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SOME NON-ESSENTIAL AEROSOL PROPELLANT USES FINALLY BANNED

FEDERAL REGULATIONS—The FDA, the EPA, and the CPSC issue regulations prohibiting certain uses of chlorofluorocarbons as propellants in self-pressurized containers, 43 F.R. 11301 (1978).

The Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Consumer Product Safety Commission (CPSC) jointly issued a final set of regulations which phase out the manufacture and interstate transport of chlorofluorocarbons.¹ Chlorofluorocarbons are molecules consisting of some combination of carbon, fluorine, and chlorine. These compounds have many uses, such as propellants for aerosols and in refrigerant fluids. But these regulations only apply to the use of chlorofluorocarbons as propellants in those self-pressurized product delivery systems which are deemed “non-essential.”

Chlorofluorocarbons, which are released into the atmosphere by the use of spray cans, affect stratospheric ozone. In fact, current estimates place the ultimate net reduction of stratospheric ozone resulting from chlorofluorocarbon emissions at 10.8% to 16.5%.² Research has linked ozone reduction in the atmosphere to a number of events: increases in melanoma and non-melanoma skin cancer incidence in humans; various effects on the climate; depressed rates of photosynthesis and growth of plants; reductions in agricultural crop yields; and increases in death from intentional misuse (inhalation).³ Since the three agencies charged with regulation of this area considered the risks posed by most propellant uses of chlorofluoro-

1. 43 Fed. Reg. 11,301 (1978).

2. NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA), ASSESSMENT REPORT, EFFECTS OF CHLOROFUOROMETHANES ON STRATOSPHERIC OZONE (1977); NASA, GODDARD SPACE FLIGHT CENTER, REFERENCE PUBLICATION 1010, CHLOROFUOROMETHANES AND THE STRATOSPHERE, 189-195 (1977).

3. NATIONAL ACADEMY OF SCIENCES COMMITTEE ON IMPACTS OF STRATOSPHERIC CHANGE, HALOCARBONS: ENVIRONMENTAL EFFECTS OF CHLOROFUOROMETHANE RELEASE, 1-1 to 1-10, 8-15 (1976); NATIONAL ACADEMY OF SCIENCES, COMMITTEE ON THE IMPACTS OF STRATOSPHERIC CHANGE, RESPONSE TO THE OZONE PROTECTION SECTIONS OF THE CLEAN AIR ACT AMENDMENTS OF 1977: AN INTERIM REPORT (1977).

carbons to be unacceptable, they developed and issued these regulations based upon a precautionary environmental policy.⁴

Many of the uses of chlorofluorocarbon propellants occur in products under the FDA's jurisdiction.⁵ Under the new FDA regulations, a food, drug, device, or cosmetic in a self-pressurized container using a chlorofluorocarbon propellant is considered adulterated and/or misbranded. As such, it is in violation of the Federal Food, Drug, and Cosmetic Act.⁶ A drug product, however, contained in a self-pressurized container and delivered by a chlorofluorocarbon propellant is not in violation of the new FDA rules if: 1) a new drug or new animal drug application for the product has been approved; 2) a petition for exemption has been filed; and 3) the product has been specified essential.⁷

The FDA lists specific products which are considered to involve essential uses of chlorofluorocarbon propellants and which are, thereby, exempt from the regulations. Contraceptive vaginal foams and bronchodilator drugs are such exceptions.⁸ The handful of exempted products all met the FDA's "essentiality" tests, under which a product is considered essential only if: 1) there is no technically feasible alternative to the use of chlorofluorocarbon in the product; 2) the product provides substantial health benefits, environmental benefits, or other public benefits that would not otherwise be obtainable; and 3) the use of the product does not involve a significant release of chlorofluorocarbons into the atmosphere or the release is justified by the benefits conferred by the product.⁹

Other products may qualify for exclusion from the ruling.¹⁰ For example, the regulations permit studies of investigational new drugs (INDs) and investigational new animal drugs (INADs) to continue after December 15, 1978,¹¹ the date after which production and packaging of chlorofluorocarbons for non-essential propellant uses

4. *Supra* note 1, at 11,304, 11,319, 11,326. The agencies recognized that the adverse effects of chlorofluorocarbon emissions could fall more upon future generations than upon those presently living, and were unwilling to await a "body count" to prove the reality of the dangers. *See* 42 Fed. Reg. 22,017, 22,026-27 (1977).

5. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-329 (1976); National Environmental Policy Act of 1969, §102(2), 42 U.S.C. §4332 (Supp. V, 1975).

6. The Federal Food, Drug, and Cosmetic Act prohibits the adulteration or misbranding of any food, drug, device, or cosmetic, which is in interstate commerce. *See* 21 U.S.C. §§342, 343, 351, 352, 361, 362, (1976), for standards relating to the determination of adulteration or misbranding of such articles.

7. *Supra* note 1, at 11,316-17, §2.125(d)-(h).

8. *Id.* at 11,316, §2.125(e).

9. *Id.* at 11,316-17, §2.125(f).

10. *Id.* at 11,316-17, §2.125(f). *See* 43 Fed. Reg. 11,301, 11,312-13 (1978).

11. *Id.* at 11,317, §2.125(h), (i), (j).

is banned. This extension allows for a situation in which the use of a chlorofluorocarbon propellant in an IND or an INAD might prove, after sufficient experimentation, to be an essential use under the FDA's essentiality criteria set forth above. Petitions to permit studies of INDs and INADs to continue after the December 15, 1978 deadline must demonstrate that there is a reasonable likelihood that the use of a chlorofluorocarbon propellant in such a product will prove to be essential.^{1 2}

The EPA's regulations are similar to those of the FDA.^{1 3} The EPA also sets forth specific essential use exemptions, based upon its own essentiality criteria.^{1 4} A few pesticide uses, in mercaptan stench warning devices, as a release agent for molds use in plastic and elastomeric material production, in non-consumer articles for electronic and electrical products, and in articles necessary for the safe maintenance and operation of aircraft are among the EPA exemptions.^{1 5} The latter two categories were purposely made broad in scope, since such articles are considered to be important for promoting public safety and welfare. Section 762.21(g) of the EPA regulations exempts those uses of chlorofluorocarbons which are essential to the military preparedness of the United States, as determined by the EPA Administrator and the Secretary of Defense.^{1 6} These uses are covered by a public Memorandum of Understanding between the EPA and the Department of Defense (DOD) which provides that the DOD will use only those products necessary to maintain U.S. military readiness. DOD must switch to alternatives to chlorofluorocarbon propellants as they become available.^{1 7}

The EPA ruling bans importing chlorofluorocarbons for use as an aerosol propellant, effective December 15, 1978.^{1 8} On the same date, the ban is effective as to both the processing of chlorofluorocarbons into aerosol propellants and the distribution into commerce of chlorofluorocarbons for such processing.^{1 9} As an aid to enforcement of the EPA's ruling, manufacturers and processors of chlorofluorocarbons for aerosol propellant uses must submit annual reports

12. *Id.*

13. The EPA's rules are promulgated under authority of § §6, 8, and 12 of T.S.C.A., 15 U.S.C. § §2605, 2607, 2611 (1976).

14. *Supra* note 1, at 11,324, §762.21. For the EPA's essential use criteria, see U.S.E.P.A., O.T.S., ESSENTIAL USE DETERMINATIONS (1977).

15. *Supra* note 1, at 11,324, §762.21.

16. *Id.* at 11,320.

17. *Id.* at 11,320.

18. *Id.* at 11,324, §762.11(b).

19. *Id.*, § § 762.12, 762.13.

to the EPA.²⁰ These reports are required to contain, *inter alia*, information about customers' purchases, such as the quantity and application of the chlorofluorocarbons.

The CPSC had concluded that no consumer product safety standard would adequately protect the public against the negative effects of chlorofluorocarbon use.²¹ It was therefore directed to work with the FDA and the EPA in banning chlorofluorocarbon-propelled products.²² Since the nature of the FDA and EPA rulings were so comprehensive, the CPSC determined that it need not take any separate banning action.²³

Despite these new regulations, the menace of ozone depletion continues to be significant. For example, non-aerosol uses of chlorofluorocarbons, as in refrigeration and air-conditioning, are not yet regulated.²⁴ Further, chlorofluorocarbons are produced worldwide, and because ozone depletion is of an ambient nature and of global effect, international cooperation is necessary to correct the problem.²⁵ Hopefully, the actions taken by the FDA and the EPA will set an example for other countries.

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20. *Supra* note 1, at 11,324, 11,325, § § 712.1-712.4.

21. 42 Fed. Reg. 24,535, 24,550 (1977).

22. *Id.* The rules were promulgated under the authority of 42 U.S.C. § 4332 (Supp. V, 1975).

23. *Supra* note 1, at 11,326.

24. The FDA, EPA, and CPSC are, however, considering a second phase of regulations which would control such uses. *See* 43 Fed. Reg. 1,997, 11,301, 11,326 (1978).

25. *E.g.*, UNITED NATIONS ENVIRONMENTAL PROGRAMME, MEETING OF EXPERTS DESIGNATED BY GOVERNMENTS, INTERGOVERNMENTAL AND NON-GOVERNMENTAL ORGANIZATIONS ON THE OZONE LAYER (1977); 43 Fed. Reg. 11,301, 11,302-03, 11,309, 11,321 (1978).