

of this program are to identify substitutes for ozone-depleting compounds, to evaluate the acceptability of those substitutes, to promote the use of those substitutes believed to present lower overall risks to human health and the environment, relative to the class I and class II compounds being replaced, as well as to other substitutes for the same end-use, and to prohibit the use of those substitutes found, based on the same comparisons, to increase overall risks.

(b) The regulations in this subpart describe persons and substitutes subject to reporting requirements under the SNAP program and explain preparation and submission of notices and petitions on substitutes. The regulations also establish Agency procedures for reviewing and processing EPA's determinations regarding notices and petitions on substitutes. Finally, the regulations prohibit the use of alternatives which EPA has determined may have adverse effects on human health or the environment where EPA has identified alternatives in particular industrial use sectors that on an overall basis, reduce risk to human health and the environment and are currently or potentially available. EPA will only prohibit substitutes where it has identified other substitutes for a specific application that are acceptable and are currently or potentially available.

(c) Notifications, petitions and other materials requested shall be sent to: SNAP Document Control Officer, U.S. Environmental Protection Agency (6205-J), 1200 Pennsylvania Ave., NW., Washington, DC 20460.

#### § 82.172 Definitions.

*Act* means the Clean Air Act, as amended, 42 U.S.C. 7401 *et seq.*

*Agency* means the U.S. Environmental Protection Agency.

*Application* means a specific use within a major industrial sector end-use.

*Class I or class II* means the specific ozone-depleting compounds described in section 602 of the Act.

*Decision* means any final determination made by the Agency under section 612 of the Act on the acceptability or unacceptability of a substitute for a class I or II compound.

*EPA* means the U.S. Environmental Protection Agency.

*End-use* means processes or classes of specific applications within major industrial sectors where a substitute is used to replace an ozone-depleting substance.

*Formulator* means any person engaged in the preparation or formulation of a substitute, after chemical manufacture of the substitute or its components, for distribution or use in commerce.

*Health and safety study* or *study* means any study of any effect of a substitute or its components on health and safety, or the environment or both, including underlying data and epidemiological studies, studies of occupational, ambient, and consumer exposure to a substitute, toxicological, clinical, and ecological, or other studies of a substitute and its components, and any other pertinent test. Chemical identity is always part of a health and safety study. Information which arises as a result of a formal, disciplined study is included in the definition. Also included is information relating to the effects of a substitute or its components on health or the environment. Any available data that bear on the effects of a substitute or its components on health or the environment would be included. Examples include:

(1) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatotoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses;

(2) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies;

(3) Assessments of human and environmental exposure, including workplace exposure, and effects of a particular substitute on the environment, including surveys, tests, and studies of:

Biological, photochemical, and chemical degradation; air, water and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., atmospheric lifetime, boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility;

(4) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a substitute; and

(5) Any assessments of risk to health or the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the substitute or its components.

*Importer* means any person who imports a chemical substitute into the United States. *Importer* includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:

- (1) The consignee;
- (2) The importer of record;
- (3) The actual owner; and
- (4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred.

*Major Industrial Use Sector or Sector* means an industrial category which EPA has reviewed under the SNAP program with historically high consumption patterns of ozone-depleting substances, including: Refrigeration and air conditioning; foam-blowing; fire suppression and explosion protection; solvents cleaning; aerosols; sterilants; tobacco expansion; pesticides; and adhesives, coatings and inks sectors.

*Manufacturer* means any person engaged in the direct manufacture of a substitute.

*Mixture* means any mixture or blend of two or more compounds.

*Person* includes an individual, corporation, partnership, association, state, municipality, political subdivision of a state, and any agency, department, or instrumentality of the United States and any officer, agent, or employee of such entities.

*Pesticide* has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the regulations issued under it.

*Potentially available* is defined as any alternative for which adequate health, safety, and environmental data, as required for the SNAP notification process, exist to make a determination of acceptability, and which the Agency reasonably believes to be technically feasible, even if not all testing has yet been completed and the alternative is not yet produced or sold.

*Premanufacture Notice (PMN) Program* has the meaning described in 40 CFR part 720, subpart A promulgated under the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

*Producer* means any person who manufactures, formulates or otherwise creates a substitute in its final form for distribution or use in interstate commerce.

*Research and development* means quantities of a substitute manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development.

*Residential use* means use by a private individual of a chemical substance or any product containing the chemical substance in or around a permanent or temporary household, during recreation, or for any personal use or enjoyment. Use within a household for commercial or medical applications is not included in this definition, nor is use in automobiles, watercraft, or aircraft.

*Significant new use* means use of a new or existing substitute in a major industrial use sector as a result of the phaseout of ozone-depleting compounds.

*Small uses* means any use of a substitute in a sector other than a major industrial use sector, or production by any producer for use of a substitute in a major industrial sector of 10,000 lbs. or less per year.

*Substitute or alternative* means any chemical, product substitute, or alternative manufacturing process, whether existing or new, intended for use as a replacement for a class I or II compound.

*Test marketing* means the distribution in interstate commerce of a substitute to no more than a limited, defined number of potential customers to explore market viability in a competitive situation. Testing must be restricted

to a defined testing period before the broader distribution of that substitute in interstate commerce.

*Use* means any use of a substitute for a Class I or Class II ozone-depleting compound, including but not limited to use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses.

*Use restrictions* means restrictions on the use of a substitute imposing either conditions on how the substitute can be used across a sector end-use or limits on the end-uses or specific applications where it can be used within a sector.

#### § 82.174 Prohibitions.

(a) No person may introduce a new substitute into interstate commerce before the expiration of 90 days after a notice is initially submitted to EPA under § 82.176(a).

(b) No person may use a substitute which a person knows or has reason to know was manufactured, processed or imported in violation of the regulations in this subpart, or knows or has reason to know was manufactured, processed or imported in violation of any use restriction in the acceptability determination, after the effective date of any rulemaking imposing such restrictions.

(c) No person may use a substitute without adhering to any use restrictions set by the acceptability decision, after the effective date of any rulemaking imposing such restrictions.

(d) No person may use a substitute after the effective date of any rulemaking adding such substitute to the list of unacceptable substitutes.

(e) *Rules Stayed for Reconsideration.* Notwithstanding any other provision of this subpart, the effectiveness of subpart G is stayed from December 8, 1994, to March 8, 1995, only as applied to use of substitutes for export.

[59 FR 13147, Mar. 18, 1994, as amended at 59 FR 63256, Dec. 8, 1994; 60 FR 3303, Jan. 13, 1995]

#### § 82.176 Applicability.

(a) Any producer of a new substitute must submit a notice of intent to introduce a substitute into interstate

commerce 90 days prior to such introduction. Any producer of an existing substitute already in interstate commerce must submit a notice as of July 18, 1994, if such substitute has not already been reviewed and approved by the Agency.

(b) With respect to the following substitutes, producers are exempt from notification requirements:

(1) *Substitutes already listed as acceptable.* Producers need not submit notices on substitutes that are already listed as acceptable under SNAP.

(2) *Small sectors.* Persons using substitutes in sectors other than the nine principal sectors reviewed under this program are exempt from the notification requirements. This exemption shall not be construed to nullify an unacceptability determination or to allow use of an otherwise unacceptable substitute.

(3) *Small volume use within SNAP sectors.* Within the nine principal SNAP sectors, persons introducing a substitute whose expected volume of use amounts to less than 10,000 lbs. per year within a SNAP sector are exempt from notification requirements. This exemption shall not be construed to allow use of an otherwise unacceptable substitute in any quantity. 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 annual production and sales information by sector.

(4) *Research and development.* Production of substitutes for the sole purpose of research and development is exempt from reporting requirements.

(5) *Test marketing.* Use of substitutes for the sole purpose of test marketing is exempt from SNAP notification requirements 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 the Agency in writing that they are conducting test marketing 30 days prior to the commencement of such marketing. Notification shall include the name of the substitute, the volume used in the test marketing, intended sector end-uses,