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 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." 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

TO: Stanley Parent
    Executive Director
    Consumer Product Safety Commission

FROM: Associate Commissioner for Compliance
      Food and Drug Administration

DATE: October 28, 1975

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
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 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 for Petition of PAM Club to Ban Products Containing Certain Fluorocarbons

I. INTRODUCTION

The Consumer Product Safety Commission has before it petitions filed by
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The Center for Science in the Public Interest (CSCI) and the PAM Club (PAM), each of which seeks to have this Commission take regulatory action concerning self-preserviced products commonly known as aerosols, have petitioned to have these products regulated. Each petition seeks to ban aerosols containing fluoro-carbons because of their contribution to the ozone layer in the stratosphere. Reports on scientific investigations on the carcinogenic effect of vinyl chloride have also been made. The Consumer Product Safety Commission has been requested to ban products containing this propellant. (Sec. 16 CFR 1500.17(a)(10) which bans self-preserviced products intended or suitable for household use that contain vinyl chloride monomer as an ingredient 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 occur due to the toxicity of aerosol spray, including human tissue burns, respiratory injuries to susceptible people, such as asthmatic and heart patients, irritation and inflammation from excess spray, long-term effects 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."

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 questions, the Commission has decided that the unique and complex substantive questions, they will be the subject of a separate decision.

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 reported deaths as a result of inhalation.

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 time the CSPI petition is filed, the jurisdictional Commission must determine its authority to take the regulatory actions petitionered for. The jurisdictional problems are complex and difficult to deal with because of the diversity of products and packaging and the fact that these products are sold in aerosol form. Today aerosol packaging is utilized for products ranging from hair sprays and foods to household cleaners, paints, and insecticides. In response to these concerns 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 (as defined by the FIFRA) are regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 155 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, which the Commission is unable to deal with, is raised, as here, the petitions raise questions wholly separate from the active ingredients of the products themselves. Both petitions, for example, question 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 regulatory 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 is inadequate, to protect the public, such substances may be declared hazardous.

Both the FHSA and the CPSA are drafted to exclude from CPSA jurisdictional aspects which are, e.g., foods, drugs, cosmetics and pesticides. Section 2(d) of the FHSA provides "(t)he term 'hazardous substance' shall not apply to pesticides subject to the... (FIFRA)...." 15 U.S.C. 1201(f) (2). Under the CPSA the term "consumer product" is defined as "any article or component part of foods, drugs,... or cosmetics,... or in many cases..." and "any consumer product,... or in any case..." and "any product... or in the household... or in any case..." 15 U.S.C. 2052(a)(1).

The Act specifically excludes from the definition of "consumer products..." "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) (J); and "drugs, devices, or cosmetics (as such terms are defined in... the FDCA)." 15 U.S.C. 2052(a)(1) (F).

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 CPSA jurisdiction.

With respect to this category of

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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 extends to the propellant utilized with this category of products can adequately deal with the problems raised in the petition therein.

The Commission, having determined that the regulatory jurisdiction to regulate the propellants utilized in conjunction with those consumer products subject to its jurisdiction under CPSCA and FHSA, must address whether it has jurisdictional preclusion under FDCA 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 (2) articles intended 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 Pharmacopoeia, 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 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 Commission has consistently 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 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 subsequently affirmed by the United States Court of Appeals for the Ninth Circuit in a case not related to "monitor and regulate anything traveling in interstate commerce which ultimately would be ingested by human beings regardless of the label appended thereto." 399 F.2d at 747. The Court expressly 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. For example, the Federal Hazardous Substances Act, as amended, 15 U.S.C. 2601 et seq., which was restructured and redefined by the Federal Hazardous Substances Act on May 3, 1973 (38 FR 10956), and March 7, 1973 (38 FR 6191), FDA proposed regulations requiring, among other things, that certain precautionary labels be posted on aerosol containers. The May 3 notice, which has since become final, was published under the authority of the Federal Hazardous Substances Act, which as of that date was administered by FDA. The final action on this rulemaking by FDA, as it is defined in 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 for aerosol propellants to alert the consumer to dangers associated with intentionally inhaling the product, a hazard that is associated primarily with the propellant. The second is that FDA carefully analyzed the six aerosol propellants, under two separate acts regulating some aerosols under one and some under another although the same hazard was presented by each. In each case, FDA may clearly see that it interpreted the terms food, drugs, and cosmetics as including propellant components when those products were marketed in an aerosol form. FDA further acted on August 26, 1974, when it banned the use of volatile chlorofluorocarbon as a propellant in drug and cosmetic products (39 FR 20305).

AGENCY FORMULATION FDA in a communication to this agency, expressed its interpretation of the FDCA as including propellants only when utilized in conjunction with foods, drugs, and cosmetics. The interpretation was made by an advisory opinion from the Department of Justice 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 "agency interpretation" in determining the scope of CPSCA. Under the CPSCA the term "consumer product" includes components of consumer products. However, bulk propellants which are intended for use in foods, drugs, cosmetics, or pesticides and are not a component of and cannot be considered consumer products and are therefore not subject to regulation under the CPSCA.

B. MECHANICAL HAZARDS

CSPI's petition raises another jurisdictional question. This question relates to mechanical hazards associated with the packaging of aerosol propellants. CPSCA is alleged to present certain mechanical hazards such as the danger that they may explode, that sharp exterior edges may cut and injure the untutored consumer, that the spray may go in a direct


*Letter of February 17, 1975 from the FDA General Counsel that states "No food from the described consumer composition is available in the Office of the Secretary.

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other than that intended by the maker thereof causing injury, or where 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 action under the CPSIA as providing it with 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, the CPSC, that is 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. See S. Rep. No. 1153, 92d Cong. and Sess., p. 27 (1972).

Regarding the regulation of mechanical hazards under the FDCA, there is no explicit decision by FDA in the area. The 1974 amendment to the FDCA in a letter suggesting that FDA may lack authority to adequately regulate mechanical hazards associated with food, drug, and cosmetic containers. Moreover, the letter suggests that it would be appropriate for the CPSC to assert jurisdiction in this area where the FDCA is deficient. Certainly this interpretation of the FDCA in a manner inconsistent with any reasonable interpretation of the CPSA to provide maximum protection to consumers in accordance with Congressional intent. Until the propellant, the aerosol container itself does not normally mix with or in any way become part of the contents of the can. In United States v. Articles of Food, supra, the Court specifically pointed out that the FDA 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 reasonable expectation of FDA finding that the container itself is 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. 12 FR 8012 (March 3, 1975). However, this labeling authority does not permit FDA to find that the container itself is a food, drug, or 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 demonstration of the likelihood of the 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 these substances 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 aerosol containers that are intended for sale to or use by a consumer notwithstanding the fact that the containers are foods, drugs, cosmetics or household substances, or that migration may occur.

Pesticides, however, are different since jurisdiction over packaging has been specifically assigned to the EPA. 72 Stat. 2338. As to the subject amendment to the 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 of aerosol containers utilized for pesticides. This is consistent with an earlier CPSC administrative decision to defer to EPA responsibility for promulgating and enforcing PPA regulations with respect to pesticides. 11

IV. DECISION

A. CPSI PETITION

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

Several of CPSI's requests deal with the alleged toxicity of aerosol ingredients. Specifically, CPSI asked the Commission to require the submission of 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 Fed. Reg., July 12, 1975) 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 proposed by FHSA and the regulations promulgated thereunder are designed primarily to test aerosols that are acute rather than chronic in nature. While at one time such testing may have been adequate, as CPSI points out, the proliferation of aerosol products and reports of adverse chronic effects has led to the need of their use leads the Commission to conclude 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 consumer's 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 aerosol campaigns, while giving serious consideration to whether such effects cannot be considered "petitions" in the legal sense.

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

Lifetime cancer study in rats and mice following short-term, low-level exposure 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 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 and recommend additional research (priority) needed to develop and/or validate test procedures; and to update and expand NACE/NSC Publication 113, "Principles and Practice for Evaluating the Toxicity of Household Substances." And where possible recommend methodology applicable to CPSC procedures.

While 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, adduction of general tests for chronic health hazards to the FHSA will require manufacturers to test for those hazards. The statutory panel of the FHSA calls for premarket testing by manufacturers in that the FHSA requires all products, including aerosols, to bear cautionary labeling for products containing ingredients or mixtures of ingredients that are toxic, corrosive, irritant, strong sensitizers, flammable or combustible or generate pressure through decomposition, heat, or chemical reaction (15 U.S.C. 1264). 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 labeled) is subject to criminal penalties without regard to the manufacturer's specific intent, 15 U.S.C. 1294. The Commission believes this action, 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 CPSC's requests dealing with the toxicity of aerosols. To the extent that CPSC 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 reassessed 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.

CPSC 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 misconceptions. Nevertheless, because products it does regulate may also be intentionally misused, the Commission plans a comprehensive educational campaign to alert consumers to this danger and will also address certain other aspects of the aerosol problem such as the danger that containers may explode when improperly disposed of. CPSC requested 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 contain ammonia and/or trichloroethylene, which the Commission's injury data show to be particularly hazardous, are already required to have such child resistant closures.

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 assessing the accessibility to their contents. Any that are so identified will be promptly informed for the institution of rule-making procedures under the FPPA. In this connection the Commission plans to extend its staff to evaluate its present test methods for hazards, such as the test for eye irritancy, to determine whether new methods are necessary. The Commission must carefully measure the risk of the 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 problem. In the event that a voluntary commitment cannot be obtained, the Commission will take formal regulatory action.

CPSC requested the Commission to investigate the safety of aerosol containers and their ingredients. The information contained in the requests 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 PAM Club petition further requests that the Commission ban all aerosols presenting a risk of injury to young children. The Commission interprets this request to apply to all 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 propelant..." the Commission believes this language is too vague for regulatory purposes. More importantly, however, the Commission disagrees with the measurement of a "death count" approach to regulation of product safety. It seems clear that the "Freon-11" and "Freon-12" are trade names of DuPont Corporation for certain fluorocarbon compounds.

NATIONAL DEFENSE AUTHORITY

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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.

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

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