosols: A cardiotoxicity study, usually measuring cardiotoxic effects in the dog, may be required. Information on central nervous system (CNS) depression may also be required.

Adhesives, Coatings, & Inks: Depending on the end-use, data requirements for this sector may be similar to the solvents sector. Submit all relevant information, to the best of your knowledge.

Sterilants: Provide copies of the toxicity testing provided for review under FIFRA. As stated above, attach copies of hazard warning statements, labels, and MSDSs that will be provided to any person likely to be exposed.

Part III, Section B - Environmental Release and Disposal at Manufacture (Page 10)

Identify by name and address all manufacturing site(s) (within the U.S. and worldwide) of each chemical or alternative technology. Also identify all site locations for manufacturing of products containing the substitute (e.g. refrigerators containing substitutes). If you are unable to identify all manufacturing sites, provide data on a typical facility. Identify all points of release and/or exposure during manufacture of the substitute and any products containing the substitute and the magnitude of the release. Also indicate the environmental media to which it is released (e.g., indoor air, outdoor air, water, land).

Part III, Section C - Occupational Exposure at Manufacture (Page 11)

Provide information on occupational exposure during manufacture of the substitute or alternative technology. This entry should include information on exposure during manufacture of the substitute itself and/or manufacture of products containing the substitute, where appropriate (e.g., refrigerators containing the

alternative). Describe all activities in which workers may be exposed to the substitute, estimate the levels of exposure, and describe any protective measures taken to limit exposure. If possible, include the approximate dimensions or range of estimates for the size of a room in which the systems will be manufactured.

Part III, Section D - Environmental Release and Disposal in End-use (Page 11)

Provide information in this section as it applies to the sector(s) in which the alternative will be used. For example, information applicable to wastewater treatment should be included for solvent cleaning alternatives but is not relevant to refrigeration substitutes. For each substitute, provide information on any releases or discharges of the chemical to the environment at the point of, or subsequent to, the end-use, including quantities (in kg/day) and the environmental media to which it is released (e.g. air, water, land).

Describe any control technologies used to limit emissions and indicate the method and location of disposal and/or treatment of the substitute. For example, explain if disposal will be performed on site, by a contractor, by a vendor, or by other means. If the substitute is to be recycled, describe any necessary equipment and programs that may be set up to encourage recycling.

Identify the recovery technology that will be used to recapture the substitute for disposal in specific end use sectors. Is current technology available to recover the substitute? If yes, please describe the technology by providing specifications or the specific industry standard. However, if current recovery technology is not available please describe how the substitute will be recovered again by providing new equipment specifications, new industry standards or the new method.

Part III, Section E - Occupational Exposure at End-use (Page 12)

Provide information on occupational exposure during end-use (e.g., during use of an alternative solvent in an open-tank cleaning system). Describe all activities in which workers may be exposed to the substitute, including details on the average and maximum number of workers, duration of activity, contact pathway, and physical form of the substitute. Estimate the average and high-end levels of exposure, including units of measure. Also describe any protective measures taken to limit exposure. If available, provide the rate of airflow in the area in which occupational exposure could occur.

Sector-Specific Information

Fire Suppression: Personal monitoring may be required for streaming agents, depending on the amount of agent required for fire suppression and the cardiotoxic level of the agent. For total flooding agents, indicate the extinguishing concentration using either a cup burner in heptane or full scale testing, and the design concentration of the substitute as defined by the National Fire Protection Association (NFPA) (cup burner plus 20 per cent). Indicate actual design concentration if it is likely to be higher, based on manufacturer recommendations.

Solvents, aerosols, and adhesives, coatings and inks. If available, provide personal monitoring data from end use. If personal monitoring data are not available, provide estimates using surrogates with similar properties for the same end use.

Part III, Section F - Consumer Exposure (Page 12)

Provide information in this section as it applies to the sector(s) and end-use(s) in which the substitute will be used. If the alternative is intended for industrial use only (e.g., a refrigerant for cold storage warehouses) you need not provide information in this section. We expect information on consumer exposure for household refrigerators and freezers; residential air conditioning; motor vehicle air conditioning; dehumidifiers; water coolers; aerosol propellants; and rigid cell foams used in residential construction or insulation.

Part III, Section G - General Population Exposure - OPTIONAL (Page 13)

You do not need to provide the information requested in the General Population Exposure section unless you choose to do so. "General Population Exposure" refers to exposure to the general population located near an industrial facility manufacturing or using the substitute.

Part IV - LIST OF ATTACHMENTS (Page 14)

Attach any continuation sheets for sections of the form, test data, and other data that may assist EPA review of an alternative after the last page of the form. Clearly identify the attachment and the section to which it relates on page 14, where appropriate. Number consecutively the pages of each attachment and enter the inclusive page numbers on page 14. Enter the total number of pages in the notice, including attachments, on page 1 of the form.

Mark (X) in the CBI box next to any attachment name that you claim as confidential. See Chapter 3 of this manual for information on how to claim any information in an attachment as confidential.

Part V - CERTIFICATION (Page 15)

The official named in Part I, Section A of the form as the person submitting the notice must sign the certification on page 15 of the notice form. This official is responsible for the truth and accuracy of each statement in the certification. If an agent assists you in preparing the notice, the agent must also sign the certification. All signatures must be original. If the submission is not signed, EPA will consider the submission incomplete and will not review the substitute.

6. JOINT REVIEW WITH OTHER EPA OFFICES

A. What is the relationship between the SNAP Program and the New Chemicals (Pre-Manufacture Notice) Program?

New chemical substitutes must undergo review both under section 612 of the Clean Air Act (the SNAP program) and section 5 of TSCA (the New Chemicals or Premanufacture Notice program). EPA has established a joint review process between the SNAP and TSCA Premanufacture Notice (PMN) programs. This process has been structured to minimize reporting burden and to ensure consistency in decisions between the two programs.

B. What forms should I submit to the SNAP program and to the New Chemicals program?

A submitter requesting review under both the SNAP and New Chemicals programs should:

- \$ Complete the PMN form (EPA Form 7710-25) following the <u>Instructions Manual</u>.
- Indicate on page 11 of the PMN form, "Optional Pollution Prevention Information," that the chemical is also to be considered under the SNAP program.
- \$ Complete a SNAP TSCA addendum form, available at http://www.epa.gov/ozone/snap/submit/index.html.

The completed PMN form and the SNAP addendum together will comprise the data submission for review and listing decisions for the SNAP program for new chemicals to be used as ODS substitutes.

Any questions regarding the completion of these forms can be directed to either the PMN pre-notice coordinator or the SNAP DCO.

C. When should I submit to the SNAP program if I am also submitting a PMN?

EPA encourages you to submit to both programs at the same time. Contacting both programs early in your preparation of your submission form and documents will help clarify procedures, ensure coordination of reviews by the two programs, and generally result in a more expeditious review of the information.

D. Do both the SNAP program and the New Chemicals program have a 90 day review?

Both the PMN and SNAP programs have a review period of 90 days. For the SNAP program, the 90-day period begins upon the date when EPA receives all information needed for review and determines your submission is complete. For the New Chemicals program, the 90-day review period is subject to suspensions and extensions described in the PMN rule (40 CFR 720.75).

E. How does EPA treat confidentiality during co-review of a chemical under the SNAP program and under the New Chemicals program?

EPA will treat all information claimed as confidential business information (CBI) submitted as part of the joint PMN/SNAP review consistent with TSCA security procedures. Confidentiality claims will be processed and reviewed in a manner consistent with 40 CFR Part 2, Subpart B.

When you send your TSCA/SNAP Addendum, please include in your cover letter a statement that you are submitting information as "Clean Air Act CBI." This will allow EPA's SNAP program to share this information with our contractors (authorized representatives) to assist in our evaluation. There is no substantive difference in how CBI is maintained under the Clean Air Act and under TSCA, but there are different offices verifying that security requirements are met.

F. What is the relationship between the SNAP Program and review of antimicrobials under FIFRA?

Any new pesticide or amendment of an existing formulation, including antimicrobials, is already subject to Agency approval under provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), P.L. 100-460, 100-464 to 100-526, and 100-532. Medical sterilants that substitute for blends of ethylene oxide and CFC-12 or HCFCs are reviewed both as substitutes for ODS under SNAP and as antimicrobials under FIFRA. FIFRA reviews will address factors commonly examined during pesticide amendments and registrations. The SNAP Program will also consider atmospheric impacts such as ozone depletion potential, global warming potential, and impacts on air quality. The two program offices responsible for these reviews will coordinate their efforts and share pertinent data to ensure appropriate technical consideration of the substitute.

G. What form do I submit to SNAP for a sterilant?

You should submit the FIFRA form for pesticide registration to EPA's Office of Pesticide Programs, and submit a copy of the SNAP Information Notice form to the SNAP DCO.

If you are submitting an amendment to a product registration under FIFRA that currently contains a class I or II ozone-depleting substance, you should note in Section II ("Amendment Information") of the FIFRA form that the amendment was filed in response to the CAA production phase-out. Similarly, if you are submitting an application for a new pesticide registration that would otherwise have been based on a class I or II compound, you should note in Section II of the FIFRA form that the registration includes a class I or II ozone-depleting substitute. You should also identify both the substitute chemical and the class I or II compound it is replacing. Further, if you are aware that a particular chemical intended for use as a substitute for an ozone-depleting substance in a pesticide formulation has already been approved through earlier SNAP/FIFRA determinations, you should also reference the relevant part of the prior review.

7. CONSULTATION WITH EPA CONCERNING THE SNAP INFORMATION NOTICE

A. Where do I get more information about submitting to the SNAP program?

Copies of the SNAP rule, listing decisions, this Instruction manual, the SNAP Information Notice form, the TSCA/SNAP Addendum and other materials relating to the rule are available online on EPA's SNAP web page (http://www.epa.gov/ozone/snap/index.html). You may contact the Stratospheric Protection Division of EPA in Washington, DC at (202) 343-9410. Written inquiries may be sent to:

SNAP Coordinator U.S. EPA Mail Code 6205J 1200 Pennsylvania Ave. NW Washington, DC 20460

B. How will EPA interact with me after I submit to the SNAP program?

EPA's 90-day notice review period begins when your notice is determined to be complete by the SNAP Document Control Officer (DCO). You will receive written notification if EPA determines that your notice is "incomplete" as described in '82.180. If your notice is complete, you will receive an acknowledgment letter confirming the date EPA received your notification and the date EPA's 90-day review period begins. If your alternative has already been listed under the SNAP program for the proposed end-use, you will be notified that your substitute is not subject to further SNAP review, and therefore you are free to begin sale immediately.

Following expiration of EPA's 90-day review period, you are free to sell, import, export, and use your substitute, provided that EPA has not already listed the alternative as unacceptable through notice-and-comment rulemaking.

Review of petitions will occur by the same process and schedule as submissions from manufacturers of new substitutes.

C. How do I contact EPA's SNAP program?

Stratospheric Ozone Information Hotline	(800) 296-1996
Stratospheric Protection Division	(202) 343-9410

APPENDIX A: LIST OF END-USES WITHIN SECTORS INCLUDED IN THE SNAP PROGRAM

Listings under the SNAP program are provided for specific end-uses that previously used ozone-depleting substances, including the end-uses listed below. A listing in an end-use does not imply EPA has reviewed the substitute for another end-use. Please specify **all** end-uses for which you would like to have your substitute evaluated. If the product or process for which the substitute is intended does not fit into one of the following end-uses, please provide a description of the product or process with adequate detail to assess the potential risks to human health and the environment presented by using the substitute therein.

Refrigeration and Air Conditioning

Note: All end-uses within this sector are further broken down into "Retrofit" and "New Equipment" subcategories

- \$ Commercial Comfort Air Conditioning (Centrifugal, Reciprocating, and Screw Chillers);
- \$ Industrial Process Refrigeration Systems;
- \$ Industrial Process Air Conditioning;
- \$ Ice Skating Rinks:
- \$ Uranium Isotope Separation Processing;
- \$ Cold Storage Warehouses;
- \$ Refrigerated Transport;
- \$ Retail Food Refrigeration;
- \$ Vending Machines;
- \$ Water Coolers;
- \$ Commercial Ice Machines;
- \$ Household Refrigerators and Freezers:
- \$ Residential and Light Commercial Air Conditioning and Heat Pumps;
- \$ Residential Dehumidifiers;
- \$ Motor Vehicle Air Conditioning;
- \$ Motor Vehicle Air Conditioning for Buses and Passenger Rail
- \$ Non-mechanical Heat Transfer;
- **S Very Low Temperature Refrigeration**

ODS replaced may include CFC-12, CFC-113, CFC-114, CFC-115, HCFC-22, blends of HCFC-22 or HCFC-142b, R-500, and R-502.

Foam Blowing

- \$ Polyurethane and Polyisocyanurate, Rigid Laminated Boardstock
- \$ Polyurethane, Rigid Appliance
- \$ Polyurethane, Rigid Spray, Commercial Refrigeration Foams, Spray Foams and Sandwich Panel Foams
- \$ Polyurethane, Rigid Slabstock and Other
- \$ Polystyrene, Extruded Boardstock and Billet
- \$ Phenolic, Insulation Board
- \$ Polyurethane, Flexible
- \$ Polyurethane, Integral Skin
- \$ Polystyrene, Extruded Sheet
- \$ Polyolefin

ODS replaced may include CFC-11, CFC-12, CFC-113, CFC-114, HCFC-141b, HCFC-142b, and HCFC-22.

Solvent Cleaning

- \$ Metals Cleaning
- \$ Electronics Cleaning
- \$ Precision Cleaning

ODS replaced may include methyl chloroform, CFC-113, and HCFC-225ca/cb.

Note that solvent cleaning applies to use in industrial cleaning equipment such as vapor degreasers or automated, conveyorized equipment. SNAP does not currently cover dry cleaning, manual cleaning with non-aerosol solvents, non-aerosol mold release agents, or component testing agents.

Fire Suppression and Explosion Protection

- \$ Streaming Agents
- \$ Total Flooding Agents

ODS replaced may include halon 1211, halon 1301, and HCFC blends.

<u>Aerosols</u>

- \$ Propellants
- \$ Solvents

ODS replaced may include CFC-11, HCFC-22, HCFC-142b, CFC-113, methyl chloroform, HCFC-141b, and HCFC-225ca/cb.

Sterilants

\$ Medical sterilants

These replace the 12/88 Blend of EtO/CFC-12 or blends of ethylene oxide and HCFC-22 or HCFC-124.

Tobacco Expansion

\$ Tobacco Expansion Agents

ODS replaced may include CFC-11.

Adhesives, Coatings, and Inks

- \$ Adhesives
- \$ Coatings
- \$ Inks

ODS replaced may include methyl chloroform or HCFC-141b.

APPENDIX B: SECTOR-SPECIFIC DATA REQUIREMENTS

The following lists give guidance about what particular characteristics are of interest within each sector, in addition to Ozone Depletion Potential and Global Warming Potential.

Refrigeration and Air Conditioning

Physical and Chemical Properties

- \$ Molecular weight
- \$ Physical state at room temperature
- \$ Boiling point
- \$ Vapor pressure (provide curve across a range of temperatures)
- \$ Critical temperature
- \$ Critical pressure
- \$ Flash point
- \$ Flammability limits (LFL, UFL)
- \$ Heat of combustion
- \$ Maximum pressure of combustion
- \$ Maximum rate of pressure increase during combustion

Suggested test data

- \$ ASTM E681 for flammability limits in air
- \$ Fractionation during leakage

Energy Efficiency

- \$ Laboratory testing of equipment using the alternative refrigerant vs. the ODS being replaced. Values should be given in kWh/day or a similar measure. Also address refrigerant/oil solubility.
- \$ Computer models should account for compressor efficiency, refrigerant transport properties and mass flow rates for given tubing geometry, capillary tube/suction line heat transfer, and liquid and vapor specific heats.

Toxicity

\$ Cardiotoxicity

Foam Blowing

Physical and Chemical Properties

- \$ Thermal Conductivity
- \$ Flash Point

Energy Efficiency

Toxicity

\$ Degradation Products

Solvents

Physical and Chemical Properties

- \$ Boiling Point
- \$ Specific Gravity
- \$ Odor Threshold
- \$ Solubility
- \$ Vapor Pressure
- \$ Dissociation constant
- \$ Volatilization from soil and water
- \$ **pH**
- \$ Flash Point
- \$ Flammability limits

Toxicity

- \$ List any PELs, STEL, AELs, etc.
- \$ Aquatic toxicity testing may be required

Fire Suppression Agents

Physical and Chemical Properties

- \$ Molecular weight
- \$ Boiling point
- \$ Specific gravity
- \$ Vapor pressure
- \$ Particle size distribution (applies to non-gaseous agents)
- \$ Vapor heat capacity
- \$ Heat of vaporization
- \$ Viscosity
- \$ Weight Equivalence
- \$ Storage Volume Equivalence
- \$ Extinguishment Concentration (specify method)
- \$ Design Concentration

Toxicity

- \$ Cardiotoxicity
- \$ Personal Monitoring (streaming agents)
- \$ Ocular and Dermal Irritation (powdered aerosols)

Formula for determining Weight and Volume Equivalence:

NOTE: Weight and volume equivalents are calculated using a single, fuel-specific design concentration (heptane); therefore, they do not represent the exact weight or volume of the agent needed to protect any specific space against any specific hazard. The information used to calculate the equivalents is provided from agent manufacturers and NFPA 2001, "Standard on Clean Agent Fire Extinguishing Systems." Equivalents are included in SNAP rulemakings for general comparison and informational purposes only.

EPA understands that fire suppression agents must be evaluated in the context of the fire extinguishing system equipment with which they are used. Design concentration, and weight and volume equivalents are only meaningful when evaluated in specific system hardware configurations. This is especially important when comparing storage volume where storage container fill density varies with the equipment used. Agent fire suppression performance will vary with the system used and the detailed design of the system. Therefore, fire suppression agent manufacturers do not generally recommend design concentrations as these are also a function of the system hardware in which they are used. Hence, these data are provided for general guidance only and do not reflect a recommendation for system design or a basis for rigorous quantitative comparison.

- (1) Weight and volume equivalent data should be presented relative to Halon 1301 at 120 per cent of cup burner as well as at 5 per cent, a typical use concentration;
- (2) weight and volume equivalents should be based on agent concentrations at Standard Temperature and Pressure;
- (3) weight and volume equivalents should be done at both the manufacturer's recommended design concentration and at 120 per cent of the cup burner value where the values are not the same;
- (4) volume equivalents will be based on agent volume only (exclusive of container volume, fill density, etc.) at 70 degrees Fahrenheit and the storage pressure specified by the manufacturer since this varies widely and the required agent mass determined in item (5) below; and

(5) the required agent weight equivalents should be determined by the following equation:

W = V/S(C/100-C)

where C = design concentration (% volume)

V = one cubic foot

S = agent specific vapor volume at 70 degrees F (ft³/lb).

(6) Appropriate references to the technical literature on which the data are based should be provided.

<u>Aerosols</u>

Physical and Chemical Properties

- \$ Molecular weight
- \$ Boiling point
- \$ Odor threshold
- \$ Solubility
- \$ Vapor pressure
- \$ Flash point
- \$ Flammability limits
- \$ Explosive range
- \$ Viscosity

Toxicity

\$ Cardiotoxicity

Adhesives, Coatings, and Inks

Physical and Chemical Properties

- \$ Molecular weight
- \$ Physical state
- \$ Melting point
- \$ Boiling point
- \$ Specific gravity
- \$ Odor threshold
- \$ Solubility
- \$ Volatilization from water and soil
- \$ pH
- \$ Flash point
- \$ Flammability limits
- \$ Explosive range

Toxicity

Data requirements are similar to those for solvents. Submit all relevant data.

<u>Sterilants</u>

Physical and Chemical Properties

- \$ Molecular weight
- \$ Physical state
- \$ Vapor pressure
- \$ Specific gravity
- \$ Flash point
- \$ Flammability limits
- \$ Explosive range

Provide copies of toxicity testing provided for review under FIFRA and/or FDA reviews

Pesticides - Review under FIFRA will cover most data analysis

Physical and Chemical Properties

\$ Provide what data are readily available

Ozone Depletion Potential

\$ Provide if information is available

Global Warming Potential

\$ Provide if information is available

Cost and Use Information