chapter 35 (§3501 et seq.) of Title 44, Public Printing and Documents, prior to the general amendment of that chapter by Pub. L. 104-13, §2, May 22, 1995, 109 Stat. 163. For complete classification of this Act to the Code, see Short Title of 1980 Amendment note set out under section 101 of Title 44 and Tables.

The Regulatory Flexibility Act, referred to in subsecs. (d)(2) and (e)(1)(B), is Pub. L. 96-354, Sept. 19, 1980, 94 Stat. 1164, which is classified generally to chapter 6 (\$601 et seq.) of Title 5, Government Organization and Employees. For complete classification of this Act to the Code, see Short Title note set out under section 601 of Title 5 and Tables.

The Equal Access to Justice Act, referred to in subsecs. (d)(2) and (e)(1)(B), is title II of Pub. L. 96-481, Oct. 21, 1980, 94 Stat. 2325. For complete classification of this Act to the Code, see Short Title note set out under section 504 of Title 5.

SUBCHAPTER VI—STRATOSPHERIC OZONE PROTECTION

§7671. Definitions

As used in this subchapter—

(1) Appliance

The term "appliance" means any device which contains and uses a class I or class II substance as a refrigerant and which is used for household or commercial purposes, including any air conditioner, refrigerator, chiller, or freezer.

(2) Baseline year

The term "baseline year" means—

(A) the calendar year 1986, in the case of any class I substance listed in Group I or II under section 7671a(a) of this title,

(B) the calendar year 1989, in the case of any class I substance listed in Group III, IV, or V under section 7671a(a) of this title, and

(C) a representative calendar year selected by the Administrator, in the case of—

(i) any substance added to the list of class I substances after the publication of the initial list under section 7671a(a) of this title, and

(ii) any class II substance.

(3) Class I substance

The term "class I substance" means each of the substances listed as provided in section 7671a(a) of this title.

(4) Class II substance

The term "class II substance" means each of the substances listed as provided in section 7671a(b) of this title.

(5) Commissioner

The term "Commissioner" means the Commissioner of the Food and Drug Administration.

(6) Consumption

The term "consumption" means, with respect to any substance, the amount of that substance produced in the United States, plus the amount imported, minus the amount exported to Parties to the Montreal Protocol. Such term shall be construed in a manner consistent with the Montreal Protocol.

(7) Import

The term "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.

(8) Medical device

The term "medical device" means any device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—

(A) if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner; and

(B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator.

(9) Montreal Protocol

The terms "Montreal Protocol" and "the Protocol" mean the Montreal Protocol on Substances that Deplete the Ozone Layer, a protocol to the Vienna Convention for the Protection of the Ozone Layer, including adjustments adopted by Parties thereto and amendments that have entered into force.

(10) Ozone-depletion potential

The term "ozone-depletion potential" means a factor established by the Administrator to reflect the ozone-depletion potential of a substance, on a mass per kilogram basis, as compared to chlorofluorocarbon-11 (CFC-11). Such factor shall be based upon the substance's atmospheric lifetime, the molecular weight of bromine and chlorine, and the substance's ability to be photolytically disassociated, and upon other factors determined to be an accurate measure of relative ozone-depletion potential.

(11) Produce, produced, and production

The terms "produce", "produced", and "production", refer to the manufacture of a substance from any raw material or feedstock chemical, but such terms do not include—

(A) the manufacture of a substance that is used and entirely consumed (except for trace quantities) in the manufacture of other chemicals, or

(B) the reuse or recycling of a substance.

(July 14, 1955, ch. 360, title VI, §601, as added Pub. L. 101-549, title VI, §602(a), Nov. 15, 1990, 104 Stat. 2649.)

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in par. (8), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

$\S\,7671a.$ Listing of class I and class II substances

(a) List of class I substances

Within 60 days after November 15, 1990, the Administrator shall publish an initial list of class I substances, which list shall contain the following substances:

> Group I chlorofluorocarbon-11 (CFC–11) chlorofluorocarbon-12 (CFC–12) chlorofluorocarbon-113 (CFC–113) chlorofluorocarbon-114 (CFC–114) chlorofluorocarbon-115 (CFC–115)

Group II halon-1211 halon-1301 halon-2402

Group III

chlorofluorocarbon-13 (CFC–13) chlorofluorocarbon-111 (CFC–111) chlorofluorocarbon-112 (CFC–112) chlorofluorocarbon-211 (CFC–211) chlorofluorocarbon-212 (CFC–212) chlorofluorocarbon-213 (CFC–213) chlorofluorocarbon-214 (CFC–214) chlorofluorocarbon-215 (CFC–215) chlorofluorocarbon-216 (CFC–216) chlorofluorocarbon-217 (CFC–217)

Group IV

carbon tetrachloride

Group V

methyl chloroform

The initial list under this subsection shall also include the isomers of the substances listed above, other than 1,1,2-trichloroethane (an isomer of methyl chloroform). Pursuant to subsection (c) of this section, the Administrator shall add to the list of class I substances any other substance that the Administrator finds causes or contributes significantly to harmful effects on the stratospheric ozone layer. The Administrator shall, pursuant to subsection (c) of this section, add to such list all substances that the Administrator determines have an ozone depletion potential of 0.2 or greater.

(b) List of class II substances

Simultaneously with publication of the initial list of class I substances, the Administrator shall publish an initial list of class II substances, which shall contain the following substances:

hydrochlorofluorocarbon-21 (HCFC-21) hydrochlorofluorocarbon-22 (HCFC-22) hydrochlorofluorocarbon-31 (HCFC-31) hydrochlorofluorocarbon-121 (HCFC-121) hydrochlorofluorocarbon-122 (HCFC-122) hydrochlorofluorocarbon-123 (HCFC-123) hydrochlorofluorocarbon-124 (HCFC-124) hydrochlorofluorocarbon-131 (HCFC-131) hydrochlorofluorocarbon-132 (HCFC-132) hydrochlorofluorocarbon-133 (HCFC-133) hydrochlorofluorocarbon-141 (HCFC-141) hydrochlorofluorocarbon-142 (HCFC-142) hydrochlorofluorocarbon-221 (HCFC-221) hydrochlorofluorocarbon-222 (HCFC-222) hydrochlorofluorocarbon-223 (HCFC-223) hydrochlorofluorocarbon-224 (HCFC-224) hydrochlorofluorocarbon-225 (HCFC-225) hydrochlorofluorocarbon-226 (HCFC-226)

hydrochlorofluorocarbon-231 (HCFC-231) hydrochlorofluorocarbon-232 (HCFC-232) hydrochlorofluorocarbon-233 (HCFC-233) hydrochlorofluorocarbon-234 (HCFC-233) hydrochlorofluorocarbon-235 (HCFC-235) hydrochlorofluorocarbon-241 (HCFC-242) hydrochlorofluorocarbon-242 (HCFC-242) hydrochlorofluorocarbon-243 (HCFC-243) hydrochlorofluorocarbon-244 (HCFC-244) hydrochlorofluorocarbon-251 (HCFC-251) hydrochlorofluorocarbon-252 (HCFC-252) hydrochlorofluorocarbon-263 (HCFC-253) hydrochlorofluorocarbon-263 (HCFC-261) hydrochlorofluorocarbon-261 (HCFC-261) hydrochlorofluorocarbon-271 (HCFC-271)

The initial list under this subsection shall also include the isomers of the substances listed above. Pursuant to subsection (c) of this section, the Administrator shall add to the list of class II substances any other substance that the Administrator finds is known or may reasonably be anticipated to cause or contribute to harmful effects on the stratospheric ozone layer.

(c) Additions to the lists

(1) The Administrator may add, by rule, in accordance with the criteria set forth in subsection (a) or (b) of this section, as the case may be, any substance to the list of class I or class II substances under subsection (a) or (b) of this section. For purposes of exchanges under section 7661f¹ of this title, whenever a substance is added to the list of class I substances the Administrator shall, to the extent consistent with the Montreal Protocol, assign such substance to existing Group I, II, III, IV, or V or place such substance in a new Group.

(2) Periodically, but not less frequently than every 3 years after November 15, 1990, the Administrator shall list, by rule, as additional class I or class II substances those substances which the Administrator finds meet the criteria of subsection (a) or (b) of this section, as the case may be.

(3) At any time, any person may petition the Administrator to add a substance to the list of class I or class II substances. Pursuant to the criteria set forth in subsection (a) or (b) of this section as the case may be, within 180 days after receiving such a petition, the Administrator shall either propose to add the substance to such list or publish an explanation of the petition denial. In any case where the Administrator proposes to add a substance to such list, the Administrator shall add, by rule, (or make a final determination not to add) such substance to such list within 1 year after receiving such petition. Any petition under this paragraph shall include a showing by the petitioner that there are data on the substance adequate to support the petition. If the Administrator determines that information on the substance is not sufficient to make a determination under this paragraph, the Administrator shall use any authority available to the Administrator, under any law administered by the Administrator, to acquire such information.

(4) Only a class II substance which is added to the list of class I substances may be removed from the list of class II substances. No substance

¹So in original. Probably should be section "7671f".