#229

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

DEC 15 1975

Mr. Sam D. Fine
Associate Commissioner for Compliance
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20204

Dear Mr. Fine:

This is in response to your memorandum of October 28, 1975, to Stanley Parent, Executive Director, Consumer Product Safety Commission, concerning jurisdiction to regulate an aerosol spray cologne which may have the capacity to explode because of an alleged defect in the container.

In your memorandum it is contended that in cases where FDA has jurisdiction over the contents of a product it also has jurisdiction to regulate mechanical defects associated with the container, and that the Consumer Product Safety Commission lacks jurisdiction because of the exclusion contained in section 2(f)(2) of the Federal Hazardous Substances Act. Based on a decision by the Commission in a related matter, it is the view of this office that the Commission does have the authority to regulate mechanical risks of injury associated with aerosol cosmetic containers, notwithstanding possible overlapping FDA authority in the area.

Under the Consumer Product Safety Act, the Commission has authority to regulate risks of injury associated with "consumer products," as that term is defined in section 3 (15 U.S.C. 2052). Specifically excluded from the definition of the term are "drugs", "devices", "cosmetics", and "food", as defined in sections 201(g), (h), (i), and (f) of the Federal Food, Drug, and Cosmetic Act. Thus, containers of aerosol products produced or distributed for sale to and use of consumers are "consumer products" unless they fall within one of the specific exclusions.

ADVISORY OPINION

The question of jurisdiction under the Federal Hazardous Substances Act is not addressed with regard to mechanical hazards presented by aerosol containers because, while that Act does deal with substances that generate pressure, it does not regulate mechanical risks of injury presented by products produced for the adult market.

The question of whether mechanical hazards associated with cosmetic, as well as food and drug, aerosol containers may be regulated under the CPSA was addressed by the Commission when it had before it the petition of the Center for Science in the Public Interest (petition number CP 74-5). This petition, among other things, asked the Commission to investigate the safety of aerosol containers with respect to both potential explosion hazards and accessibility of harmful contents to young children. After careful analysis, the Commission concluded in a comprehensive decision that, unless the potential for harm was caused by migration of a harmful substance from the container into the ingredients, the container itself could not be considered a "food", "drug", or "cosmetic", and therefore was not excluded from the term, "consumer product." A copy of this opinion, published at 40 FR 31026 (July 24, 1975) is enclosed for your information.

The two principal authorities relied upon by the Commission in reaching this jurisdictional decision were (1) a letter dated January 7, 1975, from the FDA General Counsel to the General Counsel of CPSC and (2) the court decision in United States v. Articles of Food, 370 F. Supp. 371 (E.D. Mich. 1974). The FDA letter (copy enclosed) states in part that "it does not appear to us that section 3(a)(1)(f) of the Consumer Product Safety Act totally excludes the Consumer Product Safety Commission from jurisdiction over hazards they may present that are not covered by the FD & C Act. The fact that the toxicity of substances migrating from a can to food is regulated under one law does not compel the conclusion that consumer hazards resulting from exploding bottles or jagged edges of an opened can or collapsing aluminum food trays should not be regulated under the other law. Indeed, it seems entirely reasonably to interpret the Consumer Product Safety Act to authorize the Commission to take regulatory action under the CPSA in all areas related to food which are not covered by the FD & C Act." Regarding the Articles of Food case, the Commission noted that the Court specifically stated that "It is likewise clear that ordinary packaging or food holding devices from which there is no migration are not subject to the Act." 370 F. Supp. at 373.

Recently, the Commission had occasion to rule upon whether home canning equipment with a defective seal or other defect which could cause food contamination should be considered a "consumer product" for regulatory purposes under the CPSA. The Commission concluded that because the problem was food related, it did not have jurisdiction. We do not believe, however, that this decision controls in the present situation or in any other case where the ultimate harm is not related to the properties of the ingredients. Therefore, it is the opinion of this office that, notwithstanding any concurrent jurisdiction held by FDA, purely mechanical hazards of containers of cosmetics are cognizable under the CPSA because the containers themselves are not "cosmetics". We would point out, however, that while the views expressed in this opinion are based on the most current interpretation of the law by this office, they could subsequently be changed or superseded.

Please contact me if you have any questions or comments regarding this opinion.

Sincerely,

Michael A. Brown
General Counsel

Enclosures

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Stanley Parent
Executive Director
Consumer Product Safety Commission

DATE: October 28, 1975

FROM : Associate Commissioner for Compliance
Food and Drug Administration

SUBJECT: Recall of [redacted].

An article was noted on page 4 of the September 22, 1975 issue of the Product Safety Letter concerning the removal of [redacted] because of exploding aerosol bottles. The article further stated that, in response to industry questioning the extent of CPSC jurisdiction over cosmetic packaging, the Commission felt it did have authority.

FDA is currently monitoring the recall of the 1.58 ounce size package of [redacted] (aerosol) Cologne, which has been classified as a Class II voluntary recall by us. Since the contents of the container are clearly within the jurisdiction of FDA, it is our feeling that we also have clear jurisdiction over packaging. We are of the opinion that as long as the contents in a container which exhibits a mechanical defect are under the jurisdiction of FDA, we are responsible for the entire package, including the monitoring of any recalls associated with the failure of that package. It would also appear that under Section 2(f)(2) of the Hazardous Substances Act the Commission would lack jurisdiction in this instance.

I would appreciate receiving any comments you might have on this matter.

Sam D. Fine

Sam D. Fine

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD. 20852

OFFICE OF THE
GENERAL COUNSEL

January 7, 1975

Michael A. Brown, Esq.
General Counsel
Consumer Product Safety Commission
Washington, D. C. 20207

Dear Mike:

This is in response to your letter of October 15, 1974, requesting an opinion on whether various food containers are "food" as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act, and your related letter of December 27, 1974.

Under the Act, the term "food" includes all "components" of food, and thus all "food additives" as that term is defined in section 201(s) of the Act. As you will appreciate, this is an extremely broad definition.

Earlier this year, a United States District Court held that pottery dinnerware from which lead is leached into food is subject to the food additive and food requirements of the Act. See United States v. Articles of Food Consisting . . . of Pottery, 370 F. Supp. 371 (E.D. Mich., Jan. 17, 1974), a copy of which is enclosed. Shortly thereafter, we published in the Federal Register of April 12, 1974 (39 Fed. Reg. 13285), a notice proposing to apply the food additive provisions of the law fully to all food-contact articles intended for use in the household, food service establishments, and food dispensing equipment. A copy of that proposal is also enclosed.

Accordingly, it is our opinion that all glass bottles and other containers produced for use in packaging carbonated beverages, or already containing beverages, or intended to be used for home canning purposes, are subject to the food provisions of the Act to the extent that they become a component or otherwise affect the characteristics of food. Without knowing the details about any particular container and the particular food it is intended to hold, it would be impossible to determine whether it would fit within this definition. Certainly, however, all containers and other related materials intended to be used for home canning purposes for low-acid canned foods would be included within this definition, since their adequacy clearly affects the characteristics of the food they contain.

Assuming, however, that all of these products are "food" and thus subject to regulatory control under the provisions of the Federal Food, Drug, and Cosmetic Act, it does not appear to us that section 3(a)(1)(f) of the Consumer Product Safety Act totally excludes the Consumer Product Safety Commission from jurisdiction over hazards they may present that are not covered by the FD&C Act. The fact that the toxicity of substances migrating from a can to food is regulated under one law does not compel the conclusion that consumer hazards resulting from exploding bottles or jagged edges of an opened can or collapsing aluminum food trays should not be regulated under the other law. Indeed, it seems entirely reasonable to interpret the Consumer Product Safety Act to authorize the Commission to take regulatory action under the CPSA in all areas related to food which are not covered by the FD&C Act.

This would, of course, require close coordination between the two regulatory agencies, but that would also seem to present no hurdle. A memorandum of understanding between the two agencies would undoubtedly be the proper way to proceed.

We would certainly appreciate further discussion with you on these matters.

Sincerely yours,

Peter

Peter Barton Hutt
Assistant General Counsel
Food and Drug Division

Enclosure

CONSUMER PRODUCT SAFETY COMMISSION

[Petition Nos. CP-74-5; HP-75-3]

AEROSOLS

Petition of Center for Science in the Public Interest; Petition of PAM Club To Ban Products Containing Certain Fluorocarbons

I. Introduction

The Consumer Product Safety Commission has before it petitions filed by

the Center for Science in the Public Interest (CSPI) and the PAM Club (PAM), each of which seeks to have this Commission take regulatory action concerning self-pressurized products commonly known as aerosols. Each petition to some extent raises overlapping jurisdictional and substantive questions and will be discussed herein in a consolidated fashion.

In recent years there has been a proliferation of products packaged in pressurized containers. These containers have utilized various propellant gases, such as vinyl chloride monomer and certain fluorocarbons. Recently such aerosols have been subjected to increasing scrutiny because of allegations of harmful properties associated with them. Included among these have been allegations of injuries due to toxicity, carcinogenicity, explosiveness, flammability, and eye and skin irritation. Also recent allegations have been made that the release of fluorocarbons from aerosol cans is associated with a diminution of the ozone layer in the stratosphere.[1] Reports and scientific investigations on the carcinogenic effect of vinyl chloride have already led federal agencies, including the Consumer Product Safety Commission, to ban products containing that propellant. (See 16 CFR 1500.17(a)(10) which bans self-pressurized products intended or suitable for household use that contain vinyl chloride monomer as an ingredient or in the propellant.)

II. Petitions Pending

The petitions seek the following relief:

A. CSPI

1. The Center for Science in the Public Interest requests the Commission to take the following action:

a. *Investigate the Number and Amount of Toxic Substances Used.* Injuries or potential injuries are alleged to exist due to the toxicity of aerosol spray, inducing human tissue burns, respiratory injuries to susceptible people, such as asthmatic and heart patients, irritation and inflammation from excess spray, long-term effect due to particle deposition in the lungs or particle absorption into the blood stream, and synergistic effect from combined product sprays.

b. *Investigate the Safety of Aerosol Containers.* Injuries are alleged to occur from explosion due to accidental or deliberate placement of containers in or near a heat source and also are alleged to occur due to accessibility to children.

c. *Investigate the Usefulness and Accuracy of Aerosol Spray Labeling.* Possible injuries are alleged to occur from difficulty in applying a product as directed on the label, e.g., "apply hair spray while avoiding face."

d. *Investigate the Susceptibility by Consumers to Misuse.* Deaths are alleged to occur from deliberate inhalation of toxic contents of aerosols; and possible injurious effects are alleged to occur from pollution due to overuse in the home.

e. *Investigate the Manufacturers' Honesty in Promotion of Products.* Allegations are made that imply the supplying of misinformation by manufacturers, leading to incorrect use or handling of aerosol spray products.

f. *Public Information.* It is recommended that a public education program be initiated on the dangers of household sprays used in the home.

2. The CSPI also recommends regulatory actions:

a. That aerosol spray products not be used in households.

b. That all toxic and unsafe aerosol products be banned and recalled.

c. That premarket testing of ingredients at manufacturers' expense be required.

3. CSPI recommends these interim measures:

a. Requiring child-proofing.

b. Requiring explosion-proof containers.

B. PAM

The PAM Club asks the Commission to ban:

1. The product, "Pam",

2. All aerosols which have caused more than three confirmed deaths as a result of inhalation, and

3. Aerosols containing both "Freon-11" and "Freon-12" in a mixture.

The product "Pam" is an aerosol used to lubricate cooking surfaces. Petitioners have alleged that "Pam" and similar products are dangerous when used as directed and lethal when the propellant is concentrated and intentionally inhaled.

III. Jurisdiction

At the threshold the Commission must determine its authority to take the regulatory actions petitioned for. The jurisdictional problems are complex and difficult to deal with because of the diversity of products being packaged and sold in aerosol form. Today aerosol packaging is utilized for products ranging from hair sprays and foods to household cleaners, paints, and insecticides. In providing regulatory authority over these products Congress has traditionally vested various federal agencies with jurisdiction on a functional basis. Thus, foods, drugs, and cosmetics are regulated by the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 321 *et seq.*, and economic poisons (pesticides) are regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 135 *et seq.* Other products, including those used in or about the household, are subject to regulation by this Commission under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051 *et seq.*, and the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261 *et seq.* The functional division of jurisdiction compounds the Commission's task where, as here, the petitions raise questions wholly separate from the active ingredients of the products themselves. Both petitions raise questions regarding the propellant utilized in the aerosols. The CSPI petition, in addition, raises questions concerning the packaging and use of the aerosols. Both CSPI and PAM raise the issue of misuse.

A. PROPELLANTS

The authority of this Commission to take any action with respect to the propellants utilized in aerosols must be found in two statutes under its administration—the CPSA, and the FHSA. The CPSA, *inter alia*, authorizes the Commission to regulate "consumer products" by issuing consumer product safety standards to deal with unreasonable risks of injury or by banning products for which a standard is not feasible. Under the FHSA, hazardous substances are required to bear cautionary labeling and, where the nature or the degree of the hazard is found to be so severe that cautionary labeling cannot adequately protect the public, such substances may be declared banned hazardous substances.[2]

Both the FHSA and the CPSA are drafted to exclude from CPSC jurisdiction products which are foods, drugs, cosmetics and pesticides. Section 2(f)2 of the FHSA provides "[t]he term 'hazardous substance' shall not apply to pesticides subject to the . . . [FIFRA] nor to foods, drugs, and cosmetics subject to the . . . [FDCA] . . .," 15 U.S.C. 1261(f)(2). Under the CPSA the term "consumer product" is defined as "any article or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence . . . or (ii) for personal use, consumption or enjoyment of a consumer in or around a . . . household or residence . . .," 15 U.S.C. 2052(a)(1). The Act specifically excludes from the definition of "consumer product," *inter alia*, "economic poisons (as defined by the . . . [FIFRA])," 15 U.S.C. 2052(a)(1)(D); "food . . . as defined in . . . the [FDCA] . . .," 15 U.S.C. 2052(a)(1)(I); and "drugs, devices, or cosmetics (as such terms are defined in . . . the [FDCA])," 15 U.S.C. 2052(a)(1)(H).

It is clear from the drafting of the statute as well as the legislative history that this agency has been vested with residual or "catchall" jurisdiction of hazards associated with those products not specifically exempted. Thus, hazards associated with "consumer products" such as paints, household cleaners, and any products used in or about the household that do not fall within the definitions of foods, drugs, cosmetics and pesticides are unquestionably within CPSC jurisdiction. With respect to this category of

[1] The Commission presently has two petitions before it filed by the Natural Resources Defense Council and the City of Los Angeles seeking to ban aerosols containing fluorocarbons. As these petitions raise additional jurisdictional considerations, as well as unique and complex substantive questions, they will be the subject of a separate decision.

[2] Under section 30(d), CPSA, (15 U.S.C. 2079(d)) the Commission is required to invoke the FHSA as a source of authority to eliminate a risk of injury if such risk can be adequately dealt with under that statute before resorting to the CPSA.

products, the Commission believes that CPSC jurisdiction clearly extends to the delivery system or propellant utilized in conjunction with such products. No other federal regulation or statute extending to the propellant utilized with this category of products can adequately deal with the problems raised in the petitions herein.

The Commission, having determined that it has the requisite jurisdiction to regulate the propellants utilized in conjunction with those consumer products subject to its jurisdiction under CPSA and FHSA, must address whether it has jurisdiction over propellants utilized in conjunction with foods, drugs, cosmetics, or pesticides. The FDCA defines the term "food" as "(1) articles used for food or drink for man or other animals . . . and (3) articles used for *components* of any such article," 21 U.S.C. 321(f). (Emphasis supplied.) The term "drug" is defined as "(A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a *component* of any articles specified in clause (A), (B), or (C) . . .," 21 U.S.C. 321(g)(1). (Emphasis supplied.) "The term 'cosmetic' means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a *component* of any such articles; except that such term shall not include soap," 21 U.S.C. 321(i). (Emphasis supplied.)

The FDA has broadly interpreted the term "component" and has utilized it to take regulatory action over aerosol propellants when used in conjunction with foods, drugs, and cosmetics. An assertion of jurisdiction based in part on the "component" authority has been upheld in two recent court decisions involving food contact surfaces. In the first case, FDA determined that certain cardboard wrapping containing a chemical that might become part of food was a "food additive" and therefore a food for regulatory purposes. This finding was sustained in *Natick Paperboard Corp.* v. *Weinberger*, 389 F. Supp. 794 (D. Mass. 1975). The Court, in reviewing the legislative history of the FDCA, noted that Congress intended FDA to "monitor and regulate anything traveling in interstate commerce which ultimately would be ingested by human beings regardless of the label appended thereto." 389 F. Supp. at 797. The Court further noted that remedial safety legislation such as FDCA is to be liberally interpreted consistent with the act's overriding purpose. Similarly, in *U.S.* v. *Articles of Food*, 307 F. Supp. 371 (E.D. Mich. 1974), another Court upheld FDA regulation of pottery that contained lead and was intended for use as dinnerware.

FDA has also interpreted its jurisdiction broadly in the area of aerosols. Thus, in two separate FEDERAL REGISTER notices on May 3, 1973 (38 FR 10956), and March 7, 1973 (38 FR 6191), FDA proposed regulations requiring, among other things, that certain precautionary labeling appear on aerosol containers. The May 3 notice, which has never been finalized, was published under the authority of the Federal Hazardous Substances Act, which as of that date was administered by FDA,[3] and applied to fluorocarbon aerosols intended or suitable for use in the household. The March 7 notice, which was finalized March 3, 1975, was published under the authority of the Federal Food, Drug, and Cosmetic Act and applied to aerosolized food, drug, and cosmetic products.

Two things are significant about these regulations. The first is that they proposed labeling that warns consumers of dangers associated with intentionally inhaling the product, a hazard that is associated primarily with the propellant. The second is that FDA carefully published two separate notices under two separate acts regulating some aerosols under one and some under another although the same hazard was presented by all. By these actions FDA made clear that it interpreted the terms food, drugs, and cosmetics as including propellant components when those products were marketed in an aerosol form. FDA further strengthened its interpretation on August 26, 1974, when it banned the use of vinyl chloride monomer as a propellant in drug, and cosmetic products (39 FR 30830).

Apart from regulation, FDA in a communication to this agency,[4] expressed its interpretation of the FDCA as including propellants only when utilized in conjunction with foods, drugs, and cosmetics. This interpretation is supported by an advisory opinion from the Department of Justice[5] which monitors problems of conflicting jurisdiction among federal agencies.

It is a touchstone principle that where any ambiguity exists in a regulatory statute courts will look to, and give great weight to, the interpretation of a statute by the agency charged with its administration. *Udall* v. *Tallman*, 380 U.S. 1 (1965). The Commission believes that administrative agencies should recognize this same principle through the doctrine of comity when they are required to construe the statutory scheme of a sister agency. Indeed, section 29(c), CPSA, 15 U.S.C. 2078(c), establishes a policy of cooperation among the various federal agencies regulating product safety in the administration of their respective statutory schemes.

FDA has clearly, consistently, and unambiguously asserted jurisdiction over food, drug, and cosmetic propellants, and its interpretation is supported by the Department of Justice. Its broad reading of its authority has been supported by the courts and acknowledged by Congress. The Commission, therefore, finds that it lacks jurisdiction to regulate any hazards associated with propellants used in food, drug, and cosmetic products.

Similarly, the Commission also lacks jurisdiction to regulate hazards associated with propellants used in aerosol pesticides. FIFRA defines an economic poison broadly as "(1) any substance or mixture of substances intended for preventing, destroying . . . forms of plant or animal life . . . which the Administrator shall declare to be a pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. 135(a). There seems little room for doubt that this definition is broad enough to encompass propellants of aerosol pesticides. This interpretation is borne out by the fact that on April 26, 1974, the Administrator of the Environmental Protection Agency effectively banned the use of vinyl chloride in pesticide products by suspending registration for products containing that propellant. 39 FR 14753.

The functional divisions of jurisdiction over the various types of aerosol products also precludes the Commission from asserting jurisdiction over all aerosol propellants prior to inclusion in products intended for consumers. This Commission's jurisdiction under FHSA is limited to those substances intended or packaged in a form suitable for use in the household. Bulk propellants not being so intended or packaged, are beyond the authority of that Act. Under the CPSA the term "consumer product" includes components of consumer products. However, bulk propellants which are intended for use in foods, drugs, cosmetics, or pesticides are not a component of and cannot be considered consumer products and are therefore not subject to regulation under the CPSA.

B. MECHANICAL HAZARDS

CSPI's petition raises another jurisdictional question. This question relates to mechanical hazards associated with the aerosol cans. Aerosol containers are alleged to present certain mechanical hazards such as the danger that they may explode, that sharp exterior edges may cut and injure the unwary consumer, that the spray may go in a direc-

[3] The Federal Hazardous Substances Act was transferred to the Consumer Product Safety Commission on May 14, 1973 by section 30 of the Consumer Product Safety Act.

[4] Letter of February 17, 1975 from the FDA General Counsel to the CPSC General Counsel available in the Office of the Secretary.

[5] Letter of June 10, 1975 from Wallace H. Johnson, Assistant Attorney General, U.S. Dept. of Justice, to Council on Environmental Quality, available in the Office of the Secretary.

[6] The House Committee Report accompanying the Consumer Product Safety Act in discussing the exclusion of food from the definition of consumer products states that it "intends to exclude from application of this bill all foods within the broad meaning given to that term in section 201 of the Food, Drug and Cosmetic Act." H.R. Rep. No. 1153, 92d Cong., 2d Sess. 28 (1972).

other than that intended by the consumer thereby causing injury, or that young children may be exposed to serious personal injury or illness because they may gain access to the contents.

As noted, *supra*, the Commission views its authority under the CPSA as the residual power to deal with risks of harm associated with consumer products where Congress has not specifically vested jurisdiction in another statutory scheme. This interpretation accords with the legislative history of the Consumer Product Safety Act. The Act was broadly drawn to ensure that all consumer product hazards would be regulated by one agency except those "which are either regulated under other safety laws or which the Committee has yet to determine should be subjected to safety regulation of the type envisioned by this bill." H.R. Rep. No. 1153, 92d Cong. 2d Sess. p. 27 (1972).

Regarding the regulation of mechanical hazards under the FDCA, there is no explicit decision by FDA in the area. There is, however, an interpretation by FDA in a letter suggesting that FDA may lack authority to adequately regulate mechanical hazards associated with food, drug, and cosmetic containers.[7] Moreover, this letter suggests that it would be appropriate for the CPSC to assert jurisdiction in this area where the FDCA is deficient. Certainly this interpretation construes the FDCA in a manner consistent with any reasonable interpretation of the CPSA to provide maximum protection to consumers in accordance with Congressional intent.[8]

Unlike the propellant, the aerosol container itself does not normally mix with or in any way become part of the contents of the can.[9] In *United States* v. *Articles of Food, supra*, the Court specifically pointed out that FDCA would not provide jurisdiction to regulate packaging where there is no migration:

It is likewise clear that ordinary packaging or food holding devices from which there is no migration are not subject to the Act. 370 F. Supp. at 373.

Therefore it is reasonable to believe that the aerosol container itself is not a "food," "drug," or "cosmetic."

It is true that FDA has interpreted the FDCA to permit it to warn consumers of dangers associated with exploding aerosol containers. 42 FR 8912 (March 3, 1975). However, this labeling authority does not depend on FDA finding that the container itself is a food, a drug, or a cosmetic. Rather it seems to be based on the language of 21 U.S.C. 321(n) which provides that a food, drug, or cosmetic article may be deemed misbranded if its label is misleading in that it fails to reveal facts with respect to hazards associated with use of the article. Since FDA's ability to so label aerosols does not require the container itself to be a food, drug or cosmetic, it does not preclude this Commission's setting standards to regulate the mechanical hazards of aerosol containers.

Since the Consumer Product Safety Act should be interpreted broadly and since this Commission has the expertise and authority to set safety standards to reduce the mechanical hazards associated with aerosol containers and since the agency charged with interpreting the FDCA has not interpreted its laws in any way that would be inconsistent with this jurisdiction, the Commission finds that it has jurisdiction to regulate the mechanical hazards associated with all aerosol containers that are intended for sale to or use by a consumer notwithstanding the fact that the contents are foods, drugs, cosmetics or houshold substances, or that migration may occur.

Pesticides, however, are different since jurisdiction over packaging has been specifically granted to EPA in a 1972 amendment to FIFRA. Therein EPA was given authority:

"(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 90-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this subchapter." 7 U.S.C. 136W. (c)(3) (1972).

To the extent that FIFRA has conferred jurisdiction to EPA, the Commission will not seek to extend its regulatory authority over mechanical hazards or aerosol containers utilized for pesticides. This is consistent with an earlier Commission decision[10] to defer to EPA responsibility for promulgating and enforcing PPPA regulations with respect to pesticides.[11]

IV. Decision

A. CSPI petition

CSPI has requested wide-ranging action by the Commission on aerosols, much of which does not lend itself to formal agency rulemaking.[12] Nevertheless, the Commission does believe the petition raises many significant problems with which it must deal.

Several of CSPI's requests deal with the alleged toxicity of aerosol ingredients. Specifically, CSPI asked the Commission to investigate the number and amount of toxic substances used in aerosols, and recommended that it ban the use of aerosols in the home, that it require the recall of all toxic and unsafe aerosols, and that it require premarket-testing of aerosol ingredients at manufacturer's expense.

With respect to problems of aerosol products within CPSC jurisdiction (see section III A. *Supra*) that may present long-term or chronic toxicity hazards to consumers, the Commission has decided to take whatever steps may be necessary to develop test methods for the objective evaluation of individual products. The test methods presently specified by FHSA and the regulations promulgated thereunder are designed primarily to reveal hazards that are acute rather than chronic in nature. While at one time such testing may have been adequate, as CSPI points out, the proliferation of aerosol products and reports of long-term hazards associated with their use leads the Commission to the conclusion that it is necessary to develop guidelines and screening protocols that will pinpoint ingredients or mixtures of ingredients that may produce adverse chronic effects. The Commission is currently conducting applied inhalation research to develop some of the basic criteria for objectively evaluating products for potential acute and/or chronic hazards. This type of research will continue until such generic tests can be developed. The sub-chronic or chronic inhalation tests to be developed will provide a means of evaluating aerosol products for their potential for causing harmful effects to consumers.

Research and investigations are currently being conducted by the Commission in furtherance of this goal. The Commission is sponsoring a contract study to determine particle size and chemical composition of typical aerosolized products; to determine such products' distribution in the consumers' immediate environment under conditions simulating use by consumers; to determine, in two animal species, the deposition and metabolic fate of tracer-labeled aerosols; and to determine long-term effect of several chemicals found above to be so deposited and retained in the body. The Commission has entered into a contract for a study of the effects (mechanism of action) of inhalation of commonly used volatile solvents and propellants. The investigator for this study is already under contract with another federal agency, and has already provided considerable data. This study should provide additional information on the cardiovascular and pulmonary effects of

---

[7] Letter of January 7, 1975, from FDA General Counsel to CPSC General Counsel available in the Office of the Secretary.

[8] *See Wilderness Society* v. *Morton*, 479 F. 2d 842 (D.C. Cir. 1973), *cert. denied*, 411 U.S. 917 (1973).

[9] It is conceivable that under some extraordinary circumstances some portion of the aerosol container might migrate into the product itself thus making it unfit for human use or consumption. Were this to happen, the affected containers would, of course, be subject to regulation under the FDCA for this hazard.

[10] CPSC administrative decision regarding regulatory policy, November 21, 1974.

[11] It should also be noted that since the PPPA explicitly grants authority to the Commission to regulate foods, drugs and cosmetics with respect to child-resistant packaging, no jurisdictional question arises.

[12] Note that a "petition" in this context means a request for the Commission to issue, amend, or repeal a rule, 5 U.S.C. 553(e); 15 U.S.C. 2059(a); 21 U.S.C. 701(e). All other requests for agency action, such as requests to conduct research, or to institute information campaigns, while given serious consideration, cannot be considered "petitions" in the legal sense.

commonly used aerosol propellants and solvents thus furnishing the Commission an improved basis for identifying potentially dangerous chemicals in pressurized products. The Commission has, via an interagency agreement with the Biomedical Laboratory, Toxicology Division, Edgewood Arsenal, Maryland, initiated the following inhalation studies on vinyl chloride:

Lifetime cancer study in rats and mice following short-term, low-level exposures to vinyl chloride monomer.

A three-generation animal study of the reproductive systems and processes after exposure to the vinyl chloride monomer.

The Commission has asked the National Academy of Science/National Research Council to organize and convene a series of panels and sub-panels of experts to perform the following tasks:

To evaluate the current toxicity test procedures for their reliability and applicability to the goals of the Consumer Product Safety Commission; to recommend additional research (priority) needed to develop and/or validate test procedures; and to update and expand NAS/NRC Publication 1138, "Principles and Procedures for Evaluating the Toxicity of Household Substances," and where possible recommend methodology applicable to CPSC procedures.

When reliable testing protocols have been developed, the Commission anticipates promulgation of rules establishing the test methods and supplementing the existing definitions of the term "toxic" under the FHSA.

As a practical matter, addition of generic tests for chronic health hazards to the FHSA will require manufacturers to test for those hazards. The statutory scheme of the FHSA contemplates premarket testing by manufacturers in that the FHSA requires all products, including aerosols, to bear cautionary labeling if the products contain ingredients or mixtures of ingredients that are toxic, corrosive, irritants, strong sensitizers, flammable or combustible or generate pressure through decomposition, heat, or other means. 15 U.S.C. 1261(p). The statute itself prescribes some tests to determine whether a product presents one of those hazards. Also, as it proposes doing for chronic hazards, the Commission has from time-to-time supplemented these tests by regulation. While the FHSA does not explicitly require manufacturers to test their products for these unsafe characteristics, the sale of a misbranded product (i.e., one not properly labelel) is subject to criminal penalties without regard to the manufacturer's specific intent, 15 U.S.C. 1264. The Commission believes this sanction, coupled with the Commission's ability to seize misbranded goods, results in widespread premarket testing of products to determine whether they are required to be labeled under FHSA.

The Commission believes that this research program and the premarket testing that will result from it are responsive to the group of CSPI's requests dealing with the toxicity of aerosols. To the extent that CSPI requests a ban on the sale of all aerosols under CPSC jurisdiction, the request is denied. Based on present knowledge the Commission cannot find that a ban would be justified. This judgment can of course be reversed at any time new information is acquired which shows that a ban of individual aerosol products or of all aerosols is required to protect the public.

CSPI also requested the Commission to investigate the susceptibility of aerosols to misuse by consumers and to educate consumers to the hazards associated with aerosols. The Commission, based on available information concludes that it lacks jurisdiction to regulate those products most commonly associated with intentional misuse. Nevertheless, because products it does regulate may also be intentionally misused, the Commission plans a comprehensive education campaign to alert consumers to this danger. This campaign will also address certain other aspects of the aerosol problem such as the danger that containers may explode when improperly disposed of.

CSPI asked the Commission to investigate dangers to children from the accessibility of aerosols and to require all aerosols to have child resistant closures. Certain products such as oven cleaners containing sodium and/or potassium hydroxide, which the Commission's injury data show to be particularly hazardous, are already required to have such closures (16 CFR 1700.14(a)(5)). The Commission has directed its staff to determine which other aerosol products present a hazard of serious personal injury or illness to young children by reason of the accessibility to their contents. Any that are so identified will be promptly considered for the institution of rule-making procedures under the FPPA. In this connection the Commission has also directed its staff to evaluate its present test methods for hazards, such as the test for eye irritancy, to determine whether new methods are necessary to adequately measure the risk of injury posed by aerosolized products to small children.

With respect to misdirection problems associated with aerosol containers that present a risk of injury because of inadequate means to properly direct the spray, the Commission has decided to take steps to seek prompt voluntary action to correct the problems. In the event that a voluntary commitment cannot be obtained, the Commission will take formal regulatory action.

CSPI requested the Commission to investigate the safety of aerosol containers and to require explosion proof containers. The Commission's investigation which included hearings held in February and March, 1974, and May, 1975, review of death certificates furnished by local jurisdictions and in-depth investigation of injuries reported by hospital emergency rooms through the Commission's National Electronic Injury Surveillance System (NEISS) as well as other sources demonstrates that, at this time, no unreasonable risk of injury is associated with exploding aerosol containers. Therefore, this request is denied without prejudice.

Finally CSPI asks the Commission to investigate the usefulness and accuracy of aerosol spray labeling and the honesty of manufacturers in the promotion of aerosol products. The Commission has undertaken an investigation of consumers' awareness of labeling on aerosolized household products which are associated with injuries to consumers. This study will be used by the Commission staff to determine whether existing labeling requirements for aerosolized household products could be improved to reduce or eliminate risks of injury associated with those products.

With regard to misleading or deceptive promotion (other than mislabeling) of aerosolized household products, the Commission notes that the Federal Trade Commission is the agency of the federal government with primary jurisdiction over such practices. Section 5 of the Federal Trade Commission Act authorizes the Federal Trade Commission to prevent "unfair or deceptive practices" directed toward consumers. The Commission therefore believes this request would more appropriately be directed to the FTC.

B. PAM CLUB PETITION

PAM is an aerosol product used for the lubrication of cooking surfaces. Since portions of such products inevitably become commingled with the food being cooked and because it is an edible substance, the Commission believes the product to be a "food" subject to regulation under the Federal Food, Drug, and Cosmetic Act, *supra*. The propellant, as discussed above, likewise becomes a "food" subject to regulation under FDCA. Accordingly, because the CPSC lacks subject matter jurisdiction, the PAM Club petition is denied insofar as it requests a ban of the product "PAM".

The PAM Club petition further requests the Commission to ban all aerosols which have caused more than three confirmed deaths per year due to inhalation, and seeks a ban on all aerosols containing "Freon-11" and "Freon-12" mixtures.[12] The Commission interprets this request to apply to all aerosols regardless of whether they contain a food, drug, cosmetic or pesticide. As noted above, the Commission's jurisdiction extends only to propellants in aerosol products which are not considered foods, drugs, cosmetics or pesticides.

Regarding the part of the petition which requests a ban on "specific aerosol products which have caused more than three confirmed deaths as a result of inhalation of the propellant . . .," the Commission believes this language is too vague for regulatory purposes. More importantly, however, the Commission disagrees with the establishment of a "death count" approach to regulation of product safety. It seems clear that the

[12] "Freon-11" and "Freon-12" are trade names of Dupont Corporation for certain fluorocarbon compounds.

petitioner's intent is to have the Commission respond with regulatory action before a substantial number of deaths occur and that three deaths associated with a specific problem is an adequate early warning signal. The Commission intends to fully investigate alleged problems with aerosol products under its jurisdiction when brought to its attention, and to take action where warranted. A specified number of deaths need not be the criterion for initiating regulatory action. Therefore the Commission denies the specific request to ban an aerosol product whenever three deaths have occurred as a result of inhalation of the propellant.

Regarding the portion of the petition requesting a ban on "all aerosols containing both Freon 11 and Freon 12 in a mixture", the Commission is unaware of evidence that "Freon-11" and/or "Freon-12", when used in conjunction with any product within CPSC's jurisdiction, is being misused by intentional inhalation to any extent requiring regulation. Therefore, the Commission does not at this time believe it is appropriate or necessary to initiate regulatory action.

Accordingly, for the foregoing reasons, the Commission finds that the petition fails to present reasonable grounds for the banning of any product within its jurisdiction and therefore denies requests for such bans without prejudice.

In taking this action the Commission is not ignoring the increasing problem associated with abuse of inhaling aerosols. As the Commission recognizes the possibility that certain aerosol products within its jurisdiction may pose the same hazard as "PAM", it plans to undertake a major information and education campaign to inform consumers of this problem. It is believed that this can be an important step in eradicating misuse, although it must be done with great caution as publicity can in fact aggravate the problem.

Dated: July 18, 1975.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc.75-19226 Filed 7-23-75;8:45 am]