ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–5132–8]

RIN 2060–AE51

Protection of Stratospheric Ozone; Labeling Supplemental Rulemaking

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document amends EPA's existing labeling regulations by adding an exemption from the labeling requirements regulations when controlled substances are destroyed, adding an exemption for spare parts that are used in repair, making revisions to clarify the labeling of waste, and making several other minor clarifying revisions. EPA is promulgating these revisions in response to numerous comments, in order to recognize and alleviate the burden placed on specific parties whose activities contribute no additional emissions of ozone-depleting substances. While these changes provide additional flexibility to the regulated community, they in no way compromise the environmental goals and benefits of protecting public health through the labeling regulation.

EFFECTIVE DATE: This final rule is effective February 21, 1995.

ADDRESSES: Comments on this final rule can be found in Public Docket No. A–91–60, Room M–1500 (LE–131), Waterside Mall, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. The docket 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: Mavis Sanders, Regulatory Development and Operations Section, Program Implementation Branch, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation, 6205–J, 401 M Street, SW, Washington, DC 20460. 202/233–9737.

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

I. Introduction

In a final rule published on February 11, 1993 (58 FR 8136), EPA promulgated regulations to implement section 611 of the Clean Air Act. The regulations mandate that, effective May 15, 1993, labels are required on containers of class I and class II substances and products containing or manufactured with class I substances. The rule also calls for labels on all products containing or manufactured with class I or class II substances, beginning on January 1, 2015.

The final regulations exempt products manufactured using class I substances on an intermittent basis, and not as a direct part of the manufacturing process of the product, such as that employed in spot cleaning textiles during the manufacturing process. The rule explains that such intermittent contact use of controlled substances was found to be incidental ''contact.'' The final rule also explains that intermittent ''contact'' uses, though they may involve a brief initial physical contact between the ozone-depleting ''controlled substance'' and the product, occur infrequently, typically as part of an upkeep process, and that the controlled substance does not come into contact with every product. In other situations, where the controlled substance has contact on an intermittent basis only with the surface area of manufacturing equipment, and although there may be an initial contact with the first few products themselves, the controlled substance will not contact every product manufactured thereafter. Labeling is therefore not required in either of the above cases.

After the final regulations had been published, EPA received several comments from the regulated community requesting clarification of certain parts of the regulations or requesting certain revisions to the regulations. After review of these comments and concerns, EPA determined that certain revisions and clarifications would be appropriate. EPA therefore published a notice of proposed rulemaking (NPRM) on December 30, 1993 (58 FR 69568) proposing such revisions and making such clarifications.

The proposed amendments for the labeling regulations provide exemptions from labeling requirements for companies that destroy controlled substances used in their manufacturing processes to a 98 percent destruction efficiency, using any of the following five destruction technologies approved by the Parties to the Montreal Protocol: liquid injection incineration, reactor cracking, gaseous/fume oxidation, rotary kiln incineration and cement kilns. The proposal also proposes to provide exemptions for waste that is to be discarded; however, waste containers of controlled substances that are to be recycled or reclaimed would still require a label. Additionally, the NPRM proposed to exempt purchasers of spare parts manufactured with a controlled substance from the label pass-through requirement when such purchasers sell such spare parts for the sole purpose of repair and when such products are removed from their original packaging. Spare parts manufactured with a class I substance would require a label; however, once these parts are sold to a distributor who is to sell them to repair persons, such distributors would not be

required to pass through the label, so long as the parts are sold to persons using them for repair purposes only.

The NPRM also proposed other minor amendments that would clarify the definitions of ''manufactured with,'' ''import,'' and ''importer,'' exempt containers containing trace quantities of controlled substances, clarify the ''trace quantities'' exemption for products containing, revise the label placement requirements for containers of 55 gallons or smaller, and revise the certification requirement for the ''reduced use exemption.''

EPA recieved several comments from the public on the proposed rule, but no public hearing was requested. After review of the comments, EPA is today promulgating a final rule amending the labeling regulations.

II. Destruction Exemption from the Labeling Requirements

A. Background on Destruction Policies

1. Background on Montreal Protocol's Destruction Policy

The Montreal Protocol, to which over 132 nations are now Parties, requires that each Party nation control the production and consumption of substances that deplete the ozone layer. Under the existing Protocol, ''production'' of controlled substances is defined as ''the amount of controlled substances produced, minus the amount destroyed by technologies to be approved by the Parties.'' At the second meeting of the Parties to the Protocol (the Parties) in London, a technical advisory committee was established to examine the existing destruction technologies, devise criteria by which to approve technologies, and evaluate environmental concerns associated with the technologies. Until the Fourth Meeting of the Parties, no destruction technology had been approved by the Parties.

2. Fourth Meeting of the Parties to the Montreal Protocol

At the Fourth Meeting of the Parties to the Montreal Protocol, which took place from November 23–25, 1992, in Copenhagen, the Parties approved five destruction technologies to be used for destroying controlled substances. The technologies are: liquid injection incineration, reactor cracking, gaseous/fume oxidation, rotary kiln incinerators, and cement kilns. The Parties also agreed that additional acceleration of the phaseout of controlled substances would result in the need for a greater global destruction program for these substances. With the approval of the five technologies, the Parties noted that the technologies could attain a destruction efficiency of 99.99 percent with proper controls and operating techniques; however, they did not require a specific efficiency. The Parties encouraged a ''Code of Good Housekeeping Procedures,'' set forth in the United Nations Environmental Programme (UNEP) Report entitled Ad-Hoc Technical Advisory Committee on ODS Destruction Technologies, to minimize losses to the environment through control systems and standards for operating such systems. Finally, the Parties agreed to report the quantities of ozone-depleting substances destroyed annually to the Protocol.

With the approval of the five destruction technologies, Parties to the Protocol can subtract from the definition of production that amount of controlled substance(s) that is destroyed by these means, under certain conditions discussed in the final accelerated phaseout rule that was published on December 10, 1993 (58 FR 65018).

B. Accelerated Phaseout Destruction Provisions

The final accelerated phaseout regulations,which were published in the Federal Register on December 10, 1993, (58 FR 65018), implement the United States' acceleration of the phaseout of class I substances, consistent with the recent adjustments to the Protocol agreed upon last November by the Parties in Copenhagen; accelerate the phaseout of certain class II substances; list and phase out hydrobromofluorocarbons (HBFCs); list and phase out methyl bromide; and responded to petitions received by the Agency from environmental and industry groups.

In addition, in that rule, EPA revised the definition of ''production'' such that controlled substances that are to be destroyed are eliminated from the definition of production of such chemicals. The destruction of such substances must employ any one of the five technologies identified above that are approved by the Parties.

The rulemaking defines ''destruction'' in terms of technologies approved for destruction by the Parties that result in expiration of the chemical without any commercially useful end product being produced. The Agency proposed this definition in order to distinguish destruction from transformation, which requires that the resulting end product serve a commercial purpose. The regulation indicates that to be eligible for the destruction exemption, the controlled substances must be destroyed by one of the five destruction technologies approved by the Parties.

As explained more fully in the December 10, 1993 regulation, EPA believes that, while it is not required to follow the approach of the Protocol Parties regarding destruction, it has the authority to do so.

C. Proposed Destruction Provision in the Final Labeling Rule

The preamble to the final labeling regulations (58 FR 8136, February 11, 1993) requested comment on a destruction exemption from the labeling requirements based on the then proposed accelerated phaseout rule, which was being drafted at the time. The Agency requested comment on whether it could and should provide an exemption from the labeling requirements for the use of controlled substances that are subsequently destroyed using one of the above-mentioned approved technologies with procedures that are consistent with the Resource Conservation and Recovery Act (RCRA) and the United Nations Environmental Programme (UNEP) Report entitled Ad-Hoc Technical Advisory Committee on ODS Destruction Technologies. The Agency received and reviewed several comments on the possibility of a destruction exemption provision for the labeling rule. Those comments supported the inclusion of a destruction exemption, similar to that given for transformation. The commenters reasoned that the destruction exemption was justified because destruction of ozone-depleting substances prevents emissions of those substances into the atmosphere.

D. Related Requirements of RCRA and the Proposed Hazardous Organic NESHAP (HON)

In addition to the requirements of Title VI of the Clean Air Act as amended, certain controlled substances are also regulated, under certain circumstances, by the Resource Conservation and Recovery Act (RCRA, 42 USC 6901 et seq.) and are regulated under the final Hazardous Organic NESHAPS (the HON) (59 FR 19402, April 22, 1994). The RCRA regulations would cover those controlled substances that are considered to be hazardous constituents in the waste stream (e.g., carbon tetrachloride bound for incineration). The final HON addresses air emissions of hazardous air pollutants, a category into which carbon tetrachloride, methyl chloroform, and methyl bromide fall. The following discussion outlines the coordination among the RCRA and HON regulations and the destruction exemption provision of the labeling regulations.

1. Resource Conservation and Recovery Act (RCRA) Standards

The RCRA regulations currently require that industries that incinerate waste covered by the regulations must meet ''at stacks'' destruction efficiency (DE) standards of 99.99 percent. The final accelerated phaseout regulations grant full credit for the destruction of controlled substances when they are destroyed in compliance with RCRA regulations 40 CFR 266.104. The accelerated phaseout rule indicates that the Agency grants 100 percent production allowances for companies that achieve 99.99 percent efficiency in the destruction of class I substances instead of only 99.99 percent in allowances, because, otherwise, a company would never be able to obtain credit for the full amount of the chemical used, and would eventually be unable to obtain sufficient volumes to operate.

The only substances that are covered under both RCRA as ''hazardous constituents'' and under Title VI of the Clean Air Act as controlled substances are methyl chloroform (MCF) and carbon tetrachloride (CTC). The remaining controlled substances are regulated under RCRA only when they are blended with hazardous wastes, such as when used solvents are incinerated. The incineration technologies approved by the Parties have been shown to be capable of achieving the 99.99 percent DE required by RCRA; however, the Parties do not specifically require that each of the technologies achieve such an efficiency. The Parties supported the recommendations of the Ad-Hoc Technical Committee on Destruction Technologies to require Code of Good Housekeeping procedures to be applied throughout a destruction facility.

2. Hazardous Organic NESHAP (HON) Regulations

Under some situations controlled substances are not covered by RCRA regulations, but may be covered by the HON regulations promulgated under section 112 of the Clean Air Act. The Agency published a final HON rule on April 22, 1994 (59 FR 19402), requiring companies to control toxic air emissions from chemical manufacturing processes. The HON regulates approximately 400 manufacturing processes associated with the Synthetic Organic Chemical Manufacturing Industry (SOCMI), as well as 7 non-SOCMI source categories. Section 112 of the Clean Air Act contains a list of 189 hazardous air pollutants (HAPS) of which a large portion are known to be emitted by the above-mentioned industries. Of those listed under section 112, the only substances controlled under Title VI of the CAA are methyl chloroform (MCF), carbon tetrachloride (CCL4) and methyl bromide (newly listed as a class I substance in the accelerated phaseout rule). The HON covers five kinds of emission points within such facilities where these substances are emitted, including process vents, wastewater streams, transfer operations, storage tanks, and equipment leaks. The Agency requires that emission points be controlled with a ''reference control technology'' with specific applicability criteria, such as a 98 percent control efficiency for incinerators on process vents. The HON establishes performance standards for operating the control technologies, as well as criteria for the design of the control equipment. The Agency established that when organic HAPS are released through process vent sources, companies may route these emissions to a gaseous/fume oxidation incinerator for destruction. The Agency has determined that such incinerators may operate with a destruction efficiency of 98 percent.

The final accelerated phaseout regulation states that when regulations promulgated under section 112 of the Clean Air Act apply to the destruction of a controlled substance, and RCRA regulations do not apply, and the 98 percent destruction efficiency is achieved by incinerators to which emissions of controlled substances are routed, the Agency will grant the full allotment of allowances to replace chemicals that are destroyed under the conditions of the HON. In situations where section 112 regulations apply, but an achieved destruction efficiency is less than the 98% that the HON requires, the Agency will issue allowances only for the portion actually destroyed.

F. Amendments to the Final Labeling Regulations—Products Exempt from Labeling Requirements Where Manufacturers Use Protocol-approved Destruction Technologies

1. Notice of Propsed Rulemaking

The ultimate goal of Title VI of the CAA is to minimize depletion of stratospheric ozone. A destruction exemption, which would recognize, and provide an incentive for, the elimination of emissions of controlled substances through the use of approved destruction technologies, is therefore consistent with the goals of Title VI. This exemption is one method of reducing risks of ozone depletion. The initial labeling regulations published on February 11, 1993 provide an exemption from the labeling requirements if a controlled substance used to manufacture a product is transformed, such that the controlled substance no longer poses a threat to the ozone layer; similarly, the same result comes about if a controlled substance used in the manufacture of a product is destroyed. The controlled substance is not emitted in either case and no environmental harm occurs through exempting such products from labeling.

EPA proposed that for any products manufactured with a class I or class II substance, if that substance is destroyed according to any applicable legal or regulatory requirements, using one of the five technologies approved by the Parties to the Protocol, the product would be exempt from the labeling requirements.

The Agency further proposed that the labeling exemption would apply only where a substance is destroyed to a DE of 98 percent or greater, using one of the five approved destruction technologies. A definition of ''completely destroy,'' which means to destroy to 98 percent or greater destruction efficiency, using one of the five approved technologies, was included in the proposed rulemaking. Therefore, the proposed threshold at which labeling is exempted is for those products manufactured with controlled substances that are ''completely'' destroyed.

Furthermore, EPA proposed that where the destruction of a controlled substance is regulated under RCRA, the regulated party must achieve a destruction efficiency of 99.99 percent, destroying any controlled substances using one of the five approved technologies and complying with applicable RCRA regulations as they relate to destruction of ozone-depleting substances, in order to qualify for the exemption from labeling. If the destruction of a controlled substance is not regulated under RCRA but is regulated under the HON, the regulated party must achieve a destruction efficiency of 98 percent, as well as meet any other applicable standards imposed by the HON that relate to destruction of ozone-depleting substances, destroying any controlled substances using one of the five approved technologies, in order to qualify for the exemption from labeling.

The Agency is aware that state air quality permit laws may establish efficiency standards for emissions of controlled substances where no Federal regulations exist to cover them. In addition, state laws may be more stringent than comparable Federal regulations. In either case, the Agency

stated in the proposal that it expects companies that are regulated under such state laws governing the control of emissions of controlled substances in industrial processes to be in full compliance with such laws.

EPA also proposed that those companies that are not covered by either RCRA regulations or the HON must follow the Code of Good Housekeeping Practices, as described in the UNEP Ad-Hoc Technical Advisory Committee on ODS Destruction Technologies, as well as the whole of Chapter 5 of that report, in addition to meeting the 98 percent DE, using one of the five approved destruction technologies.

The UNEP Ad-Hoc Technical Advisory Committee on ODS Destruction Technologies recommends that atmospheric releases of controlled substances shall be monitored at all facilities with air emission discharges. For controlled substances, that report recommends that flow meters or continuously recording weighing equipment for individual containers should be used. At a minimum, containers should be weighed ''full'' and ''empty'' to establish quantities destroyed.

While there are no recordkeeping requirements specifically associated with the destruction exemption from labeling, the accelerated phaseout regulations (58 FR 65018) provide that companies relying on the destruction provisions of that rule must maintain records of destruction. For those companies, these same records will be consulted in inspecting eligibility for the destruction exemption from labeling. For manufacturers that do not receive production or consumption allowances, records required under other relevant regulations that determine the amount destroyed, the destruction efficiency, and the performance standards of operation must be made available to EPA upon request.

2. Response to Comments

The Agency requested comments on its proposal to exempt products from the labeling requirements where controlled substances used to manufacture the product are destroyed according to the criteria proposed by EPA. One commenter supported the use of destruction efficiencies that will be set in the HON, in instances where RCRA standards do not apply.

A commenter questioned the inclusion of the references to state regulations in this proposal because, according to the commenter, it makes EPA an enforcer of state laws and can potentially add federal penalties to state penalties assessed as a result of an inadvertent violation of a state law. EPA has removed the references to state regulations from the definition of ''completely destroy'' (§ 82.104(c)). It is not the Agency's intent to enforce state regulations, though EPA of course expects compliance with these laws.

Nine commenters agreed with the proposed destruction exemption requirements. However, several commenters requested an expanded definition of destruction technologies to include technologies not listed as one of the five acceptable destruction technologies outlined by the Montreal Protocol Parties. EPA disagrees with these requests. The intent of the destruction exemption under the labeling rule is to credit processes that emit trace quantities or no quantities of class I substances. As a Party to the Protocol, EPA believes that the U.S. should not expand the destruction exemption beyond the list of destruction technologies approved by the Parties. The five technologies approved by the Parties have been carefully reviewed and have been found to protect the environment from the harm caused by the release of control substances. EPA believes that no other technologies should be included until the Parties have reviewed such technologies and been assured of their safety. As the Parties review and approve additional technologies, EPA will explore expanding its list under these regulations. However, today's rulemaking will cover only those five destruction technologies approved by the Parties to the Protocol.

One commenter requested clarification that off-site destruction can qualify for this exemption. It is the Agency's intent to include off-site destruction as part of the destruction exemption. That same commenter requested that EPA make the UNEP Report available through the SPD hotline. Chapter 5 of the UNEP Report is currently available through the SPD hotline and can be found in Air Docket A–91–60.

3. Today's Rule

In light of the above discussion, EPA establishes in today's rule the destruction exemption as proposed in the December 30, 1993 Federal Register. Today's action specifies that those persons using a controlled substance in their manufacturing process, but then completely destroying that substance using one of the five approved destruction technologies, are exempt from labeling the product.

III. Labeling Requirements of Containers of Waste

A. Initial Requirements for Containers of Controlled Substance Waste and Wastes Containing Trace Amounts of Controlled Substances

EPA indicated in the final labeling regulations that a person handling containers of waste that contain class I or class II substances destined for incineration would benefit from the specific chemical information in the warning statement when handling. Though the label does not specifically address handling practices of such substances, it would inform technicians handling the containers of chemicals and would encourage them to dispose of them or recycle them correctly. In addition, containers of waste can be introduced into interstate commerce and must then be labeled as ''containing'' a controlled substance.

Under the initial final rule, EPA also required that containers of such waste materials destined to be recycled or reclaimed bear the warning statement to ensure that the technician of a reclamation facility is aware of the substances contained in order to exercise proper caution. Reclaimed substances are also resold by the reclaimer, and thus are required under the current rule to be labeled upon their introduction into interstate commerce.

The Agency did not require in its original final rule that empty containers that once contained a controlled substance and are subsequently recycled and incorporated into another product bear a label. The original rule also permitted the removal of a label on a container that no longer contains a controlled substance. If such a container is subsequently charged with a class I or class II substance, a label is be required. Also, the final rule excluded containers, such as trucks, railroad cars, or crates, used to transport a ''product containing'' or ''container containing'' from the labeling requirements, because only the immediate container holding the controlled substance must be labeled.

B. Proposed Labeling Requirements of Containers of Regulated Waste

After the promulgation of the original labeling regulations, EPA received new information from the regulated community regarding the labeling requirements for containers of waste. The Agency required labeling of waste in the original labeling rule because it believed that the labeling information would be important to waste handlers and recycling and reclamation facilities. In addition, by requiring waste to be

labeled, EPA attempted to encourage industry to minimize the amount of controlled substances in the waste stream and ultimately in the upper stratosphere. For this reason, the preamble to the original rule stated that all amounts, including trace quantities of controlled substances in waste, trigger the labeling requirements. The regulated community commented to EPA following publication of the final rule, addressing both the final rule and applicability determinations prepared by EPA on labeling of waste. Written comments on the Agency's treatment of waste and the relevant applicability determinations are available in the Air Docket A–91–60.

As a result of these comments, EPA proposed revisions to its original position on labeling waste containing controlled substances, in order to better facilitate industry's compliance with the regulations. The revisions that were proposed on December 30, 1993 are summarized below.

EPA stated in the notice of proposed rulemaking that containers of waste cannot be defined as products, ''because they are not manufactured from raw or recycled materials in order to perform a specific task, nor does waste encounter a point of sale to an ultimate consumer.'' The Agency also stated that a container (such as a dumpster or a barrel) carrying a ''product containing'' which is ultimately disposed of or incinerated, such as a can of adhesive or foam scrap, does not fall within the definition of ''container containing.'' Therefore, waste materials containing controlled substances are not required to be labeled under these regulations.

EPA also believes that containers of class I or class II waste do not fall under the definition of ''container containing,'' in that the waste is not ''intended to be transferred to another container, vessel or piece of equipment in order to realize its intended use.'' EPA's intention in including ''intended use'' in its definition was to target items to be consumed, thus giving consumers information on which to base a purchase decision. Waste is neither purchased nor ''used'' and thus, does not fall into the category of items to be consumed. In order to make this clear, EPA proposed a new § 82.106(b)(3) of the regulatory text, which includes ''waste containing controlled substances or blends of controlled substances bound for discard'' in the list of exemptions from warning label requirements. EPA also proposed a definition of ''waste,'' for purposes of this rule, that includes items or substances discarded with the intent that they will serve no further useful purpose. The term discarded can include being deposited in a landfill, being destroyed in an incinerator or chemical process, or undergoing some other type of final waste handling. Consequently, waste that is going to be discarded is not required to be labeled under this rulemaking.

Furthermore, the Agency stated that it believes that there is not a significant environmental benefit associated with labeling wastes of controlled substances. The labeling rule lays out requirements that will affect consumers' decisions, and thus, manufacturers' production decisions upstream. A label applied to the product(s) manufactured with or containing a controlled substance will provide such information to the consumer. Duplicating efforts by labeling the waste from a product that no longer serves its useful purpose has no influence on purchasing or consumer decisions, since waste is neither purchased nor used. Since waste is not a consumer item, a waste handler, whose business it is to handle all types of unwanted materials, would not be dissuaded from accepting a certain waste because of its effect on the ozone layer.

However, EPA stated that it believes that containers that contain used or contaminated controlled substances, such as some refrigerants, methyl chloroform, carbon tetrachloride, other CFCs and HCFCs, and blends of controlled substances that are bound for recycling or reclamation do fall under the definition of ''container containing.'' These substances will be transferred to realize their ''intended use'' and will later be used by consumers. Consequently, EPA proposed to continue requiring these containers to be labeled and did not propose such containers to be exempt from such requirements under this amendment. Such quantities are easily identifiable and are often recycled or reclaimed for manufacture or use in new products which would in turn require the mandated warning statement. Therefore, EPA stated that it believes that the mandated warning statement is warranted on containers of contaminated (or used) controlled substances and blends of controlled substances when they are introduced into interstate commerce for purposes of recycling or reclamation.

Because of the demand for and the high cost of controlled substances, EPA stated that it further believes that those using controlled substances will recycle or reclaim rather than discard them. Regulations promulgated pursuant to sections 608 and 609 of the Clean Air Act require recovery and recycling of refrigerants; efficient management of other uses of controlled substances would preclude discarding as a prudent option. In cases where these substances cannot be reused, recycled, or reclaimed, they are most often destroyed rather than deposited in a landfill or disposed in some other manner that would allow emissions of the substance. As hazardous wastes, carbon tetrachloride, methyl chloroform, and methyl bromide cannot be placed in a landfill, these chemicals most often are incinerated if not reused. Additionally, no non-containerized liquid wastes can be placed in landfills.

C. Response to Comments

One commenter requested clarification of the definition of discard. Another commenter requested that the definition of discard be included in the preamble. EPA has defined discarding to include depositing in a landfill, destroying in an incinerator or chemical process, or undergoing some other type of final waste handling that does not include re-use, recycling, or reclamation. The use of the term ''discard'' is meant to differentiate that which will no longer be used in any manner because of landfilling or incineration, from that which will undergo some type of change or treatment to make it appropriate for further use.

Two commenters requested an exemption for scrap foam and scrap disposal products destined for recycling, while another commenter sought clarification for products containing other controlled substances that are bound for recycling. EPA's intent in the proposed amendment was not to require labeling of scrap foam, either destined for discard or for recycling. Rather, the Agency states that the warning statement is required on containers of used controlled substances and blends of controlled substances that are introduced into interstate commerce for purposes of recycling or reclamation. Containers of actual controlled substances or blends of controlled substances (i.e. bulk containers of actual chemical substances) can be distinguished from products that themselves contain controlled substances. The latter do not require labeling when disposed in any fashion (including recycling or reclamation).

Two commenters stated that EPA should exempt waste products destined for destruction in a cement kiln or burned for energy recovery. In the final accelerated phaseout rule (58 FR 65018), EPA responded to comments by making clear that destruction of class I substances in one of the five approved

destruction technologies, which provides energy recovery as a by-product of the destruction process, would fall under the definition of destruction for purposes of the labeling exemption for waste. Energy recovery through the use of one of the five approved technologies does not disqualify a product manufactured with a class I substance that is destroyed by that technology from the labeling exemption. This remains consistent with the accelerated phaseout rule. A parallel situation exists when waste fuel is blended for purposes of providing auxiliary fuels for destruction facilities. When these fuels are intended to use one of the five approved destruction technologies for energy recovery, the waste fuels do not require labeling under today's rule. In either case, waste bound for energy recovery does not require labeling because it uses an incineration process and is ultimately destroyed.

Several commenters agreed with the proposed exemption for waste bound for discard; however, these commenters stated that the Agency should expand the definition of waste to be consistent with RCRA, which includes in its definition substances to be recycled. The purposes of the definition of waste under RCRA and under the labeling rule are very different. RCRA ensures that all hazardous waste materials, whether they are recycled, reclaimed, landfilled, incinerated, or otherwise disposed, are properly handled. The purpose of the labeling rule, however, is to provide purchasers with information upon which to make purchasing decisions. Therefore, since substances that are recycled continue to be passed through the stream of commerce to the ultimate consumer, who should know of its contents, bulk containers of these recycled substances require labeling.

One of these commenters added that reclamation/recovery facilities are not consumers, and therefore do not serve the intent of the labeling rule which is to provide consumers with information upon which to make purchasing decisions. As stated above, recycled waste continues to be subject to labeling requirements because it is part of the stream of commerce and reclaimers are not considered ultimate consumers.

Another of these commenters stated that waste generators may not know how waste will be disposed of, therefore it would be difficult properly label waste and that warning labels on wastes may discourage recycling. EPA believes that since waste generators make the decision of where products are to be sent, they therefore have both control and knowledge of waste disposal methods. Additionally, it is the intent of the labeling rule to encourage recycling efforts as waste handlers realize the benefits of additional availability and supply of recycled substances.

Another commenter requested further clarification on how an exemption applies to waste products bound for discard when they enter interstate commerce. The labeling rule draws distinctions based on materials that fall under the definition of ''container containing'' that are introduced into interstate commerce. Substances to be recycled and reclaimed that are introduced into interstate commerce fall under the definition of ''container containing'' under the labeling rule. As outlined in the original rule, substances are defined as ''container containing'' if they must be transferred to another container to realize their intended use by consumers. Because recycled and reclaimed substances must be transferred to other containers before continuing in the stream of commerce, labeling is required for such substances under today's rule. On the other hand, substances bound for discard (including destruction), are not ''containers containing'' under the labeling rule, because they are not ''intended to be transformed to another container in order to realize [their] intended use.''

D. Today's Rule

While it could be argued that requiring the labeling of waste provides valuable information about the contents of a waste to the handler, other regulations provide for similar information to be conveyed. For example, any waste considered to be hazardous (which includes carbon tetrachloride, methyl chloroform, and methyl bromide) must have its contents reported on the manifest required to accompany the waste under the Resource Conservation and Recovery Act (RCRA). Furthermore, EPA believes that the intent of the section 611 labeling provisions is to provide consumers with information upon which to make purchasing decisions, rather than to inform persons of contents for purposes of handling a substance, product or waste.

In summary, the Agency recognizes that waste should not be defined as a product under these regulations, nor should containers of waste be regarded as containers containing controlled substances, because they are not ''intended to be transferred to another container, vessel or piece of equipment in order to realize its intended use.'' Consequently, as proposed, EPA adds in today's rule a new 82.106(b)(3), which provides exemptions from the labeling requirements, to include, ''Waste containing controlled substances or blends of controlled substances bound for discard.'' EPA emphasizes, however, that containers of used or contaminated controlled substances or of blends of these controlled substances that enter into interstate commerce and that are bound for recycling or reclamation are not proposed to be exempted, and thus would continue to require labeling. The definition of ''waste'' for purposes of this rulemaking means, ''items or substances that are discarded with the intent that such items or substances will serve no further useful purpose.''

IV. Labeling Requirements for Spare Parts to be Used Solely for Repair

A. Proposal

The original labeling rule did not require a product which has already been purchased and used to be labeled if the product components were manufactured with a controlled substance or a controlled substance was used in the repair itself. EPA believes that such a product is not being introduced into interstate commerce since the product is already owned by the ultimate consumer. In a product labeling applicability determination, (Letter from John Rasnic, Director EPA Stationary Source Compliance Division, to Michael Conlon, dated April 19, 1993 and Section 611 Applicability Determination Record Number 6, dated April 20, 1993), following the promulgation of the final rule, EPA clarified that the repair provision of the rule allows the repair of a product using a component manufactured with an ODS or using an ODS in the repair of the product without triggering labeling requirements.

Subsequent to promulgation, the Agency has received new information from several companies regarding spare parts that are intended for repair purposes only. Many companies who distribute spare parts stock up to several million of these parts in inventory purchased from vendors. These companies then sell these spare parts piecemeal to persons who repair original products. Due to the pass-through exemption for persons incorporating a product manufactured with a controlled substance that was purchased from a supplier, and due to the applicability determination regarding repairs, the repair person would not be required to label the repaired product. To require companies that order spare parts in bulk from suppliers to pass through labeling information with each order—perhaps containing several hundred individual

spare parts from numerous bulk shipments—is exceedingly burdensome to those companies purchasing and selling the spare parts. Typically, the bulk shipment will be labeled on a shipping crate or an invoice to indicate that the parts within that shipment were manufactured with a controlled substance. The company ordering the spare parts breaks down the shipment into bins, currently necessitating a label or labeling information to be generated for each individual part contained in that shipment. In most cases, a repair person purchases hundreds of various individual spare parts at a time from the company, making the pass-through of any labeling information extremely cumbersome and time-consuming.

Many of the original manufacturers of these spare parts are foreign manufacturers, exacerbating the burden of tracking the use of controlled substances in the manufacture of each spare part in inventory. Developing and maintaining inventories of these spare parts is extremely costly, often many times more costly than the sale price of the spare parts themselves.

EPA's decision not to require manufacturers incorporating products manufactured with controlled substances to comply with the labeling pass-through requirement was based in part on the overwhelming tracking burden imposed in determining which components were actually made using a controlled substance. A similar situation exists for those purchasing spare parts for repair purposes. Many distributors stock hundreds of thousands of spare parts to be sold to repair persons. The burden of tracking each part that is to then be sold to a person using that part for repair—which is exempted from the labeling requirements—becomes overwhelming and is without environmental benefit.

Furthermore, the repair person has specific requirements for a spare part that will work with the existing product to be repaired; consumer discretion on his or her part based on the use of an ODS is unlikely. Because the repair person is not required to pass through any labeling information in the repair of the product, requiring the labeling of spare parts themselves serves no environmental benefit. Additionally, numerous companies that stock spare parts for the repair of their products have themselves totally stopped using controlled substances and are currently encouraging suppliers to use safe alternatives in manufacturing spare parts that they purchase.

In light of the information above, EPA proposed that purchasers of spare parts manufactured with a controlled substance and purchased from a vendor for the sole purpose of repair, or distributed for purposes of repair only, not be required to pass through the labeling information.

B. Response to Comments

EPA requested comments on its proposal to exempt from the label pass-through requirement those spare parts that are to be used for repair purposes. Nine commenters agreed with the proposed spare parts exemption.

One commenter suggested EPA exempt repair parts that contain a de minimis amount of class I chemicals. The final labeling regulation states that products containing a class I substance and containers containing a class I or class II substance bear warning labels. Because spare parts containing these substances clearly fall in the category of ''products containing,'' they are required to be labeled. However, products containing trace quantities of a class I substance as an impurity or a residue, where the controlled substance serves no useful purpose in the product, are exempted from the labeling requirements.

Two commenters stated that the labeling exemption for spare parts should apply to manufacturers as well as others involved in the distribution process because tracking and labeling requirements for these spare parts is exceedingly burdensome and time consuming. EPA disagrees with the statement that labeling of these products by the original manufacturer represents an undue burden. Tracking and labeling spare parts made with a controlled substance by the original manufacturer is comparable to that of any other manufacturer of products which require labeling. Therefore, pass-through exemptions from labeling, which does not include manufacturers, will remain as proposed.

One of these commenters added that there are instances where ''currently or potentially available'' alternatives have not been identified for specific applications. In this case, according to the commenter, labeling requirements for spare parts where alternatives have not been identified would penalize that industry. The original final regulations provide for exemptions from labeling requirements for products manufactured using a class I substance where there are no substitute products or processes that 1) do not rely on the use of class I substances, 2) reduce the overall risk to human health and the environment, and 3) are currently or potentially available. Manufacturers whose products meet this criteria can apply to EPA for an exemption from labeling requirements as outlined in the original final in the section marked Petitions (§ 82.120).

Another commenter requested clarification that the exemption applies to wholly-owned subsidiaries of the manufacturers of spare parts and that individual packages that arrive under one airway bill with alternative labeling are not subject to labeling upon entry into the country. The original rule states that wholly-owned subsidiaries are part of a parent company and are subjected to the labeling regulations; therefore, the spare parts exemption also applies to these wholly-owned subsidiaries. Additionally, if a consolidated shipment is properly labeled using an alternative label, then individual packages within that shipment do not require labeling. For spare parts that fall under the exemption established in today's rulemaking, importers and distributors are only required to pass through the label when moving the labeled shipments as packaged by the manufacturer.

C. Today's Rule

In summary, EPA establishes in today's rule that purchasers of spare parts manufactured with a controlled substance and purchased from a vendor for the sole purpose of repair, or distributed for purposes of repair only, not be required to pass through the labeling information. EPA wishes to emphasize that this exemption to the pass-through requirement does not apply to products containing a controlled substance or containers of controlled substances, nor does it apply to spare parts used to manufacture products. Manufacturers of spare parts made with controlled substances are still required to apply the appropriate labels. Moreover, importers and distributors moving the labeled shipments as packaged by the manufacturer must still pass through the labeling information.

V. Clarification of the Meaning of Products ''Manufactured With''

The original final rule discussed the applicability of the labeling requirements for products *manufactured with* controlled substances. Some confusion over when labeling is required for such products has emerged since the publication of that final rule. The following discussion should clarify such labeling questions.

In reviewing whether a product must be labeled, one must examine from two perspectives. Is labeling required because it is a product ''containing'' a controlled substance? If not, is labeling then required because it is a product

''manufactured with'' a controlled substance?

The final rule states that a controlled substance that is inadvertently produced or remains as a residue from a chemical reaction, leaving trace quantities of that substance in the final product, does not trigger the labeling requirements. However, there may be cases where a product is exempt from being labeled a product ''containing'' (in this case because it is only present in trace quantities), but where a product may still require labeling because it is considered to be ''manufactured with'' that controlled substance.

The introduction of carbon tetrachloride as an explosion suppressant in the manufacture of certain chemicals serves as an example. The carbon tetrachloride is introduced, then withdrawn from the chemical product. Trace quantities of the carbon tetrachloride remain in the chemical; however, such quantities serve no useful purpose in the final product. As a result, the product is exempt from being labeled as a product containing carbon tetrachloride. However, because the carbon tetrachloride is introduced into the chemical product directly in the manufacturing process, actually having physical contact with the product, the product would need to be labeled as ''manufactured with'' carbon tetrachloride, unless other exemptions apply.

In order to be consistent with this view, EPA proposed to revise the definition of ''manufactured with.'' The original regulations stated that a product is manufactured with a controlled substance if the manufacturer used a controlled substance directly in the product's manufacture, ''but the product itself does not contain a controlled substance at the point of introduction into interstate commerce.'' However, to further clarify that trace quantities may actually be contained in a product manufactured with a controlled substance, EPA proposed to revise the definition of ''manufactured with,'' to state that a product ''does not contain more than trace quantities of the controlled substance.* * *''

Six commenters agreed with these proposed changes. One commenter disagreed with EPA's position that carbon tetrachloride should trigger labeling unless the substance is subsequently destroyed or transformed, because the carbon tetrachloride is withdrawn from the product and only trace quantities remain. EPA supports it's original position, based on the fact that the introduction of carbon tetrachloride, which is used on a routine basis, constitutes use as part of the direct manufacturing process. As a result, today's rule establishes the modified definition of ''manufactured with'' as proposed.

VI. Exemption for Trace Quantities

The preamble to the original labeling rule discussed the applicability of the labeling requirements for products *containing trace quantities* of controlled substances. However, some confusion over when labeling is required for such products has arisen since the publication of that rule.

The regulatory text in section 82.106, referring to the warning statement requirements, lists certain exemptions from these requirements. The first of these addresses ''Products in which trace quantities of a controlled substance remain as a residue or impurity.* * *'' EPA has determined that a trace quantity *remaining* in a product can only be *contained within* a chemical product; therefore, it is logical that this exemption specifically applies to products ''containing'' rather than products ''manufactured with.'' Products that are manufactured using a controlled substance, but that contain only trace quantities of the substance, are not required to be labeled as a ''product containing''; however, they are required to be labeled as a ''product manufactured with.'' To clarify this point, EPA proposed to amend section 82.106(b)(1), which provides exemptions from the labeling requirements, to read: ''Products *containing* trace quantities of a controlled substance remaining as a residue or impurity due to a chemical reaction, and where the controlled substance serves no useful purpose in or for the product itself.'' However, if such a product was manufactured using the controlled substance, such product is required to be labeled as a ''product manufactured with'' the controlled substance.

There was also some confusion as to whether a container containing a trace amount of a controlled substance must be labeled. EPA understands that to determine whether a container contains a trace amount of a controlled substance, where such a determination falls outside of normal procedures, may be difficult and costly. For example, a container of a non-controlled substance that may hold a trace amount of a controlled substance as an impurity of the manufacturing process would be subject to labeling under current labeling requirements. As a product, however, that same container would be exempt from the labeling requirements. In many cases, expensive testing must be conducted to determine if a trace quantity of the controlled substance is in fact contained in the container. Requiring the labeling of containers containing trace quantities of a controlled substance is inconsistent with the trace quantities exemption of the current labeling rule and with the intent of the Agency to require labeling of ''containers of'' controlled substances.

EPA received three comments agreeing with the exemption for trace quantities. One commenter asked for clarification of the definition of trace quantity. Another commented that trace quantities should be defined with a quantifying limit above which labeling would be required. Another commenter recommended that EPA publish guidance on what constitutes a ''trace quantity'', and suggests using analytical detection limits for the exemption level. Because the labeling rule covers a multitude of substances, products, and volumes, EPA believes it cannot responsibly put forth a standardized threshold for ''trace quantity.'' However, EPA believes that the term ''trace amounts'' should be interpreted consistently with *Webster's Ninth New Collegiate Dictionary* (copyright 1990), which defines trace amounts to mean ''a chemical element present in minute quantities.'' Reasonable interpretations of what constitutes a trace amount will likely be parallel to reasonable interpretations made by EPA. EPA is today revising its regulations, as proposed, to make the exemption clear. EPA will add the new 82.106(b)(2), (discussed above), stating that containers containing trace quantities of a controlled substance, which remain as a residue or impurity, are exempt from the labeling requirements.

VII. Labeling Requirements of Containers of 55 Gallons and Smaller Containing Controlled Substances

The original labeling regulations indicated that the use of supplemental printed material may be used to label containers of controlled substances that are larger than 55 gallon drums, as long as the information is viewed at the time of purchase or time of delivery, provided the purchase is not considered complete until delivery is accepted. EPA reasoned that such information, rather than the containers themselves, is usually viewed by the recipient of such containers. The regulations also indicated that the warning statement must be placed directly on containers of controlled substances that are smaller than 55 gallon drums.

EPA proposed in the December 30, 1993 amendment that supplemental printed material may also be used to

convey the warning statement for containers that are 55 gallons and smaller. EPA requested comment on its proposal to allow alternative placement of warning statements on 55 gallon or smaller containers. Seven commenters agreed with this proposed change with no requests for additional information or clarification. Consequently, EPA is revising section 82.108 (c) of its labeling regulation to strike ''larger than a 55 gallon drum'' from the provision allowing alternative placement of the warning statement on containers of controlled substances.

VIII. Definition of Importer

For purposes of section 611, EPA clarifies that importers of ''products manufactured with controlled substances'' are included in the definition of ''importer.'' While the intent of the § 611 regulations was to cover imports of products manufactured with class I substances, the original definition did not explicitly include such a phrase. This came about as an oversight in transferring the definition from the phaseout regulations, where imports of containers and products containing controlled substances are regulated. Section 611 clearly mandates that ''products manufactured with controlled substances'' be labeled before they are introduced into interstate commerce. Therefore, for purposes of the labeling requirements and consistency with the statute, the definition of ''importer'' under section 611 is amended to include the phrase ''products manufactured with.''

One commenter stated that the requirement to apply labels for imported products at the border is highly impractical, burdensome, time consuming and costly. While this issue, however, was not addressed in the proposed labeling amendments, EPA wishes to clarify that importers are responsible for ensuring that labels are properly affixed, but the labeling regulations do not require that the label can only be affixed at the border. The requirements may equally be met by ensuring that the label is affixed before the product reaches the border. The importer may negotiate with its supplier to ensure that labels are affixed prior to shipment. No other comments were received; the change in the definition of ''importer'' is established in today's rule, as proposed.

IX. Certification Requirements for Reduced Use Exemption

In section 82.122, EPA states that companies that reduced their use of CFC–113 and/or methyl chloroform (MCF) by 95 percent or greater over their 1990 usage level could certify the reduction in writing to EPA and be exempt from the labeling requirements. In addition to other requirements for inclusion in the written certification, the regulations require that persons certifying to EPA must state that they will not exceed 5 percent of their 1990 use following the certification; however, the statement conveyed was numerically and grammatically incorrect. It reads: ''Persons certifying must also include a statement that indicates that their future annual use will not at no time exceed 95 percent of their 1990 usage'' (p. 8169).

EPA corrects this section of the regulations to state that a company must certify to EPA that its future use will not exceed 5 percent of its 1990 usage without notifying the Agency. Such notification would immediately result in labeling of the company's products. This subpart (§ 82.122 (a)(4)) would thus read: ''Persons certifying must also include a statement that indicates their future annual use will at no time exceed 5 percent of their 1990 usage.''

X. Imports and Products Introduced In Bond at the U.S./Mexico Border

The original labeling regulations state that products or containers introduced ''in bond'' at the Mexico border are not considered to be ''imports.'' However, the preamble states that such products or containers are being introduced into U.S. interstate commerce and are therefore subject to the labeling requirements.

EPA proposed in its December 30, 1993 amendment that all products and containers subject to the labeling requirements that are made or charged in Mexico and subsequently brought into the U.S. must be labeled at the border where they are being introduced into U.S. interstate commerce. In order to facilitate enforcement of this rule, the Agency only requires that warning labels be placed on regulated products and containers at the border by persons introducing them into U.S. interstate commerce, rather than at the manufacturing facility in Mexico. However, the importer may contract with the Mexican manufacturer to provide the applicable warning statement prior to shipping.

This change supersedes EPA's reference to products or containers admitted in bond in the original labeling rule, since for purposes of the labeling requirements, the regulated products and containers are in fact being treated as ''imports.'' This change makes the definition of import somewhat different from that in the final phaseout regulations. For purposes of the phaseout regulations, it is appropriate to exempt such products of U.S. origin that are brought back into the U.S. from Mexico in bond from the definition of import because allowances have already been expended and additional consumption allowances should not be required to bring these products back into the U.S.

However, it is appropriate and consistent with the intent of § 611 to require labeling of these imported goods, since labeling is to occur regardless of whether the product is distributed domestically or imported. The Agency therefore is striking from the definition of ''import'' in section 82.104 (j) of the labeling regulation the exemption for bringing controlled substances, containers of, or products manufactured with, controlled substances into the U.S. from Mexico where such substance, container or product was admitted into Mexico in bond and is of U.S. origin. EPA requested and received no comments on the changes and consequently they remain in today's final regulation.

In addition, EPA notes that the preamble to the original labeling rule contained an inaccuracy in describing an arrangement regarding products brought from Mexico into the United States inbond. The preamble stated that, ''Under the Maquiladora Agreement, the United States and Mexico established a free-trade zone along a segment of the U.S./Mexico border.'' There is no formal agreement as such between the two countries in this regard; rather, an arrangement exists, primarily under Mexican law, whereby controlled substances crossing the border from the U.S. into Mexico ''inbond'' (under a bond ensuring that the substance will remain in Mexico only temporarily) will be returned to the U.S., without being subject to Mexican import tariffs. In addition, the preamble to the original rule stated that ''products are permitted to be transported across [the Maquiladora] zone without any U.S. Customs restrictions being imposed.'' This statement is misleading in that U.S. Customs does assist EPA in monitoring compliance with and enforcing U.S. environmental laws that generally apply without distinction to Maquiladora products. The preamble to the final rule should therefore be read to reflect these corrections. EPA requested comments on these corrections and received none. Consequently, the changes remain as proposed.

XI. Incidental Uses of Controlled Substances

In the original final regulations, the definition of ''manufactured with''

excluded the use of a controlled substance ''Where the manufacturing equipment has had physical contact with a controlled substance in an intermittent manner, not as a routine part of the direct manufacturing process * * *'' (See p. 8165). The preamble gave as an example the occasional cleaning of an ink plate, where direct contact occurs only between the controlled substance and the manufacturing equipment, not between the controlled substance and the product itself (other than the first one or two products going through the equipment following equipment maintenance). However, the preamble, in addressing this point, specifically noted that this exclusion should also apply in the case of a controlled substance having intermittent contact with the product itself, such as a textile where direct contact occurs through spot cleaning of some individual textiles, but where direct contact is not a normal or usual occurrence in the manufacture of the product.

The Agency intended for the regulatory text to reflect the full discussion in the preamble to the final rule. Therefore, EPA proposed to exempt from the labeling requirements products where there are intermittent uses of controlled substances that may involve an initial contact with the product itself, as well as with the equipment. The exception was proposed to read: ''[W]here the manufacturing equipment *or product* has had physical contact with a controlled substance in an intermittent manner, not as a routine part of the direct manufacturing process * * *'' EPA received no comments on this issue. EPA therefore will revise the regulatory text as proposed.

XII. Request for Comments Regarding Plasma Etching

In the preamble of the original labeling rule, EPA states that ''plasma etching'' is considered a process that entails transformation, and thus products manufactured using plasma etching need not be labeled, unless they are otherwise subject to the regulations.'' Since publication of the final rule, EPA has heard from one plasma etcher who has discovered that the plasma etching process may not necessarily transform all but trace quantities of controlled substances used in the process. At times, it is estimated that as much as 40 percent may not be transformed.

EPA has not received any additional comments on whether plasma etching can be considered generally to constitute transformation under the final labeling rule, which defines transformation as, ''to use and entirely consume a class I or class II substance, except for trace quantities, by changing it into one or more substances not subject to this subpart in the manufacturing process of a product or chemical.'' Consequently, without further data illustrating that plasma etching does or does not transform all but trace quantities, EPA cannot make any general statements about plasma etching; however, if a particular plasma etching process meets the requirements for ''transformation'', then the manufacturer need not label the product.

XIII. Miscellaneous

One commenter requested clarification on the requirements in the original rule (February 11, 1994), to list multiple class I or class II substances on a warning label (§ 82.110), and whether the word ''may'' implies that it is not mandatory to list all applicable substances. In situations where products are manufactured with or contain multiple substances, those substances must be represented on the warning label. These substances can be identified by either 1) listing them directly on the label, or 2) by using an asterisk (*) in place of the substance name with a corresponding list of those substances in a legible and conspicuous location. The word ''may'' is intended to imply the option to use of either of the above labeling alternatives, not to imply that labeling is not mandatory in cases where multiple class I or class II substances are used.

XIV. 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 lead to a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely and materially affect 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 amendment to the final rule 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 Act

The Regulatory Flexibility Act, 5 U.S.C. 601–602, requires that Federal agencies examine the impacts of their regulations on small entities. Under 5 U.S.C. 604(a), whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available for public comment an initial regulatory flexibility analysis (RFA). Such an analysis is not required if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, pursuant to 5 U.S.C. 605(b).

EPA believes that any impact that this amendment will have on the regulated community will serve only to provide relief from otherwise applicable regulations, and will therefore limit the negative economic impact associated with the regulations previously promulgated under Section 608. An examination of the impacts on small entities was discussed in the final rule (58 FR 28660). That final rule assessed the impact the rule may have on small entities. A separate regulatory impact analysis accompanied the final rule and is contained in Docket A–92–01. I certify that this amendment to the labeling rule will not have any additional negative economic impacts on any small entities.

C. Paperwork Reduction Act

Any information collection requirements in a rule must be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Because no additional informational collection requirements are required by this amendment, EPA has determined that the Paperwork Reduction Act does not apply to this rulemaking and no new Information Collection Request document has been prepared.

XV. Judicial Review

Under Section 307(b)(1) of the Act, EPA 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 in the United States Court of Appeals for the District of Columbia Circuit

within sixty days of publication of this action in the Federal Register. Under Section 307(b)(2), the requirements of this rule may not be challenged later in judicial proceedings brought to enforce those requirements.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Interstate commerce, Nonessential products, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: December 23, 1994.

Carol M. Browner,

Administrator.

Part 82, title 40, Code of Federal Regulations 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, 7671–7671(q).

2. Subpart E, consisting of §§ 82.100 through 82.124, is revised to read as follows:

Subpart E—The Labeling of Products Using Ozone-Depleting Substances

Sec.

Subpart E—The Labeling of Products Using Ozone-Depleting Substances

§ 82.100 Purpose.

The purpose of this subpart is to require warning statements on containers of, and products containing or manufactured with, certain ozone-depleting substances, pursuant to section 611 of the Clean Air Act, as amended.

§ 82.102 Applicability.

(a) In the case of substances designated as class I or class II substances as of February 11, 1993, the applicable date of the requirements in this paragraph (a) is May 15, 1993. In the case of any substance designated as a class I or class II substance after February 11, 1993, the applicable date of the requirements in this paragraph (a) is one year after the designation of such substance as a class I or class II substance unless otherwise specified in the designation. On the applicable date indicated in this paragraph (a), the requirements of this subpart shall apply to the following containers and products except as exempted under paragraph (c) of this section:

(1) All containers in which a class I or class II substance is stored or transported.

(2) All products containing a class I substance.

(3) All products directly manufactured with a process that uses a class I substance, unless otherwise exempted by this subpart or, unless the Administrator determines for a particular product that there are no substitute products or manufacturing processes for such product that do not rely on the use of a class I substance, that reduce overall risk to human health and the environment, and that are currently or potentially available. If the Administrator makes such a determination for a particular product, then the requirements of this subpart are effective for such product no later than January 1, 2015.

(b) Applicable January 1, 2015 in any case, or one year after any determination between May 15, 1993 and January 1, 2015, by the Administrator for a particular product that there are substitute products or manufacturing processes for such product that do not rely on the use of a class I or class II substance, that reduce the overall risk to human health and the environment, and that are currently or potentially available, the requirements of this subpart shall apply to the following:

(1) All products containing a class II substance.

(2) All products manufactured with a process that uses a class II substance.

(c) The requirements of this subpart shall not apply to products manufactured prior to May 15, 1993, provided that the manufacturer submits documentation to EPA upon request showing that the product was manufactured prior to that date.

§ 82.104 Definitions.

(a) *Class I substance* means any substance designated as class I in 40 CFR part 82, appendix A to subpart A, including chlorofluorocarbons, halons, carbon tetrachloride and methyl chloroform and any other substance so designated by the Agency at a later date.

(b) *Class II substance* means any substance designated as class II in 40 CFR part 82, appendix A to subpart A, including hydrochlorofluorocarbons and any other substance so designated by the Agency at a later date.

(c) *Completely destroy* means to cause the destruction of a controlled substance by one of the five destruction processes approved by the Parties at a demonstrable destruction efficiency of 98 percent or more or a greater destruction efficiency if required under other applicable federal regulations.

(d) *Consumer* means a commercial or non-commercial purchaser of a product or container that has been introduced into interstate commerce.

(e) *Container* means the immediate vessel in which a controlled substance is stored or transported.

(f) *Container containing* means a container that physically holds a controlled substance within its structure that is intended to be transferred to another container, vessel or piece of equipment in order to realize its intended use.

(g) *Controlled substance* means a class I or class II ozone-depleting substance.

(h) *Destruction means* the expiration of a controlled substance, that does not result in a commercially useful end product using one of the following controlled processes in a manner that complies at a minimum with the ''Code of Good Housekeeping'' of Chapter 5.5 of the United National Environment Programme (UNEP) report entitled, *Ad-Hoc Technical Advisory Committee on ODS Destruction Technologies*, as well as the whole of Chapter 5 from that report, or with more stringent requirements as applicable. The report is available from the Environmental Protection Agency, Public Docket A–91–60, 401 M Street, SW., Washington, DC 20460 The controlled processes are:

(1) Liquid injection incineration;

(2) Reactor cracking;

(3) Gaseous/fume oxidation;

(4) Rotary kiln incineration; or

(5) Cement kiln.

(i) *Distributor* means a person to whom a product is delivered or sold for purposes of subsequent resale, delivery or export.

(j) *Export* means the transport of virgin, used, or recycled class I or class II substances or products manufactured or containing class I or class II

substances from inside the United States or its territories to persons outside the United States or its territories, excluding United States military bases and ships for on-board use.

(k) *Exporter* means the person who contracts to sell class I or class II substances or products manufactured with or containing class I or class II substances for export or transfers such substances or products to his affiliate in another country.

(l) *Import* means to land on, bring into, or introduce into, or attempt to land on, bring into, or introduce into any place subject to the jurisdiction of the United States whether or not such landing, bringing, or introduction constitutes an importation within the meaning of the customs laws of the United States, with the exception of temporary off-loading of products manufactured with or containers containing class I or class II substances from a ship are used for servicing of that ship.

(m) *Importer* means any person who imports a controlled substance, a product containing a controlled substance, a product manufactured with a controlled substance, or any other chemical substance (including a chemical substance shipped as part of a mixture or article), 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 listed on U.S. Customs Service forms for the import;

(3) The actual owner if an actual owner's declaration and superseding bond has been filed; or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred.

(n) *Interstate commerce* means the distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or District of Columbia. The entry points for which a product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.

(o) *Manufactured with a controlled substance* means that the manufacturer of the product itself used a controlled substance directly in the product's manufacturing, but the product itself does not contain more than trace quantities of the controlled substance at the point of introduction into interstate commerce. The following situations are excluded from the meaning of the phrase ''manufactured with'' a controlled substance:

(1) Where a product has not had physical contact with the controlled substance;

(2) Where the manufacturing equipment or the product has had physical contact with a controlled substance in an intermittent manner, not as a routine part of the direct manufacturing process;

(3) Where the controlled substance has been transformed, except for trace quantities; or

(4) Where the controlled substance has been completely destroyed.

(p) *Potentially available* means that adequate information exists to make a determination that the substitute is technologically feasible, environmentally acceptable and economically viable.

(q) *Principal display panel (PDP)* means the entire portion of the surface of a product, container or its outer packaging that is most likely to be displayed, shown, presented, or examined under customary conditions of retail sale. The area of the PDP is not limited to the portion of the surface covered with existing labeling; rather it includes the entire surface, excluding flanges, shoulders, handles, or necks.

(r) *Product* means an item or category of items manufactured from raw or recycled materials, or other products, which is used to perform a function or task.

(s) *Product containing* means a product including, but not limited to, containers, vessels, or pieces of equipment, that physically holds a controlled substance at the point of sale to the ultimate consumer which remains within the product.

(t) *Promotional printed material* means any informational or advertising material (including, but not limited to, written advertisements, brochures, circulars, desk references and fact sheets) that is prepared by the manufacturer for display or promotion concerning a product or container, and that does not accompany the product to the consumer.

(u) *Retailer* means a person to whom a product is delivered or sold, if such delivery or sale is for purposes of sale or distribution in commerce to consumers who buy such product for purposes other than resale.

(v) *Spare parts* means those parts that are supplied by a manufacturer to another manufacturer, distributor, or retailer, for purposes of replacing similar parts with such parts in the repair of a product.

(w) *Supplemental printed material* means any informational material (including, but not limited to, package inserts, fact sheets, invoices, material safety data sheets, procurement and specification sheets, or other material) which accompanies a product or container to the consumer at the time of purchase.

(x) *Transform* means to use and entirely consume a class I or class II substance, except for trace quantities, by changing it into one or more substances not subject to this subpart in the manufacturing process of a product or chemical.

(y) *Type size* means the actual height of the printed image of each capital letter as it appears on a label.

(z) *Ultimate consumer* means the first commercial or non-commercial purchaser of a container or product that is not intended for re-introduction into interstate commerce as a final product or as part of another product.

(aa) *Warning label* means the warning statement required by section 611 of the Act. The term warning statement shall be synonymous with warning label for purposes of this subpart.

(bb) *Waste* means, for purposes of this subpart, items or substances that are discarded with the intent that such items or substances will serve no further useful purpose.

(cc) *Wholesaler* means a person to whom a product is delivered or sold, if such delivery or sale is for purposes of sale or distribution to retailers who buy such product for purposes of resale.

§ 82.106 Warning statement requirements.

(a) *Required warning statements.* Unless otherwise exempted by this subpart, each container or product identified in § 82.102 (a) or (b) shall bear the following warning statement, meeting the requirements of this subpart for placement and form:

WARNING: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(b) *Exemptions from warning label requirement.* The following products need not bear a warning label:

(1) Products containing trace quantities of a controlled substance remaining as a residue or impurity due to a chemical reaction, and where the

controlled substance serves no useful purpose in or for the product itself. However, if such product was manufactured using the controlled substance, the product is required to be labeled as a ''product manufactured with'' the controlled substance, unless otherwise exempted;

(2) Containers containing a controlled substance in which trace quantities of that controlled substance remain as a residue or impurity;

(3) Waste containing controlled substances or blends of controlled substances bound for discard;

(4) Products manufactured using methyl chloroform or CFC–113 by persons who can demonstrate and certify a 95% reduction in overall usage from their 1990 calendar year usage of methyl chloroform or CFC–113 as solvents during a twelve (12) month period ending within sixty (60) days of such certification or during the most recently completed calendar year. In calculating such reduction, persons may subtract from quantities used those quantities for which they possess accessible data that establishes the amount of methyl chloroform or CFC–113 transformed. Such subtraction must be performed for both the applicable twelve month period and the 1990 calendar year. If at any time future usage exceeds the 95% reduction, all products manufactured with methyl chloroform or CFC–113 as solvents by that person must be labeled immediately. No person may qualify for this exemption after May 15, 1994;

(5) Products intended only for export outside of the United States shall not be considered ''products introduced into interstate commerce'' provided such products are clearly designated as intended for export only;

(6) Products that are otherwise not subject to the requirements of this subpart that are being repaired, using a process that uses a controlled substance.

(7) Products, processes, or substitute chemicals undergoing research and development, by which a controlled substance is used. Such products must be labeled when they are introduced into interstate commerce.

(c) *Interference with other required labeling information.* The warning statement shall not interfere with, detract from, or mar any labeling information required on the labeling by federal or state law.

§ 82.108 Placement of warning statement.

The warning statement shall be placed so as to satisfy the requirement of the Act that the warning statement be ''clearly legible and conspicuous.'' The warning statement is clearly legible and conspicuous if it appears with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase. Such placement includes, but is not limited to, the following:

(a) *Display panel placement.* For any affected product or container that has a display panel that is normally viewed by the purchaser at the time of the purchase, the warning statement described in § 82.106 may appear on any such display panel of the affected product or container such that it is ''clearly legible and conspicuous'' at the time of the purchase. If the warning statement appears on the principal display panel or outer packaging of any such affected product or container, the warning statement shall qualify as ''clearly legible and conspicuous,'' as long as the label also fulfills all other requirements of this subpart and is not obscured by any outer packaging, as required by paragraph (b) of this section. The warning statement need not appear on such display panel if either:

(1) The warning statement appears on the outer packaging of the product or container, consistent with paragraph (b) of this section, and is clearly legible and conspicuous; or

(2) The warning statement is placed in a manner consistent with paragraph (c) of this section.

(b) *Outer packaging.* If the product or container is normally packaged, wrapped, or otherwise covered when viewed by the purchaser at the time of the purchase the warning statement described in § 82.106 shall appear on any outer packaging, wrapping or other covering used in the retail display of the product or container, such that the warning statement is clearly legible and conspicuous at the time of the purchase. If the outer packaging has a display panel that is normally viewed by the purchaser at the time of the purchase, the warning statement shall appear on such display panel. If the warning statement so appears on such product's or container's outer packaging, it need not appear on the surface of the product or container, as long as the statement also fulfills all other requirements of this subpart. The warning statement need not appear on such outer packaging if either:

(1) the warning statement appears on the surface of the product or container, consistent with paragraph (a) of this section, and is clearly legible and conspicuous through any outer packaging, wrapping or other covering used in display; or

(2) the warning statement is placed in a manner consistent with paragraph (c) of this section.

(c) *Alternative placement.* The warning statement may be placed on a hang tag, tape, card, sticker, invoice, bill of lading, supplemental printed material, or similar overlabeling that is securely attached to the container, product, outer packaging or display case, or accompanies the product containing or manufactured with a controlled substance or a container containing class I or class II substances through its sale to the consumer or ultimate consumer. For prescription medical products that have been found to be essential for patient health by the Food and Drug Administration, the warning statement may be placed in supplemental printed material intended to be read by the prescribing physician, as long as the following statement is placed on the product, its packaging, or supplemental printed material intended to be read by the patient: ''This product contains [insert name of substance], a substance which harms the environment by depleting ozone in the upper atmosphere.'' In any case, the warning statement must be clearly legible and conspicuous at the time of the purchase.

(d) *Products not viewed by the purchaser at the time of purchase.* Where the purchaser of a product cannot view a product, its packaging or alternative labeling such that the warning statement is clearly legible and conspicuous at the time of purchase, as specified under paragraphs (a), (b), or (c) of this section, the warning statement may be placed in the following manner:

(1) Where promotional printed material is prepared for display or distribution, the warning statement may be placed on such promotional printed material such that it is clearly legible and conspicuous at the time of purchase; or

(2) The warning statement may be placed on the product, on its outer packaging, or on alternative labeling, consistent with paragraphs (a), (b), or (c) of this section, such that the warning statement is clearly legible and conspicuous at the time of product delivery, if the product may be returned by the purchaser at or after the time of delivery or if the purchase is not complete until the time of delivery (e.g., products delivered C.O.D.).

§ 82.110 Form of label bearing warning statement.

(a) *Conspicuousness and contrast.* The warning statement shall appear in conspicuous and legible type by typography, layout, and color with other printed matter on the label. The warning

statement shall appear in sharp contrast to any background upon which it appears. Examples of combinations of colors which may not satisfy the proposed requirement for sharp contrast are: black letters on a dark blue or dark green background, dark red letters on a light red background, light red letters on a reflective silver background, and white letters on a light gray or tan background.

(b) *Name of substance.* The name of the class I or class II substance to be inserted into the warning statement shall be the standard chemical name of the substance as listed in 40 CFR part 82, appendix A to subpart A, except that:

(1) The acronym ''CFC'' may be substituted for ''chlorofluorocarbon.''

(2) The acronym ''HCFC'' may be substituted for ''hydrochlorofluorocarbon.''

(3) The term ''1,1,1-trichloroethane'' may be substituted for ''methyl chloroform.''

(c) *Combined statement for multiple class I substances.* If a container containing or a product contains or is manufactured with, more than one class I or class II substance, the warning statement may include the names of all of the substances in a single warning statement, provided that the combined statement clearly distinguishes which substances the container or product contains and which were used in the manufacturing process.

(d) *Format.* (1) The warning statement shall be blocked within a square or rectangular area, with or without a border. (2) The warning statement shall appear in lines that are parallel to the surrounding text on the product's PDP, display panel, supplemental printed material or promotional printed material.

(e) *Type style.* The ratio of the height of a capital letter to its width shall be such that the height of the letter is no more than 3 times its width; the signal word ''WARNING'' shall appear in all capital letters.

(f) *Type size.* The warning statement shall appear at least as large as the type sizes prescribed by this paragraph. The type size refers to the height of the capital letters. A larger type size materially enhances the legibility of the statement and is desirable.

(1) *Display panel or outer packaging.* Minimum type size requirements for the warning statement are given in Table 1 to this paragraph and are based upon the area of the display panel of the product or container. Where the statement is on outer packaging, as well as the display panel area, the statement shall appear in the same minimum type size as on the display panel.

TABLE 1 TO § 82.110(f)(1)

	Area of display panel (sq. in.)					
	0–2	>2–5	>5–10	>10–15	>15–30	>30
Type size (in.) [1]						
Signal word	3/64	1/16	3/32	7/64	1/8	5/32
Statement	3/64	3/64	1/16	3/32	3/32	7/64

>Means greater than.
[1] Minimum height of printed image of letters.

(2) *Alternative placement.* The minimum type size for the warning statement on any alternative placement which meets the requirements of § 82.108(c) is 3/32 inches for the signal word and 1/16 of an inch for the statement.

(3) *Promotional printed material.* The minimum type size for the warning statement on promotional printed material is 3/32 inches for the signal word and 1/16 of an inch for the statement, or the type size of any surrounding text, whichever is larger.

§ 82.112 Removal of label bearing warning statement.

(a) *Prohibition on removal.* Except as described in paragraph (b) or (c) of this section, any warning statement that accompanies a product or container introduced into interstate commerce, as required by this subpart, must remain with the product or container and any product incorporating such product or container, up to and including the point of sale to the ultimate consumer.

(b) *Incorporation of warning statement by subsequent manufacturers.* A manufacturer of a product that incorporates a product that is accompanied by a label bearing the warning statement may remove such label from the incorporated product if the information on such label is incorporated into a warning statement accompanying the manufacturer's product, or if, pursuant to paragraph (c) of this section, the manufacturer of the product is not required to pass through the information contained on or incorporated in the product's label.

(c) *Manufacturers that incorporate products manufactured with controlled substances.* A manufacturer that incorporates into its own product a component product that was purchased from another manufacturer, was manufactured with a process that uses a controlled substance(s), but does not contain such substance(s), may remove such label from the incorporated product and need not apply a warning statement to its own product, if the manufacturer does not use a controlled substance in its own manufacturing process. A manufacturer that uses controlled substances in its own manufacturing process, and is otherwise subject to the regulations of this subpart, must label pursuant to § 82.106, but need not include information regrading the incorporated product on the required label.

(d) *Manufacturers, distributors, wholesalers, retailers that sell spare parts manufactured with controlled substances solely for repair.* Manufacturers, distributors, wholesalers, and retailers that purchase spare parts manufactured with a class I substance from another manufacturer or supplier, and sell such spare parts for the sole purpose of repair, are not required to pass through an applicable warning label if such products are removed from the original packaging provided by the manufacturer from whom the products are purchased. Manufacturers of the spare parts manufactured with controlled substances must still label their products; furthermore, manufacturers, importers, and distributors of such products must pass through the labeling information as long as products remain assembled and packaged in the manner assembled and packaged by the original manufacturer. This exemption shall not apply if a spare part is later used for manufacture and/or for purposes other than repair.

§ 82.114 Compliance by manufacturers and importers with requirements for labeling of containers of controlled substances, or products containing controlled substances.

(a) *Compliance by manufacturers and importers with requirements for labeling of containers of controlled substances, or products containing controlled substances.* Each manufacturer of a product incorporating another product or container containing a controlled substance, to which § 82.102 (a)(1), or, (a)(2) or (b)(1) applies, that is purchased or obtained from another manufacturer or supplier, is required to pass through and incorporate the labeling information that accompanies such incorporated product in a warning statement accompanying the manufacturer's finished product. Each importer of a product, or container containing a controlled substance, to which § 82.102 (a)(1), (a)(2), or (b)(1) applies, including a component product or container incorporated into the product, that is purchased from a foreign manufacturer or supplier, is required to apply a label, or to ensure that a label has been properly applied, at the site of U.S. Customs clearance.

(b) *Reliance on reasonable belief.* The manufacturer or importer of a product that incorporates another product container from another manufacturer or supplier may rely on the labeling information (or lack thereof) that it receives with the product, and is not required to independently investigate whether the requirements of this subpart are applicable to such purchased product or container, as long as the manufacturer reasonably believes that the supplier or foreign manufacturer is reliably and accurately complying with the requirements of this subpart.

(c) *Contractual obligations.* A manufacturer's or importer's contractual relationship with its supplier under which the supplier is required to accurately label, consistent with the requirements of this subpart, any products containing a controlled substance or containers of a controlled substance that are supplied to the manufacturer or importer, is evidence of reasonable belief.

§ 82.116 Compliance by manufacturers or importers incorporating products manufactured with controlled substances.

(a) *Compliance by manufacturers or importers incorporating products manufactured with controlled substances, or importing products manufactured with controlled substances.* Each manufacturer or importer of a product incorporating another product to which § 82.102 (a)(3), or, (b)(2) applies, that is purchased from another manufacturer or supplier, is not required to pass through and incorporate the labeling information that accompanies such incorporated product in a warning statement accompanying the manufacturer's or importer's finished product. Importers of products to which § 82.102 (a)(3) or (b)(2) applies are required to apply a label, or to ensure that a label has been properly applied at the site of U.S. Customs clearance.

(b) *Reliance on reasonable belief.* The importer of a product purchased or obtained from a foreign manufacturer or supplier, which product may have been manufactured with a controlled substance, may rely on the information that it receives with the purchased product, and is not required to independently investigate whether the requirements of this subpart are applicable to the purchased or obtained product, as long as the importer reasonably believes that there was no use of controlled substances by the final manufacturer of the product being imported.

(c) *Contractual obligations.* An importer's contractual relationship with its supplier under which the supplier is required to accurately label, consistent with the requirements of this subpart, any products manufactured with a controlled substance that are supplied to the importer, or to certify to the importer whether a product was or was not manufactured with a controlled substance is evidence of reasonable belief.

§ 82.118 Compliance by wholesalers, distributors and retailers.

(a) *Requirement of compliance by wholesalers, distributors and retailers.* All wholesalers, distributors and retailers of products or containers to which this subpart applies are required to pass through the labeling information that accompanies the product, except those purchasing from other manufacturers or suppliers spare parts manufactured with controlled substances and selling those parts for the demonstrable sole purpose of repair.

(b) *Reliance on reasonable belief.* The wholesaler, distributor or retailer of a product may rely on the labeling information that it receives with the product or container, and is not required to independently investigate whether the requirements of this subpart are applicable to the product or container, as long as the wholesaler, distributor or retailer reasonably believes that the supplier of the product or container is reliably and accurately complying with the requirements of this subpart.

(c) *Contractual obligations.* A wholesaler, distributor or retailer's contractual relationship with its supplier under which the supplier is required to accurately label, consistent with the requirements of this subpart, any products manufactured with a controlled substance that are supplied to the wholesaler, distributor or retailer is evidence of reasonable belief.

§ 82.120 Petitions.

(a) *Requirements for procedure and timing.* Persons seeking to apply the requirements of this regulation to a product containing a class II substance or a product manufactured with a class I or a class II substance which is not otherwise subject to the requirements, or to temporarily exempt a product manufactured with a class I substance, based on a showing of a lack of currently or potentially available alternatives, from the requirements of this regulation may submit petitions to: Labeling Program Manager, Stratospheric Protection Division, Office of Atmospheric Programs, U.S. Environmental Protection Agency, 6202–J, 401 M Street, S.W., Washington, D.C. 20460. Such persons must label their products while such petitions are under review by the Agency.

(b) *Requirement for adequate data.* Any petition submitted under paragraph (a) of this section shall be accompanied by adequate data, as defined in § 82.120(c). If adequate data are not included by the petitioner, the Agency may return the petition and request specific additional information.

(c) *Adequate data.* A petition shall be considered by the Agency to be supported by adequate data if it includes all of the following:

(1) A part clearly labeled ''Section I.A.'' which contains the petitioner's full name, company or organization name, address and telephone number, the product that is the subject of the petition, and, in the case of a petition to temporarily exempt a product manufactured with a class I substance from the labeling requirement, the manufacturer or manufacturers of that product.

(2) For petitions to temporarily exempt a product manufactured with a class I substance only, a part clearly labeled ''Section I.A.T.'' which states the length of time for which an exemption is requested.

(3) A part clearly labeled ''Section I.B.'' which includes the following statement, signed by the petitioner or an authorized representative:

''I certify under penalty of law that I have personally examined and am familiar with the information submitted in this petition and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information.''

(4) A part clearly labeled ''Section I.C.'' which fully explains the basis for the petitioner's request that EPA add the labeling requirements to or remove them from the product which is the subject of the petition, based specifically upon the technical facility or laboratory tests, literature, or economic analysis described in paragraphs (c) (5), (6) and (7) of this section.

(5) A part clearly labeled ''Section II.A.'' which fully describes any technical facility or laboratory tests used to support the petitioner's claim.

(6) A part clearly labeled ''Section II.B.'' which fully explains any values taken from literature or estimated on the basis of known information that are used to support the petitioner's claim.

(7) A part clearly labeled ''Section II.C.'' which fully explains any economic analysis used to support the petitioner's claim.

(d) *Criteria for evaluating petitions.* Adequate data in support of any petition to the Agency to add a product to the labeling requirement or temporarily remove a product from the labeling requirement will be evaluated based upon a showing of sufficient quality and scope by the petitioner of whether there are or are not substitute products or manufacturing processes for such product:

(1) That do not rely on the use of such class I or class II substance;

(2) That reduce the overall risk to human health and the environment; and

(3) That are currently or potentially available.

(e) *Procedure for acceptance or denial of petition.* (1) If a petition submitted under this section contains adequate data, as defined under paragraph (c) of this section, the Agency shall within 180 days after receiving the complete petition either accept the petition or deny the petition.

(2) If the Agency makes a decision to accept a petition to apply the requirements of this regulation to a product containing or manufactured with a class II substance, the Agency will notify the petitioner and publish a proposed rule in the Federal Register to apply the labeling requirements to the product.

(3) If the Agency makes a decision to deny a petition to apply the requirements of this regulation to a product containing or manufactured with a class II substance, the Agency will notify the petitioner and publish an explanation of the petition denial in the Federal Register.

(4) If the Agency makes a decision to accept a petition to temporarily exempt a product manufactured with a class I substance from the requirements of this regulation, the Agency will notify the petitioner and publish a proposed rule in the Federal Register to temporarily exempt the product from the labeling requirements. Upon notification by the Agency, such manufacturer may immediately cease its labeling process for such exempted products.

(5) If the Agency makes a decision to deny a petition to temporarily exempt a product manufactured with a class I substance from the requirements of this regulation, the Agency will notify the petitioner and may, in appropriate circumstances, publish an explanation of the petition denial in the Federal Register.

§ 82.122 Certification, recordkeeping, and notice requirements.

(a) *Certification.* (1) Persons claiming the exemption provided in § 82.106(b)(2) must submit a written certification to the following address: Labeling Program Manager, Stratospheric Protection Division, Office of Atmospheric Programs, 6205–J, 401 M Street, S.W., Washington, D.C. 20460.

(2) The certification must contain the following information:

(i) The exact location of documents verifying calendar year 1990 usage and the 95% reduced usage during a twelve month period;

(ii) A description of the records maintained at that location;

(iii) A description of the type of system used to track usage;

(iv) An indication of which 12 month period reflects the 95% reduced usage, and;

(v) Name, address, and telephone number of a contact person.

(3) Persons who submit certifications postmarked on or before May 15, 1993, need not place warning labels on their products manufactured using CFC–113 or methyl chloroform as a solvent. Persons who submit certifications postmarked after May 15, 1993, must label their products manufactured using CFC–113 or methyl chloroform as a solvent for 14 days following such submittal of the certification.

(4) Persons certifying must also include a statement that indicates their future annual use will at no time exceed 5% of their 1990 usage.

(5) Certifications must be signed by the owner or a responsible corporate officer.

(6) If the Administrator determines that a person's certification is incomplete or that information supporting the exemption is inadequate, then products manufactured using CFC–113 or methyl chloroform as a solvent by such person must be labeled pursuant to § 82.106(a).

(b) *Recordkeeping.* Persons claiming the exemption under section 82.106(b)(2) must retain supporting documentation at one of their facilities.

(c) *Notice Requirements.* Persons who claim an exemption under § 82.106(b)(2) must submit a notice to the address in paragraph (a)(1) of this section within 30 days of the end of any 12 month period in which their usage of CFC–113 or methyl chloroform used as a solvent exceeds the 95% reduction from calendar year 1990.

§ 82.124 Prohibitions.

(a) *Warning statement.* (1) *Absence or presence of warning statement.* (i) Applicable May 15, 1993, except as indicated in paragraph (a)(5) of this section, no container or product identified in § 82.102(a) may be introduced into interstate commerce unless it bears a warning statement that complies with the requirements of § 82.106(a) of this subpart, unless such labeling is not required under § 82.102(c), § 82.106(b), § 82.112 (c) or (d), § 82.116(a), § 82.118(a), or temporarily exempted pursuant to § 82.120.

(ii) On January 1, 2015, or any time between May 15, 1993 and January 1, 2015 that the Administrator determines for a particular product manufactured with or containing a class II substance that there are substitute products or manufacturing processes for such product that do not rely on the use of a class I or class II substance, that reduce the overall risk to human health and the environment, and that are currently or potentially available, no product identified in § 82.102(b) may be introduced into interstate commerce unless it bears a warning statement that complies with the requirements of § 82.106, unless such labeling is not required under § 82.106(b), § 82.112 (c) or (d), § 82.116(a) or § 82.118(a).

(2) *Placement of warning statement.* (i) On May 15, 1993, except as indicated in paragraph (a)(5) of this section, no container or product identified in § 82.102(a) may be introduced into interstate commerce unless it bears a warning statement that complies with

the requirements of § 82.108 of this subpart, unless such labeling is not required under § 82.102(c), § 82.106(b), § 82.112 (c) or (d), § 82.116(a), § 82.118(a), or temporarily exempted pursuant to § 82.120.

(ii) On January 1, 2015, or any time between May 15, 1993 and January 1, 2015 that the Administrator determines for a particular product manufactured with or containing a class II substance that there are substitute products or manufacturing processes for such product that do not rely on the use of a class I or class II substance, that reduce the overall risk to human health and the environment, and that are currently or potentially available, no product identified in § 82.102(b) may be introduced into interstate commerce unless it bears a warning statement that complies with the requirements of § 82.108 of this subpart, unless such labeling is not required under § 82.106(b), § 82.112 (c) or (d), § 82.116(a) or § 82.118(a).

(3) *Form of label bearing warning statement.* (i) Applicable May 15, 1993, except as indicated in paragraph (a)(5) of this section, no container or product identified in § 82.102(a) may be introduced into interstate commerce unless it bears a warning statement that complies with the requirements of § 82.110, unless such labeling is not required pursuant to § 82.102(c), § 82.106(b), § 82.112 (c) or (d), § 82.116(a), § 82.118(a), or temporarily exempted pursuant to § 82.120.

(ii) On January 1, 2015, or any time between May 15, 1993 and January 1, 2015 that the Agency determines for a particular product manufactured with or containing a class II substance, that there are substitute products or manufacturing processes that do not rely on the use of a class I or class II substance, that reduce the overall risk to human health and the environment, and that are currently or potentially available, no product identified in § 82.102(b) may be introduced into interstate commerce unless it bears a warning statement that complies with the requirements of § 82.110, unless such labeling is not required pursuant to § 82.106(b), § 82.112 (c) or (d), § 82.116(a), or § 82.118(a).

(4) On or after May 15, 1993, no person may modify, remove or interfere with any warning statement required by this subpart, except as described in § 82.112.

(5) In the case of any substance designated as a class I or class II substance after February 11, 1993, the prohibitions in paragraphs (a)(1)(i), (a)(2)(i), and (a)(3)(i) of this section shall be applicable one year after the designation of such substance as a class I or class II substance unless otherwise specified in the designation.

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