

(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 accu-

rate 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.

§ 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), 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), 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-234)
 hydrochlorofluorocarbon-235 (HCFC-235)
 hydrochlorofluorocarbon-241 (HCFC-241)
 hydrochlorofluorocarbon-242 (HCFC-242)
 hydrochlorofluorocarbon-243 (HCFC-243)
 hydrochlorofluorocarbon-244 (HCFC-244)
 hydrochlorofluorocarbon-251 (HCFC-251)
 hydrochlorofluorocarbon-252 (HCFC-252)
 hydrochlorofluorocarbon-253 (HCFC-253)
 hydrochlorofluorocarbon-261 (HCFC-261)
 hydrochlorofluorocarbon-262 (HCFC-262)
 hydrochlorofluorocarbon-271 (HCFC-271)

The initial list under this subsection shall also include the isomers of the substances listed above. Pursuant to subsection (c), 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), as the case may be, any substance to the list of class I or class II substances under subsection (a) or (b). 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), 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) 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 referred to in subsection (a), including methyl chloroform, may be removed from the list of class I substances.

(d) New listed substances

In the case of any substance added to the list of class I or class II substances after publication of the initial list of such substances under this section, the Administrator may extend any schedule or compliance deadline contained in section 7671c or 7671d of this title to a later date than specified in such sections if such schedule or deadline is unattainable, considering when such substance is added to the list. No extension under this subsection may extend the date for termination of production of any class I substance to a date more than 7 years after January 1 of the year after the year in which the substance is added to the list of class I substances. No extension under this subsection may extend the date for termination of production of any class II substance to a date more than 10 years after January 1 of the year after the year in which the substance is added to the list of class II substances.

(e) Ozone-depletion and global warming potential

Simultaneously with publication of the lists under this section and simultaneously with any addition to either of such lists, the Administrator shall assign to each listed substance a numerical value representing the substance's ozone-depletion potential. In addition, the Administrator shall publish the chlorine and bromine loading potential and the atmospheric lifetime of each listed substance. One year after November 15, 1990 (one year after the addition of a substance to either of such lists in the case of a substance added after the publication of the initial lists of such substances), and after notice and opportunity for public comment, the Administrator shall publish the global warming potential of each listed substance. The preceding sentence shall not be construed to be the basis of any additional regulation under this chapter. In the case of the substances referred to in table 1, the ozone-depletion potential shall be as specified in table 1, unless the Administrator adjusts the substance's ozone-depletion potential based on criteria referred to in section 7671(10) of this title:

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

TABLE 1

Substance	Ozone-depletion potential
chlorofluorocarbon-11 (CFC-11)	1.0
chlorofluorocarbon-12 (CFC-12)	1.0
chlorofluorocarbon-13 (CFC-13)	1.0
chlorofluorocarbon-111 (CFC-111)	1.0
chlorofluorocarbon-112 (CFC-112)	1.0
chlorofluorocarbon-113 (CFC-113)	0.8
chlorofluorocarbon-114 (CFC-114)	1.0
chlorofluorocarbon-115 (CFC-115)	0.6
chlorofluorocarbon-211 (CFC-211)	1.0
chlorofluorocarbon-212 (CFC-212)	1.0
chlorofluorocarbon-213 (CFC-213)	1.0
chlorofluorocarbon-214 (CFC-214)	1.0
chlorofluorocarbon-215 (CFC-215)	1.0
chlorofluorocarbon-216 (CFC-216)	1.0
chlorofluorocarbon-217 (CFC-217)	1.0
halon-1211	3.0
halon-1301	10.0
halon-2402	6.0
carbon tetrachloride	1.1
methyl chloroform	0.1
hydrochlorofluorocarbon-22 (HCFC-22)	0.05
hydrochlorofluorocarbon-123 (HCFC-123)	0.02
hydrochlorofluorocarbon-124 (HCFC-124)	0.02
hydrochlorofluorocarbon-141(b) (HCFC-141(b))	0.1
hydrochlorofluorocarbon-142(b) (HCFC-142(b))	0.06

Where the ozone-depletion potential of a substance is specified in the Montreal Protocol, the ozone-depletion potential specified for that substance under this section shall be consistent with the Montreal Protocol.

(July 14, 1955, ch. 360, title VI, § 602, as added Pub. L. 101-549, title VI, § 602(a), Nov. 15, 1990, 104 Stat. 2650.)

§ 7671b. Monitoring and reporting requirements

(a) Regulations

Within 270 days after November 15, 1990, the Administrator shall amend the regulations of the Administrator in effect on such date regarding monitoring and reporting of class I and class II substances. Such amendments shall conform to the requirements of this section. The amended regulations shall include requirements with respect to the time and manner of monitoring and reporting as required under this section.

(b) Production, import, and export level reports

On a quarterly basis, or such other basis (not less than annually) as determined by the Administrator, each person who produced, imported, or exported a class I or class II substance shall file a report with the Administrator setting forth the amount of the substance that such person produced, imported, and exported during the preceding reporting period. Each such report shall be signed and attested by a responsible officer. No such report shall be required from a person after April 1 of the calendar year after such person permanently ceases production, importation, and exportation of the substance and so notifies the Administrator in writing.

(c) Baseline reports for class I substances

Unless such information has previously been reported to the Administrator, on the date on

which the first report under subsection (b) is required to be filed, each person who produced, imported, or exported a class I substance (other than a substance added to the list of class I substances after the publication of the initial list of such substances under this section) shall file a report with the Administrator setting forth the amount of such substance that such person produced, imported, and exported during the baseline year. In the case of a substance added to the list of class I substances after publication of the initial list of such substances under this section, the regulations shall require that each person who produced, imported, or exported such substance shall file a report with the Administrator within 180 days after the date on which such substance is added to the list, setting forth the amount of the substance that such person produced, imported, and exported in the baseline year.

(d) Monitoring and reports to Congress

(1) The Administrator shall monitor and, not less often than every 3 years following November 15, 1990, submit a report to Congress on the production, use and consumption of class I and class II substances. Such report shall include data on domestic production, use and consumption, and an estimate of worldwide production, use and consumption of such substances. Not less frequently than every 6 years the Administrator shall report to Congress on the environmental and economic effects of any stratospheric ozone depletion.

(2) The Administrators of the National Aeronautics and Space Administration and the National Oceanic and Atmospheric Administration shall monitor, and not less often than every 3 years following November 15, 1990, submit a report to Congress on the current average tropospheric concentration of chlorine and bromine and on the level of stratospheric ozone depletion. Such reports shall include updated projections of—

(A) peak chlorine loading;

(B) the rate at which the atmospheric abundance of chlorine is projected to decrease after the year 2000; and

(C) the date by which the atmospheric abundance of chlorine is projected to return to a level of two parts per billion.

Such updated projections shall be made on the basis of current international and domestic controls on substances covered by this subchapter as well as on the basis of such controls supplemented by a year 2000 global phase out of all halocarbon emissions (the base case). It is the purpose of the Congress through the provisions of this section to monitor closely the production and consumption of class II substances to assure that the production and consumption of such substances will not:

(i) increase significantly the peak chlorine loading that is projected to occur under the base case established for purposes of this section;

(ii) reduce significantly the rate at which the atmospheric abundance of chlorine is projected to decrease under the base case; or

(iii) delay the date by which the average atmospheric concentration of chlorine is pro-