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Protection of Stratospheric Ozone: Reconsideration of the 610 Nonessential Products Ban; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7101–1]

RIN 2060–AH99

Protection of Stratospheric Ozone: Reconsideration of the 610 Nonessential Products Ban

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rulemaking amends the current regulations that implement the statutory ban on nonessential products that release Class I ozone-depleting substances under section 610 of the Clean Air Act, as amended. This final rule does not affect the use of Class II ozone-depleting substances. This rulemaking was developed by EPA based on new and compelling information that was gathered and indicates limited continued use by some sectors of Class I substances in products where the use of those substances today should be considered a ''nonessential use of Class I substances in a product'' based on the availability and widespread use of alternatives. The products affected by this rulemaking are aerosol products, pressurized dispensers, plastic foam products, and air-conditioning and refrigeration products that contain or are manufactured with Class I substances (*e.g.,* chlorofluorocarbons). Through this action, an additional category of products will be added and some products will be removed from the list of banned products (i.e., products that cannot be introduced into interstate commerce).

EFFECTIVE DATE: January 14, 2002.

ADDRESSES: Comments and materials supporting this rulemaking are contained in Public Docket No. A–98–31, Waterside Mall (Ground Floor) Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 in room M–1500. Dockets may be inspected from 8:00 a.m. until 5:30 p.m., Monday through Friday. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Cindy Newberg, Stratospheric Program Implementation Branch, Global Programs Division, Office of Atmospheric Programs, Office of Air and Radiation (6205–J), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, (202) 564–9729. The Stratospheric Ozone Information Hotline at 1–800–296–1996 can also be contacted for further information.

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I. Regulated Entities

Entities potentially regulated by this action are those that wish to sell and/or distribute in interstate commerce aerosols, pressurized dispensers, plastic foam products, refrigerators and air-conditioning equipment that contain chlorofluorocarbons (CFCs). Regulated categories and entities include:

Category	Example of regulated entities
Industry	Aerosol packagers. Aerosol manufacturers. Air-Conditioning and refrigeration equipment manufacturers. Specialty chemical manufacturers. Foam manufacturers. Air conditioning and refrigeration distributors. Air conditioning and refrigeration retailers.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your company is regulated by this action, you should carefully examine the applicability criteria contained in section 610 of the Clean Air Amendments of 1990, discussed in regulations codified at 40 CFR part 82, subpart C and published on January 15, 1993 (58 *FR* 4768); December 30, 1993 (58 FR 69672) and discussed below. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

Title VI of the Clean Air Act (the ''Act'') divides ozone-depleting chemicals into two distinct classes. Class I is comprised of chlorofluorocarbons (CFCs), halons, carbon tetrachloride and methyl chloroform, methyl bromide and hydrobromofluorocarbons. Class II is comprised of hydrochlorofluorocarbons (HCFCs). (See listing notice January 22, 1991; 56 *FR* 2420.) Section 610(b) of the Act, as amended, requires EPA to promulgate regulations banning nonessential products releasing Class I substances. EPA published a final rule for the Class I Nonessential Products Ban on January 15, 1993 (58 *FR* 4768). A final rule establishing regulations that implemented the statutory ban on nonessential products containing or manufactured with Class II ozone-depleting substances under section 610(d) of the Clean Air Act, as amended, was issued December 30, 1993 (58 *FR* 69637). That final rule was developed to clarify definitions and provide exemptions, as authorized under section 610(d). All of the regulations are codified at 40 CFR part 82, subpart C. Comments and materials supporting those rulemakings are contained in Public Dockets A–91–39 and in A–93–20.

On June 14, 1999, EPA proposed changes to the Class I Nonessential Products Ban (64 *FR* 31772). Today's action is based on those proposed changes and comments the Agency received in response to that NPRM.

In a separate action, EPA's Significant New Alternatives Policy (SNAP) program, recently made available for public comment new information concerning the use of Class II substances and non-ozone depleting alternatives in

the production of plastic foam products. That information includes: sector description and size, non-ozone depleting alternatives currently used in each sector and technically viable alternatives. That document, Protection of Stratospheric Ozone: Notice of Data Availability; New Information Concerning SNAP Program Proposal on HCFC Use in Foams (May 23, 2001, 66 *FR* 28408) does not pertain directly to today's action. However, in gathering information for that document, the Agency did not uncover any additional information that indicated significant continued use of CFCs in foam manufacturing.

A. Class I Ban

Section 610(b) of the Act directs EPA to identify nonessential products that ''release Class I substances into the environment (including any release during manufacture, use, storage, or disposal)'' and to ''prohibit any person from selling or distributing any such product, or offering any such product for sale or distribution, in interstate commerce.''

Section 610(b)(1) and (2) specify products to be prohibited under this requirement, including ''chlorofluorocarbon-propelled plastic party streamers and noise horns'' and ''chlorofluorocarbon-containing cleaning fluids for noncommercial electronic and photographic equipment.''

Section 610(b)(3) extends the prohibition to other products determined by EPA to release Class I substances and to be nonessential. In determining whether a product is nonessential, EPA is to consider the following criteria: ''the purpose or intended use of the product, the technological availability of substitutes for such product and for such Class I substance, safety, health, and other relevant factors.''

The regulatory Class I Ban promulgated by EPA under these statutory provisions currently identifies as nonessential, and therefore subjects to the prohibitions, the following:

(A) plastic party streamers and noise horns propelled by chlorofluorocarbons;

(B) cleaning fluids for electronic and photographic equipment which contain a chlorofluorocarbon, including but not limited to liquid packaging, solvent wipes, solvent sprays, and gas sprays, except for those sold or distributed to a commercial purchaser;

(C) plastic flexible or packaging foam product which is manufactured with or contains a chlorofluorocarbon, including but not limited to:

I. open cell polyurethane flexible slabstock foam,
II. open cell polyurethane flexible molded foam,
III. open cell rigid polyurethane poured foam,
IV. closed cell extruded polystyrene sheet foam,
V. closed cell polyethylene foam, and
VI. closed cell polypropylene foam, except flexible or packaging foam used in coaxial cable; and

(D) any aerosol product or other pressurized dispenser which contains a chlorofluorocarbon, *except:*

—medical devices listed in 21 CFR 2.125(e),
—lubricants for pharmaceutical and tablet manufacture,
—gauze bandage adhesives and adhesive removers,
—topical anesthetic and vapocoolant products,
—lubricants, coatings or cleaning fluids for electrical or electronic equipment, which contain CFC–11, CFC–12, or CFC–113 for solvent purposes, but which contain no other CFCs,
—lubricants, coatings or cleaning fluids used for aircraft maintenance, which contain CFC–11 or CFC–113, but which contain no other CFCs,
—mold release agents used in the production of plastic and elastomeric materials, which contain CFC–11 or CFC–113, but which contain no other CFCs,
—spinnerette lubricant/cleaning sprays used in the production of synthetic fibers, which contain CFC–114, but which contain no other CFCs,
—containers of CFCs used as halogen ion sources in plasma etching,
—document preservation sprays which contain CFC–113, but which contain no other CFCs, and
—red pepper bear repellent sprays which contain CFC–113, but which contain no other CFCs.

Verification and public notice requirements have been established for distributors of certain products intended exclusively for commercial use.

Through this action, an additional category of banned products will be added and some products will be removed from the exempted list. The preamble to the 1993 rulemaking implementing the Class I Ban established that EPA should in the future reconsider exceptions granted and limitations of the Ban under that rulemaking based on new and compelling information regarding the availability of substitutes for Class I substances. In 1993, EPA limited consideration of banned products to aerosols, pressurized dispensers, and foams. These sectors traditionally used ozone-depleting substances and were subject to the statutory Class II Ban. Since that rulemaking was issued, the phaseout of production and consumption of Class I substances has become effective and the Significant New Alternatives Policy (SNAP) program mandated under section 612 of the Act has been established. The phaseout of newly manufactured Class I substances and the identification of acceptable substitutes provide compelling reasons to reconsider the initial decisions regarding both product-specific exemptions and the decision to limit the Ban's effect to major sectors that traditionally used ozone-depleting substances.

1. Reconsideration

The regulations implementing the Class I Ban provide for EPA to reconsider decisions that were made regarding specific products and product categories. EPA indicated in 1993 that the Agency would reconsider decisions in the future based on developments of products using substitutes to Class I substances. EPA has previously reconsidered specific decisions. In December 1993 (58 *FR* 69672), EPA reconsidered the application of the Class I Ban to replacement parts that were previously manufactured and stored for future use, such as car seats designed and manufactured for a particular vehicle model.

Based on development of new substitutes and the characterization of the criteria for nonessentiality discussed below, particularly as applied to the use of Class I substances in products that are themselves not nonessential, on June 14, 1999, (64 *FR* 31774) EPA proposed that it was appropriate to reconsider previous determinations. Specifically, EPA proposed to reconsider the determinations for the air-conditioning and refrigeration, solvents, and foam-blowing sectors.

2. Determinations Under 610

As stated above, section 610(b)(3) extends the prohibition on sale of nonessential products to other products determined by EPA to release Class I substances and to be nonessential. In determining whether a product is nonessential, EPA is to consider the following criteria: ''the purpose or intended use of the product, the technological availability of substitutes for such product and for such Class I substance, safety, health, and other relevant factors.'' The statute requires EPA to consider each criterion but did not outline either a ranking or a methodology for comparing their

relative importance, nor does it require that any minimum standard within each criterion be met. To develop the initial rulemaking, EPA considered all of these criteria in determining whether a product was nonessential. In addition, EPA reviewed the criteria used in the development of its 1978 ban on aerosol propellant uses of CFCs under the Toxic Substances Control Act (TSCA). Today's action follows similar methodology.

3. The Purpose or Intended Use of the Product

This criterion relates to the importance of the product, in terms of benefits to society, specifically whether the product is sufficiently important that the benefits of its continued production outweigh the associated danger from the continued use of a Class I ozone-depleting substance in it, or alternatively, whether the product has little benefit, such that even a lack of available substitutes might not prevent the product from being considered nonessential. The initial Class I final rulemaking included a discussion about the contributions of a product to the quality of life.

The distinction between a ''nonessential product'' and a ''nonessential use of Class I substances in a product'' is a relevant criterion. For example, while foam cushioning products for beds and furniture are not ''frivolous,'' the use of a Class I substance in the manufacturing process for foam cushioning where substitutes are readily available is considered nonessential. The ability of manufacturers to switch from using a Class I substance is a relevant indicator for this criterion. The initial Class I final rule states that ''the Agency believes that in sectors where the great majority of manufacturers had already shifted to substitutes, the use of a Class I substance in that product may very well be nonessential.'' Consequently, EPA believes it is appropriate under this criterion to examine sectors where most of the market has previously switched out of CFCs.

4. The Technological Availability of Substitutes

EPA has previously interpreted this criterion to mean the existence and accessibility of alternative products or alternative chemicals for use in, or in place of, products releasing Class I substances. EPA believes that the phrase ''technological availability'' includes both currently available substitutes (*i.e.,* presently produced and sold in commercial quantities) and potentially available substitutes (*i.e.,* determined to be technologically feasible, environmentally acceptable and economically viable, but not yet produced and sold in commercial quantities). However, EPA considers the current availability of substitutes more compelling than the potential availability of substitutes in determining whether a product is nonessential.

The corresponding criterion from the 1978 aerosol ban is the ''nonavailability of alternative products.'' In its supporting documentation, EPA stated that this was the primary criterion for determining if a product had an ''essential use'' under the 1978 rule. EPA emphasized, however, that the absence of an available alternative did not alone disqualify a product from being banned as nonessential.

The availability of substitutes is clearly a critical criterion for determining if a product containing a Class I substance is nonessential. In certain cases, a substitute that is technologically feasible, environmentally acceptable and economically viable, but not yet produced and sold in commercial quantities, may meet this criterion with respect to certain products. However, EPA believes that, where substitutes are readily available, the use of Class I substances could be considered nonessential even in a product that is extremely important.

EPA does not necessarily advocate the use of all substitutes that are currently being used in place of CFCs in the products EPA identifies as nonessential. In many cases potential substitutes are subject to other regulatory programs. For example, the SNAP program promulgated under CAA 612 carefully considers the relative health and environmental risks and merits of different substitutes for ozone-depleting substances. Substitutes are listed under that regulatory program as acceptable, unacceptable, or acceptable subject to use restrictions for specific uses. However, within the limited purposes of the nonessential products bans, EPA considers the existence and accessibility of alternative products or alternative chemicals for use in, or in place of, products releasing Class I substances. Any future use of such substitutes must comport with any conditions of the SNAP program, if applicable.

5. Safety and Health

EPA interprets these two criteria to mean the effects on human health and the environment of the products releasing Class I substances or their substitutes. In evaluating these criteria, EPA considered the direct and indirect effects of product use, and the direct and indirect effects of alternatives, such as ozone depletion potential, flammability, toxicity, corrosiveness, energy efficiency, ground-level air hazards, and other environmental factors.

If any safety or health issues prevented a substitute from being used in a given product, EPA then considered that substitute to be ''unavailable'' at the time for that specific product or use. EPA noted in the initial rulemaking that as new information becomes available on the health and safety effects of possible substitutes, EPA could reevaluate determinations made regarding the nonessentiality of products.

6. Medical Products

Section 610(e) states that ''nothing in this section shall apply to any medical devices as defined in section 601(8).'' Section 601(8) defines ''medical device'' as ''any device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—(A) if such device, product, drug, or drug delivery system utilizes a Class I or Class II substance for which no safe and effective alternative has been developed and, where necessary, approved by the Commissioner of the Food and Drug Administration (FDA); and (B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator.''

The FDA is currently reviewing its determinations under 21 CFR 2.125(e). At this time, the FDA lists 12 medical devices for human use as essential uses of CFCs in 21 CFR 2.125(e). These devices consist of certain metered dose inhalers (MDIs), contraceptive vaginal foams, intra-rectal hydrocortisone acetate, polymyxin B sulfate-bacitracin-zinc-neomycin sulfate soluble antibiotic powder without excipient for topical use, and anesthetic drugs for topical use on accessible mucous membranes where a cannula is used for application. For additional information regarding FDA determinations and plans for potential regulatory changes, see 62 FR 10242 (March 6, 1997).

Medical products as determined by FDA and listed as essential at 21 CFR 2.125(e) are exempt from the Class I Ban at 40 CFR part 82, subpart C. This document does not propose any changes to this current exemption. However, other medical-related products not contained in the FDA's list of essential uses (21 CFR 2.125(e)), and therefore not

subject to 610(e), that were considered in the initial Class I Ban rulemaking, and given exemptions, under 610(b) are reconsidered in this action. Those products are gauze bandage adhesives and adhesive removers, lubricants for pharmaceutical and tablet manufacture, and topical anesthetic and vapocoolant products.

7. Other Products

In drafting the initial rulemaking to prohibit certain products under section 610(b)(3), the Agency considered every major use sector that used Class I substances including: Refrigeration and air-conditioning, solvent use, fire extinguishing, foam blowing, and aerosol use. Based on that review, EPA identified three broadly defined product categories for further evaluation: Aerosol products and pressurized dispensers containing CFCs or halons, plastic flexible and packaging foams, and halon fire extinguishers for residential use.

EPA believed that in each of these sectors two important conditions existed: Substitutes were already available for the product or the Class I substance used or contained in that product; and, either the affected industry had, for the most part, moved out of the use of Class I substances or the market share of products using or containing Class I substances was small and shrinking. In addition, in the case of aerosols and plastic flexible and packaging foams, section 610(d) imposed a self-effectuating ban on the sale or distribution of such products containing or produced with Class II substances after January 1, 1994.

The 1993 rulemaking specifically discussed the other sectors and provided information regarding the Agency's determinations. Refrigeration and air-conditioning, including mobile air-conditioning, represented the largest total use of Class I substances in the United States in 1993. At the time the initial rulemaking was promulgated, substitutes were available for some refrigeration and air-conditioning products. For example, the automotive manufacturers were in the process of switching to HFC–134a for new models rather than CFC–12 in their air-conditioning systems. However, potential substitutes for other refrigeration and air-conditioning uses were still being evaluated.

EPA did not include prohibitions on the use of Class I substances in refrigeration or air-conditioning in the 1993 rulemaking because determinations regarding substitutes for all such uses were not anticipated to be available within the time-frame of that rulemaking. Accordingly, EPA could not conclude that the use of Class I refrigerants in all refrigeration or air-conditioning uses were nonessential at the time of that rulemaking. Furthermore, at that time, EPA had not yet issued final regulations that specifically addressed non-automotive or stationary refrigeration and air-conditioning uses of Class I substances (subsequently promulgated under CAA section 608 and codified at 40 CFR part 82, subpart F). These regulations addressed standards for the recovery and reuse of refrigerants.

Solvent uses of Class I substances, including commercial electronics de-fluxing, precision cleaning, metal cleaning and dry cleaning also represented a significant use in 1993. Industry had already identified potentially available substitutes for nearly all of the thousands of products then manufactured with Class I solvents, and many companies had already phased out the use of CFCs in certain products. EPA did not address solvent use in that rulemaking (accept where the solvent application was within an aerosol or pressurized dispenser) because the sheer number of products and the range of potential substitutes made it impossible for EPA to conclude definitively that substitutes were available for any of these specific uses, and thus that such uses were nonessential, within the short statutory time-frame for the Class I Ban rulemaking. Moreover, EPA believed a ban on such uses would be unnecessary as most manufacturers were phasing out use as particular substitutes became available, in anticipation of the impending production phaseout.

EPA considered the use of Class I substances in fire extinguishing applications in its initial review as well. Halons were widely used in fire extinguishing systems. These fire extinguishing systems include both total flooding systems (such as stationary fire suppression systems in large computer facilities) and streaming systems (such as hand-held fire extinguishers). In evaluating possible nonessential uses of halons in fire fighting, the Agency divided the fire protection sector into six broad end uses: (1) Residential/Consumer Streaming Agents, (2) Commercial/Industrial Streaming Agents, (3) Military Streaming Agents, (4) Total Flooding Agents for Occupied Areas, (5) Total Flooding Agents for Unoccupied Areas, and (6) Explosion Inertion. EPA concluded that substitutes for halons, whether other halocarbons or alternatives such as water, should meet four general criteria to provide a basis for determining that the use of halon in residential fire extinguishers is nonessential. They must be effective fire protection agents, they must have an acceptable environmental impact, they must have a low toxicity, and they must be relatively clean. In addition, they must be commercially available as a halon replacement in the near future. EPA concluded that while satisfactory substitutes were not yet available in most commercial and military applications within the short statutory time-frame of the rulemaking, certain substitutes were already commercially available for hand-held halon fire extinguishers in residential settings. Consequently, the Agency decided to evaluate this application more closely in order to determine whether residential fire extinguishers containing halon should be designated nonessential products, or whether the continued use of halons, despite the imposition of the excise tax and the impending production phaseout, indicated that this application did not meet the criteria for nonessentiality. Ultimately, after reviewing the issue and soliciting comment, the final rulemaking did establish a ban on the use of halon in residential streaming applications. Furthermore, the use of CFCs in fire extinguishing equipment was also restricted.

EPA considered aerosols and pressurized dispensers likely candidates for designation as nonessential products in 1993 because a great deal of information on substitutes for CFCs in these applications already existed. Research on substitutes for CFCs in aerosol applications began in the 1970s in response to the early studies on stratospheric ozone depletion and the 1978 ban on the use of CFCs as aerosol propellants. Consequently, extensive data already existed on possible substitutes for most remaining aerosol uses.

The 1978 aerosol ban prohibited the manufacture of aerosol products using CFCs as propellants. Other uses of CFCs in aerosols (such as solvents, active ingredients, or sole ingredients) were not included in the ban. In addition, certain ''essential uses'' of CFCs as aerosol propellants were exempted from the ban because no adequate substitutes were available at the time. Consequently, although the use of CFCs in aerosols was reduced dramatically by the 1978 ban, the production of a number of specific aerosol products containing CFCs was still legal including: Metered dose inhalant drugs; medical solvents such as bandage adhesives and adhesive removers; skin chillers for medical purposes; aerosol tire inflators; mold release agents;

lubricants, coatings, and cleaning fluids for industrial/institutional applications to electronic or electrical equipment; special-use pesticides; aerosols for the maintenance and operation of aircraft; diamond grit spray; single-ingredient dusters and freeze sprays; noise horns; mercaptan stench warning devices; pressurized drain openers; aerosol polyurethane foam dispensers; and whipped topping stabilizers. In 1993, EPA concluded that satisfactory substitutes were available for most uses of CFCs in aerosols and pressurized dispensers. As a result, the Agency banned all uses of CFCs in aerosols and pressurized dispensers except for certain products, such as medical devices, that it specifically exempted.

8. Reconsidering Nonessential Determinations

New and compelling information has been gathered by EPA that indicates that in some sectors there is limited continued use of Class I substances in products where the use of the substance today should be considered a ''nonessential use of Class I substances in a product.'' Since the promulgation of the initial regulations under section 610, the SNAP program has been established and now provides information regarding acceptable substitutes for various applications. While the SNAP program does not determine the efficacy of substitute substances as potential replacements for ozone-depleting substances, for most applications there are sources of information regarding the effectiveness of the substitutes, such as laboratory testing and information provided by major users and trade associations. For example, many substitutes have been listed by SNAP as acceptable for various refrigeration applications. Newly manufactured refrigerators in the United States for residential use are employing these available substitutes. As described in this notice, the Agency has determined that the use of a Class I substance in refrigeration applications now meets the definition of nonessentiality and that it is, therefore, reasonable now to promulgate revisions to the regulations that extend the Class I Ban to refrigeration applications. Similarly, substitutes now appear to be available for certain foam, aerosol, and pressurized dispenser uses.

Today's action amends the Class I Ban to meet the Agency's obligations to eliminate the nonessential uses of Class I substances. Specifically, EPA has determined that it is appropriate to reconsider the determinations of nonessentiality for the air-conditioning and refrigeration, foam-blowing, aerosols, and pressurized dispensers product categories. Today's action amends the Class I Ban to include additional nonessential uses of CFCs for these end-use applications.

B. Class II Ban

On December 30, 1993, EPA published a final rulemaking (580 FR 69637) addressing issues related to the statutory prohibition against the sale or distribution, or offer for sale or distribution in interstate commerce of nonessential products containing or manufactured with a Class II substance, imposed by section 610(d) of the Act. Section 610(d)(1) states that after January 1, 1994, ''it shall be unlawful for any person to sell or distribute, or offer for sale or distribution, in interstate commerce—(A) any aerosol product or other pressurized dispenser which contains a Class II substance; or (B) any plastic foam product which contains, or is manufactured with, a Class II substance.'' Section 610(d)(2) authorizes EPA to grant certain exceptions and section 610(d)(3) creates exclusions from the Class II Ban in certain circumstances.

Section 610(d)(2) authorizes the Administrator to grant exceptions from the Class II Ban for aerosols and other pressurized dispensers where ''the use of the aerosol product or pressurized dispenser is determined by the Administrator to be essential as a result of flammability or worker safety concerns,'' *and* where ''the only available alternative to use of a Class II substance is use of a Class I substance which legally could be substituted for such Class II substance.''

Section 610(d)(3) states that the ban of Class II substances in plastic foam products shall not apply to ''foam insulation products'' or ''an integral skin, rigid, or semi-rigid foam utilized to provide for motor vehicle safety in accordance with Federal Motor Vehicle Safety Standards where no adequate substitute substance (other than a Class I or Class II substance) is practicable for effectively meeting such standards.'' Unlike the Class I Ban, the Class II Ban was self-executing. Section 610(d) bans the sale of the specified Class II products by its own terms, without any reference to required EPA regulations. However, EPA did issue regulations implementing the Class II Ban in order to better define the products banned under section 610(d) and to grant authorized exceptions under section 610(d)(2). Section 301(a) of the Act gives EPA the authority to promulgate such regulations as are necessary to carry out its functions under the Act, and EPA determined that it was necessary to issue the Class II Ban regulations for those purposes.

1. Determinations Under Section 610(d)

The statutory criteria for providing an exemption from the Class II Ban are explicit. For any potential exemption, the use of the aerosol product or pressurized dispenser must be found to be essential based on flammability or worker safety concerns and EPA must find that the only available alternative to use of a Class II substance is use of a Class I substance which could legally be substituted for such Class II substance.

The initial final rulemaking regarding the Class II Ban provided exemptions for:

—Lubricants, coatings, or cleaning fluids for aircraft maintenance containing HCFCs as solvents;
—Lubricants, coatings, or cleaning fluids for electrical, electronic or photographic equipment containing HCFCs as solvents;
—Aircraft pesticides;
—Mold release agents containing HCFCs as solvents;
—Mold release agents containing HCFC–22 as a propellant, for use where no alternative, including an alternative formulation, is available and where the seller must notify purchaser about the restriction;
—Spinnerette lubricant/cleaning sprays containing HCFCs as solvents and/or propellants;
—Document preservation sprays containing HCFCs as solvents;
—Document preservation sprays containing HCFCs as propellants, for use on thick books, books with coated or dense paper, and tightly bound documents, only;
—Portable fire extinguishing equipment containing HCFCs as fire extinguishants, for use in non-residential applications only;
—Wasp and hornet sprays, for use near high-tension power lines only and where the seller must notify purchaser about restrictions; and
—the definition of foam insulation product.

2. Reconsideration

Since the issuance of the final rule providing exemptions from the statutory Class II Ban, EPA amended the final rule with regard to fire suppression based on compelling information that the Agency received. That amended regulation was issued in the **Federal Register** on December 4, 1996 (61 FR 64424) and subsequently codified at 40 CFR part 82, subpart C.

EPA has received information indicating that it may be appropriate to

reconsider the continued relevance of the current list of exemptions for specific aerosol products and pressurized dispensers; and potentially the definition of foam insulation product. The Agency is aware that since the issuance of that initial final rulemaking, there has been further substitution away from ozone-depleting substances for a variety of insulating foam, aerosol products and pressurized dispensers.

3. Potential Future Notice of Proposed Rulemaking

EPA is currently reviewing information concerning the above aerosol and foam products and pressurized dispensers, as well as the exemptions from the Class II Ban provided in the December 1993 rulemaking. Since the implementation of the Class II Ban on January 1, 1994, progress has been made to further identify substitutes for various applications. In addition, as stated above, the SNAP program has been established and provides lists of acceptable substitutes for various applications, including applications affected by the Class II Ban. When EPA completes its evaluation of the existing exemptions for HCFCs in pressurized dispensers and aerosol products, as well as the definition of foam insulation product, the Agency may proceed with a notice of proposed rulemaking if the Agency determines that any rule revisions are appropriate.

III. Summary and Response to Comments

On June 14, 1999, EPA issued an NPRM proposing changes to the Class I Ban (64 FR 31772). EPA received ten comments regarding this rulemaking. These comments are contained in Air Docket A–98–31. While most of the comments suggested minor changes or clarifications with regard to the proposal, nine of the ten comments generally supported EPA in acting to revise the Class I Ban.

A. Foam Products

EPA proposed to ban the sale and distribution and offer of sale or distribution in interstate commerce of all foam products (both insulating and non-insulating) that release Class I substances into the environment (including any release during manufacture, use, storage, or disposal). EPA stated in the NPRM its belief that there are acceptable substitutes available for replacing any continued use of Class I substances as blowing agents for foam products. EPA requested comments on revising the Class I Ban to ban the sale and distribution or offer of sale and distribution in interstate commerce of *any* foam plastic product or plastic foam product that releases Class I substances into the environment (including any release during manufacture, use, storage, or disposal). EPA stated that it would consider any specific data indicating that substitutes are not available for certain foam products.

EPA received two comments that specifically addressed plastic foam products. Both comments address specific types of foam. The first comment, from a manufacturer, stated that they currently have a stockpile of CFC–11 for producing integral skin foam. According to the comment, the company has continued to use small quantities of CFC–11 while conducting research and development of alternative foam systems. The company stated that ''it is the only producer of CO_2 blown systems for integral skin foams that has developed foam systems meeting FAA requirements for commercial aircraft.'' The company further stated that it has ''manufactured a large number of molded articles with the new non-CFC blown systems over the last several years'' and that ''this accomplishment has required a considerable research and development work for several different foam systems.'' The company stated that the change to the new molds and tooling was underway and would be complete within a few months. The commenter believes that they should be permitted to produce some integral skin with the remaining CFC–11 that they have on hand, particularly if they ''encounter any unforeseen problems.'' The commenter further questioned why EPA is pursuing this rulemaking since the commenter believes there will only be a ''very minor impact on ozone depletion.''

EPA applauds the efforts of this manufacturer in replacing CFCs in its processes. EPA recognizes that foam blowing companies have invested significant time and effort in developing substitute products. However, EPA does not agree with the commenter's reasons to exempt the use of the CFCs that remain on hand. Since the commenter indicates there are alternatives already available for the products that it manufactures, EPA believes this indicates that the continued use of CFC–11 in this plastic foam product meets the definition of nonessential. Therefore, EPA does not believe that the final rule should be modified to exempt the continued production of integral skin foam products with CFC–11. However, EPA recognizes the concerns with existing inventories of manufactured products containing Class I substances that have already been completely manufactured and placed into inventory. Therefore, existing inventories of previously manufactured products are considered below at section IV: Effective Dates.

With regard to the general comment regarding the benefits from this rulemaking, EPA believes that it is obligated under the criteria established by section 610 of the Act to list products that are nonessential. The recovery of the ozone layer and its resulting benefits are based on the cumulative implementation of all the programs established under Title VI of the Act, not one individual rule.

EPA received a comment from the National Aeronautics and Space Administration (NASA) regarding the use of specific plastic foam products for the space shuttle. NASA identified one particular product, BX–250, a foam which is part of the thermal protection system of the Space Shuttle External Tank and which uses CFC–11 as a blowing agent. NASA stated that ''although extensive efforts have been made and continue to be made to replace this material, no viable alternative has been identified.'' NASA requested that EPA revise the proposed rule to provide an exemption for CFC–blown foam products in applications that are associated with space vehicles. NASA suggested that EPA consider using the same language that EPA has previously adopted under 40 CFR part 63, subpart GG (40 CFR 63.742) for the National Emissions Standards for Hazardous Air Pollutants (NESHAPs) program. NASA provided EPA with additional information concerning its proactive pursuit of potential alternative blowing agents.

Since human space flight safety is of paramount importance to NASA, prior to implementing any new material, that material must undergo a rigorous development and qualification program for which no suitable substitute has yet been identified. NASA requested that EPA consider using the language at 40 CFR 63.742:

Space vehicle means a man-made device, either manned or unmanned, designed for operation beyond earth's atmosphere. This definition includes integral equipment such as models, mock-ups, prototypes, molds, jigs, tooling, hardware jackets, and test coupons. Also included is auxiliary equipment associated with test, transport, and storage, which through contamination can compromise the space vehicle performance.

EPA agrees that an exception is necessary, but EPA disagrees with NASA's proposed language. This language is far broader than what EPA concludes is actually necessary based on an evaluation of the information NASA presented. If EPA were to simply exempt all foams used for any applications associated with space vehicles EPA could be exempting products where there are already suitable substitutes. NASA only provided information concerning one particular type of foam used in applications associated with the Space Shuttle External Tank. Therefore, based on that information, through this action, EPA will modify § 82.66(c) to provide an exemption for foam products manufactured with or containing Class I substances that are used as part of the thermal protection system of external tanks for space vehicles and will add the definition of space vehicles found at § 63.742 to § 82.62. The exemption will be limited to the use of CFC–11 as a blowing agent and where no other CFCs are contained in the foam product. Although EPA did not propose this exemption or the additional definition, they are logical outgrowths of the comment submitted by NASA and thus it is appropriate to proceed to final action without providing any additional proposal or opportunity for further comment.

B. Aerosol Products and Pressurized Dispensers

As stated above, EPA initially provided exemptions for a narrow list of aerosol products and pressurized dispensers that release Class I substances into the environment. EPA proposed to eliminate exemptions for: gauze bandage adhesives & adhesive removers, topical anesthetic and vapocoolant products, lubricants for pharmaceutical tablet manufacture, containers of CFCs used as halogen ion sources in plasma etching, and red pepper bear repellent sprays containing CFC–113 as a solvent. EPA stated in the NPRM that the Agency believes there are substitutes available for these uses of Class I products and therefore these exemptions should be eliminated. Additionally, EPA did not propose any changes to the exemption for medical devices that are determined to be essential by the Food and Drug Administration and are listed at 21 CFR 2.125(e). Also, given the statutory links established between the Class I and Class II Bans for aerosol products and pressurized dispensers, namely the criterion in 610(d) that states that exemptions are available only where the alternative to the use of a Class II substance is the legal use of a Class I substance, EPA did not propose to eliminate exemptions for aerosol products or pressurized dispensers from the Class I Ban that are also exempted from the Class II Ban. However, EPA stated that if the Agency subsequently issues a proposed rulemaking reconsidering exemptions from the Class II Ban, that notice will also include the reconsideration for the remaining aerosol products and pressurized dispensers under the Class I Ban as well. EPA requested comments on the proposed changes to the list of exemptions for aerosol and pressurized dispensers that release Class I substances into the environment, and specifically any data indicating that such uses are still essential.

EPA received three comments that directly concern the proposed changes to the aerosol and pressurized dispensers. All three comments generally support the proposed changes to the Class I Ban. The first comment stated that the proposed changes to the ban were reasonable and agreed that for all of the listed products there are suitable substitutes for the Class I components. The comment stated that the market impact of these regulatory changes would be small.

The second comment, from a trade association, approved of EPA's decision to delay any proposed changes to the exemptions that are linked to the Class II Ban by the statutory language in 610(d). The commenter provided additional information regarding the Class II Ban and its exemptions. The third comment, from a manufacturer of aerosol products and pressurized dispensers, provided information concerning products with exemptions linked to both the Class I and Class II Bans. EPA will consider the information provided by these commenters in the future when the Agency addresses the Class II Ban and the linked Class I and Class II exemptions. Regarding the commenters' statements on the impact of today's action, EPA agrees with the comments and the assessment of the limited impacts of this action.

Therefore, EPA is taking final action to eliminate the Class I exemptions, as proposed; and will consider Class II exemptions at a later date.

C. Air-Conditioning and Refrigeration Appliances

Today, there are substitutes identified for a variety of refrigeration and air-conditioning applications. While substitutes continue to be developed and evaluated for these applications, the Agency stated in the June 14, 1999, NPRM that it was confident that there are sufficient technologically available substitutes for the use of Class I substances in all refrigeration and air-conditioning applications as documented in the docket for this rulemaking. EPA further stated that while there may be a limited number of products manufactured abroad and imported into the United States, as well as some potential domestic manufacturing of refrigeration and air-conditioning products containing Class I substances that EPA is not aware of and given the designated criteria for nonessentiality, EPA believed that air-conditioning and refrigeration appliances that contain CFCs meet the criteria for nonessential uses of a Class I substance. Therefore, EPA stated that it now was reasonable to consider broadening the applicability of the Class I Ban to include air-conditioning and refrigeration applications. EPA proposed to amend § 82.66 to add a provision banning the sale and distribution or offer for sale or distribution of air-conditioning and/or refrigeration appliances that contain Class I substances. EPA requested comments on expanding the Class I Ban to include air-conditioning and refrigeration appliances. In particular, EPA requested comments regarding whether there are sufficient technologically available substitutes for the use of Class I substances in all new air-conditioning and refrigeration appliances.

EPA received three comments on air-conditioning and refrigeration applications. The first commenter, a trade association, stated that it generally supported the proposal but noted that it had recommendations regarding implementation. Their support, according to the comment, is based on the knowledge that non-CFC technology for domestic refrigeration is widely disseminated.

The second commenter, a manufacturer, generally supports the efforts of EPA to restrict the manufacture of refrigerators and room air conditioners containing CFCs. The manufacturer stated that this is ''a positive move that will hasten the day when CFCs (for which substitutes are available) can be eliminated completely from commerce.'' Both these commenters stated that they did not believe that the ban would in any way unfairly treat foreign manufacturers or importers. The association noted that ''most, perhaps all, of the firms that are importing these products are also producing and/or selling non-CFC units.'' EPA agrees that replacement technology is widely available and

therefore the use of CFCs in this category of products now meets the criteria for nonessentiality. Furthermore, EPA agrees that the effects of this rule will be consistent for both domestic and imported goods.

Comments from the manufacturer applauded EPA for not including the servicing of existing products with Class I refrigerants in this rulemaking and stated that banning use of CFCs for servicing would be unfair to consumers who opt for repairing older appliances. EPA agrees with the commenters' statements about not including servicing of existing products, and has not done so in this rulemaking. Under section 608 of the Act, EPA has issued requirements pertaining to the service, maintenance, repair, and disposal of these appliances.

Another commenter noted that while EPA clearly states that this proposed addition of air-conditioning and refrigeration appliances covers the sale and distribution of new products, it is unclear with regards to used products (64 FR 31778). The commenter believes this is so since regulatory language at § 82.66 did not provide specific reference to new products but rather bans classes of products. The commenter alleges that the language ''any air-conditioning or refrigeration appliance which contains a Class I substance used as a refrigerant'' could imply that all are banned, not just new. EPA disagrees with this commenter's interpretation. The Agency stated previously, and with regard to all products covered under the Class I and Class II Bans, that the effectiveness of these regulations is limited to all sales and distribution in interstate commerce up to and including the sale to the ultimate end user, but that the ban does not extend to a resale of the products after a period of use. EPA previously stated on December 30, 1993, that the resale of used products means a sale, by a person after a period of use other than demonstration use. The Agency recognizes that more than one consumer often derives utility from owning and using certain durable goods and therefore stated (58 FR 69643) that:

> while EPA's interpretation of ''interstate commerce'' is such that interstate commerce includes the entire chain of sale and distribution from the manufacturer of a new product to its ultimate consumer, the Agency recognizes in the NPRM that in the case of durable consumer goods such as boats and motor vehicles, resale of the product to additional consumers may occur after the original sale of the new product to the ultimate consumer after some period of use by the original ultimate consumer.

Therefore, EPA believes that the language at § 82.66 has been properly constructed and is consistent with EPA's past approach under the 610 ban. EPA believes that the interpretation of interstate commerce remains as including the entire chain of sale and distribution from the manufacturer of a new product to its ultimate consumer but does not extend to any resale by that initial ultimate consumer to additional consumers after some period of use has occurred.

EPA received a comment from the Department of the Navy on behalf of the Department of Defense (DoD) that generally supported the proposed regulations as drafted. However, the Navy asked to clarify whether their interpretation of the term ''appliance,'' consistent with section 601 of the Act and previously promulgated at 40 CFR part 82, subpart F was also the definition used with regard to this action. Section 601 of the Act states that an appliance is used for ''household or commercial purposes.'' Therefore, EPA has previously stated in regulations implementing Section 608 of the Act that the definition of ''appliance'' includes ''all air-conditioning and refrigeration equipment except that designed and used exclusively for military applications' (58 FR 28660). EPA continues to agree with this interpretation.

DoD stated that while it has aggressively sought to eliminate Class I ozone-depleting substances from military equipment, in some cases equipment using Class I ozone-depleting substances is still being procured until suitable substitutes are fully qualified and new equipment or equipment modifications are available. For example, the Department of the Navy was scheduled to take delivery of its final CFC–114 shipboard chillers in early 2000. Additional chillers using non-ozone-depleting refrigerants are in the final qualification process and according to the comment, were scheduled for delivery late in 2000. The comment further stated that the existing chillers that use CFC–114 are to be converted to a non-ozone-depleting substance within the next few years. EPA applauds the efforts of DoD to replace the uses of all ODSs. EPA reminds DoD that the section 608 codified language limits the exemption of military appliances to those that are designed and used ''exclusively'' for military applications. EPA believes DoD will be able to find suitable substitutes for all ODS use in a timely manner.

D. Metered Dose Inhalers

EPA received two comments regarding metered dose inhalers (MDIs). EPA specifically noted in the preamble to the proposed rule (64 FR 31778) that:

> EPA is not proposing any changes to the exemption for medical devices that are determined to be essential by the Food and Drug Administration and are listed at 21 CFR 2.125(e). Products such as metered dose inhalers (MDIs) are listed at 21 CFR 2.125(e). The Class I Ban will continue to provide an exemption for the sale and distribution or offer of sale or distribution in interstate commerce of MDIs that release Class I substances into the environment, as well as any other essential medical device listed at 21 CFR 2.125(e).

The first commenter stated that EPA should not permit the marketing and sales of CFC-containing MDIs that ''do not themselves qualify under the Act for essential use allowances under section 604.'' The commenter believes that ''while the agency has consistently urged the FDA not to approve new CFC-MDIs, the EPA fails to prohibit marketing of new CFC-containing MDIs under section 610 even though it is well within the authority, if not the mandate, of the agency to do so.'' EPA notes that the proposed changes in the June 14, 1999, NPRM did not contemplate any changes with regard to the FDA linked exemptions. EPA disagrees with this commenter's interpretations. EPA regularly consults with the FDA to authorize production of limited quantities of Class I substances for use in medical devices, including MDIs, as specified under section 604(d) of the Act. However, EPA defers to FDA on all medical judgments pertaining to approval of new medical products, including MDIs. EPA has neither the authority nor the medical expertise, to consult with FDA on such matters and has never urged the FDA to not approve new CFC-MDIs. EPA continues to believe that the most appropriate means for linking these rules is through cross reference to 21 CFR 2.125(e) where any medical device, including but not limited to MDIs, is listed as essential.

EPA received a second comment regarding MDIs. This commenter stated that to be a medical device under section 601(8) of the Act, a product must be approved and determined to be essential by the FDA Commissioner. The commenter stated that FDA may move the list of essential uses to another section and suggested that EPA ''take this opportunity now to amend its section 610 implementing regulations so as to except products deemed essential by FDA under the CAA—rather than refer to 21 CFR 2.125(e).'' The commenter recommended that § 82.66(d)(2)(i) should be amended to read: ''medical devices determined to be essential by the Food and Drug

Administration.'' EPA disagrees with this commenter. EPA does not believe it is necessary to take any action regarding the reference to 21 CFR 2.125(e) at this time. If the FDA were to move the list of exempted products, EPA would undertake any necessary regulatory actions at that time only if such steps were necessary. Moreover, EPA would likely not consider language that is as broadly constructed as the language suggested by the commenter. EPA believes that because FDA now lists all essential medical devices in 21 CFR 2.125(e), it is appropriate to retain the reference to that rule in the 610 ban.

IV. Effective Dates and Grandfathering

EPA proposed a 60-day effective date for this rulemaking, but discussed the possibility of a longer time frame if necessary. EPA received two comments supporting the proposed effective date for the amendments. However, these two comments, as well as an additional comment, raised concerns regarding products that were already manufactured and placed into inventory prior to the effective date. One commenter stated that the effective date for the provisions on air-conditioning and refrigeration products should be based on the date of import for goods that are imported, and based on date of manufacture for goods that are produced domestically. The commenter stated that this was necessary to allow for goods already in inventory to be sold or distributed. However, the commenter states that the general effective date for the rulemaking should be 60 days from the date of publication of the final rule in the **Federal Register** because the industry has been aware of the action for several years.

EPA recognizes the concerns with products that have already been manufactured and placed into initial inventory. Given that the ban is on all sales and distribution of all products until the sale to the ultimate end user, EPA has in previous rulemakings promulgated under section 610 of the Act, permitted products that are manufactured and placed into initial inventory by a specific date to be ''grandfathered'' and thus sold and distributed in interstate inventory. Through this rulemaking, EPA is establishing a provision to permit air-conditioning and refrigeration appliances containing a Class I substance as a refrigerant that are placed into initial inventory by January 14, 2002 to continue to be sold and distributed through sale to the ultimate consumer. As with all provisions of the ban, this provision includes both products manufactured in the United States and those manufactured abroad and subsequently imported into the United States, as well as products manufactured domestically for export.

EPA received a comment raising concerns about existing inventories regarding a specific type of integral skin foam used in commercial aviation that will now be covered by the ban based on today's action. EPA agrees with this commenter's concerns about such previously manufactured products and is adding a similar provision to also grandfather existing inventories of completely manufactured products. These products must be manufactured and placed into initial inventory by January 14, 2002 to qualify for the grandfathering provision.

To ensure consistent interpretation regarding what is meant by initial inventory, EPA is restating in this FRM the interpretation provided in the preamble to the December 30, 1993 FRM. EPA stated that initial inventory means ''that the original product has completed all of its manufacturing processes and is ready for sale by the manufacturer (e.g., the foam is manufactured).'' The Agency further clarified that ''that product may be subsequently incorporated into another product by a different manufacturer after purchase.'' To continue selling products after the effective date of the provisions, the manufacturer or distributor ''must be able to show, upon request by EPA, that the product was in fact manufactured, and thus placed into initial inventory.'' EPA stated that shipping forms, lot numbers, manufacturer date stamps or codes, invoices, or the like are normally kept records that could be maintained from the time the product was put into initial inventory as proof of the date a product was placed into initial inventory (58 FR 69661).

To facilitate consistent understanding, through this action, EPA is adding to its list of definitions, a definition of ''initial inventories'' as defined above. Products that are manufactured and placed into initial inventories by January 14, 2002 may continue to be sold and distributed in interstate commerce, not withstanding the 610 ban.

V. Summary of Today's Action

Through this action, EPA is today amending the current regulations that implement the statutory ban on nonessential products. EPA is replacing the previous list of banned plastic foam products with a more encompassing prohibition that exempts only one particular foam product used to provide thermal protection to external tanks for space vehicles. EPA is also amending the list of banned products to include any air-conditioning or refrigeration appliances that contain a Class I substance used as a refrigerant. In addition, EPA is adding definitions of space vehicles and initial inventories to the definitions section of the regulation and is exempting air-conditioning and refrigeration products, as well as integral skin foam used in the commercial aviation industry, when such products are fully manufactured and placed into initial inventory by a specific date.

VI. Summary of Supporting Analysis

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined by OMB and EPA that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

B. Regulatory Flexibility

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities, and that it is therefore not necessary to prepare a regulatory flexibility analysis for this final rule. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to

identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' 5 U.S.C. 603 and 604.

This final rule will not have a significant economic impact on a substantial number of small entities for the following reasons. First, as discussed elsewhere in this preamble, acceptable substitutes for CFCs are widely available and currently used by domestic manufacturers for the applications covered by this rule. Second, the rule affects the use of CFCs only. Except for a limited number of essential uses (e.g., Metered Dose Inhalers), production and importation of CFCs has been prohibited in the United States since January 1, 1996. Since production ceased, inventories have been dwindling. The information the Agency has reviewed, indicates that CFCs are primarily being used to service existing equipment such as older automobile air conditioners. EPA believes it very unlikely that there is any significant use of CFCs in manufacturing new products affected by this rulemaking by any businesses, large or small. In addition, EPA's contacts with manufacturers and organizations representing these manufacturers supports the view that there is little if any ongoing manufacturing of products using Class I substance. In developing information for this and other rulemakings, except where noted in the response to comments in today's action, EPA did not encounter any manufacturers large or small that are continuing to use Class I substances in their products. Moreover, in the few exception cases (see preamble III. Summary and Response to Comments), EPA was able to accommodate most of the commenters' concerns, notably by including provisions to ''grandfather'' existing inventories of products already manufactured and placed in initial inventories, allowing these existing inventories to be sold. The findings in the development of this rulemaking and others are in keeping with EPA's view that non-Class-I substitutes are widely used and available, and that the transition away from Class I substances for the affected products is essentially complete.

C. Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act'') (signed into law on March 22, 1995) requires that the Agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year. Section 203 requires the Agency to establish a plan for obtaining input from and informing, educating, and advising any small governments that may be significantly or uniquely affected by the rule. Section 204 requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any action containing a significant Federal intergovernmental mandate. Under section 205 of the Unfunded Mandates Act, the Agency must identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a budgetary impact statement must be prepared. The Agency must select from those alternatives the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule, unless the Agency explains why this alternative is not selected or the selection of this alternative is inconsistent with law.

Because this final rule is estimated to result in the expenditure by State, local, and tribal governments or the private sector of less than $100 million in any one year, the Agency has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. Because small governments will not be significantly or uniquely affected by this rule, the Agency is not required to develop a plan with regard to small governments. Finally, because this FRM does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials.

D. Paperwork Reduction Act

This action requires no information collection subject to the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and therefore no information collection request will be submitted to OMB for review.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications within the meaning of Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule alters the applicability of the Class I Ban to certain ozone depleting substances but does not impose any enforceable duties on the states or local governments. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (NTTAA), section 12(d), Public Law 104–113, requires federal agencies and departments to use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments. If use of such technical standards is inconsistent with applicable law or otherwise impractical, a federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of the agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards.

This final rule does not mandate the use of any technical standards; accordingly, the NTTAA does not apply to this rule.

G. Applicability of Executive Order 13045

This final rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not an economically significant regulatory action as defined in Executive Order 12866 and because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

H. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

On January 1, 2001, Executive Order 13084 superseded by Executive Order 13175. However, this rule was developed during the period when Executive Order 13084 was still in force, and so tribal considerations were addressed under Executive Order 13084. Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective January 14, 2002.

J. Executive Order 13211: Energy Effects

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

VII. Judicial Review

Under section 307(b)(1) of the Clean Air Act, EPA hereby finds that these regulations are of national applicability. Accordingly, judicial review of this action is available only by the filing of a petition for review of this action in the United States Circuit Court of Appeals for the District of Columbia Circuit within 60 days of publication. Under section 307(b)(2) of the Act, the requirements that are the subject of today's rule may not be challenged later in judicial proceedings brought to enforce these requirements.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Exports, Government procurement, Imports, Labeling, Reporting and recordkeeping requirements.

Dated: November 1, 2001.

Christine Todd Whitman,

Administrator.

Title 40, Code of Federal Regulations, part 82, is amended to read as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

2. Section 82.62 is amended by removing paragraph designations (a) through (i), placing the existing definitions in alphabetical order, and adding new definitions for ''Initial Inventory'' and ''Space Vehicles'' to read as follows:

§ 82.62 Definitions.

* * * * *

Initial Inventory means that the original product has completed all of its manufacturing processes and is ready for sale by the manufacturer. Products in initial inventory may be subsequently incorporated into another product by a different manufacturer after purchase. To continue selling products after the effective date of the provisions, the manufacturer or distributor must be able to show, upon request by EPA, that the product was in fact manufactured, and thus placed into initial inventory prior to the effective date. Shipping forms, lot numbers, manufacturer date stamps or codes, invoices, or the like are normally kept records that could be maintained from the time the product was put into initial inventory and may be used to demonstrate when a product was placed in initial inventory.

* * * * *

Space Vehicles means a man-made device, either manned or unmanned, designed for operation beyond earth's atmosphere. This definition includes integral equipment such as models, mock-ups, prototypes, molds, jigs, tooling, hardware jackets, and test coupons. Also included is auxiliary equipment associated with test, transport, and storage, which through contamination can compromise the space vehicle performance.

3. Section 82.65 is amended by adding paragraphs (h) and (i) to read as follows:

§ 82.65 Temporary exemptions.

* * * * *

(h) Any person may sell or distribute, or offer to sell or distribute, in interstate commerce, at any time, any air-conditioning or refrigeration products specified as nonessential in § 82.66(e) that are manufactured and placed into initial inventory by January 14, 2002.

(i) Any person may sell or distribute, or offer to sell or distribute, in interstate commerce, at any time, any integral skin foam products manufactured with a Class I substance for use in commercial aviation and specified as nonessential in § 82.66(c) that are manufactured and placed into initial inventory by January 14, 2002.

4. Section 82.66 is amended by:

a. Revising paragraph (c);

b. Removing paragraphs (d)(2)(ii) through (iv), (ix), and (xi);

c. Redesignating paragraphs (d)(2)(v) through (viii) as paragraphs (d)(2)(ii) through (v) respectively;

d. Redesignating paragraphs (d)(2)(x) as paragraph (d)(2)(vi); and

e. Adding a new paragraph (e).

The additions and revisions read as follows:

§ 82.66 Nonessential Class I products and exceptions.

* * * * *

(c) Any plastic foam product which is manufactured with or contains a Class I substance; except any plastic foam product blown with CFC–11, but which contains no other Class I substances and where this product is used to provide thermal protection to external tanks for space vehicles;

(d) * * *

(e) Any air-conditioning or refrigeration appliance as defined in CAA 601(l) that contains a Class I substance used as a refrigerant.

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