MOU 225-76-2003

Memorandum of Understanding
Between The U.S. Consumer Product Safety Commission
and The U.S. Food and Drug Administration

PURPOSE

The purpose of this Memorandum of Understanding is to be delineate the areas of jurisdiction of respective signatories for administration of the Consumer Product Safety Act and the Federal Food, Drug, and Cosmetic Act with respect to food, food containers, and food-related articles and equipment

LEGAL BACKGROUND

A. CPSC Responsibilities. The Consumer Product Safety Commission (CPSC) administers the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 et seq.), which was enacted to protect the public from unreasonable risks of injury associated with consumer products. In order to accomplish its mission the Commission is authorized, among other things, to issue consumer product safety standards, to establish requirements for warnings and instructions, to declare consumer products banned hazardous products when the public cannot be protected adequately be feasible consumer product safety standards, and to require manufacturers, distributors, and retailers to report potential substantial product hazards associated with consumer products to the Commission, and after opportunity for a hearing, to give notice, and/or repair, replace or refund the purchase price of the consumer product found to present a substantial product hazard.

The term "consumer product" is defined in section 3 (a) (1) of the CPSA (15 U.S.C. 2052 (a) (1)) as follows:

The term "consumer product" means any article, or component part there of, product or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term dose not include--*** I) food, The term " food" as used in this subparagraph means all " food", as defined in section 201 (f) of the Federal Food, Drug, and Cosmetic Act,***

Thus, articles classified as "food" under the Federal Food, Drug and Cosmetic Act (FDC Act) (21 U.S.C. 301 et seq.) are not "consumer products" and cannot be regulated under the CPSA.*/ The definition of the term "food" in Section 201 (f) of the FDC Act (21.U.S.C. 321(f)) is, therefore, critical in delineating the scope of CPSC's jurisdiction over "consumer products": The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

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*/ Substances which are "foods" subject to the FDA Act are also excluded from definition of "hazardous substance" under section 2(f) 2 of the Federal Hazardous Substances Act (15 U.S.C. 1261 (f)2). They therefore cannot be regulated by CPSC under that Act. However, under section 2(2) (C) of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 (2) (C)) food may be subject by CPSC to a child-resistant (special) packaging requirement.

B. FDA Responsibilities. The Food and Drug Drug Administration (FDA) of the Department of Health, Education, and Welfare has the responsibility for enforcing the FDC Act which, among other things, prohibits the introduction into interstate commerce of articles of food that are adulterated or misbranded. An "adulterated food", as described in section 402 (21 U.S.C. 342) , is one which, because of its contents is, among other things, injurious to health or otherwise unfit for food. A "misbranded food" under section 403 of the Act (21 U.S.C. 343) , is one which, among other things, is false or misleading in any particular of its labeling. The purpose of the FDC Act is to ensure that foods are wholesome, safe to eat, produced under sanitary conditions, and labeled and packaged in a truthful, informative, and non deceptive manner. Under the FDC Act, FDA is also responsible for ensuring that "food additives", as defined in section 201 (s) (21 U.S.C. 321 (s)), are safe under the conditions of their intended use.

NEED FOR CLARIFICATION

The need for this Memorandum of Understanding arose because of uncertainty concerning the scope of the statutory exclusion under CPSA for all articles defined as "food" by the FDC Act. The need for clarification is acute because determination of whether a potentially hazardous consumer article is a "food" determines as well whether consumers are to be protected from risk of injury or illness by CPSC pursuant to the CPSA or by FDA pursuant to the FDC Act. Congress recognized the need for cooperation between CPSC and other federal agencies when, in section 29 (c) of the CPSA (15 U.S.C. 2078 (c)), it provided that the Commission and heads of other departments and agencies engaged in administering programs related to product safety shall, to the maximum extent practicable, cooperate and consult in order to insure fully coordinated efforts.

While this Memorandum addresses the significant food-related jurisdictional issues encountered since enactment of the CPSA in 1972, it is recognized by the two agencies that additional points needing clarification may arise in the future and that changes in this agreement may become necessary

AGREEMENT

CPSC and FDA have agreed upon the following principles:

A. Aerosol Propellants. Aerosol propellants included in a food product may be substantially dissipated before food is ingested. Nevertheless, they are "components" of food and thus " food" within the meaning of the FDC Act and subject to regulation by FDA.

B. Food Contact Surfaces (Migration). Articles having food contact surfaces, such as food containers, and food cooking, eating, and preparation articles, from which there is migration of a substance from the contact surface to the food are food " components" and thus "food" within the meaning of the FDC Act and subject to regulation by FDA.

Natick Paperboard Co., v Weinberger, 525 F.2d 1102 (1st Cir. 1975); United States v Articles of Food Pottery, 370 F.Supp. 371 (E.D. Mich. 1974). However, in any case where there is migration, FDA will have regulatory authority over the article as a "food", and CPSC will have regulatory authority over article for hazards unrelated to migration (See paragraph C below)

C. Food Contact Surfaces (No "Migration"). Articles employed in the preparation or holding of food may cause contamination or spoilage without migrating or otherwise becoming a component of the food, e.g., home canning equipment that fails to provide a seal adequate to keep air from passing into stored food; pressure cookers, slow cookers, refrigerators, or freezers which fail to perform at proper temperatures, thereby rendering food unfit to eat; can openers which, in opening a can, cause metal particles from the can (not the can opener) to be deposited in food. Because such articles do not present a hazard by becoming components of food, they are subject to regulation as "consumer products" by CPSC under the CPSA. (FDA may, of course, take action under the FDC Act against food contaminated or spoiled by such articles if interstate commerce is involved. FDA may also regulate the equipment and procedures employed by commercial processors of food which has been or is to be shipped in interstate commerce when necessary to assure the wholesomeness or safety of such food).

D. Food Containers (Mechanical Hazards). Food containers may present mechanical risks of injury not related to food contamination or spoilage, e.g., a defect in the container which leads to an explosion or breakage of the container, sharp edges presented by the container, defects in the nozzle, etc. Because such articles do not present hazards by becoming components of food, they are subject to regulation by CPSC under CPSA. Such articles may also be subject to overlapping jurisdiction for the FDA under the FDC Act, because FDA has jurisdiction over a food container (even where the container is not a food) which "is composed, in whole or part, of any poisonous or deleterious substance which may render the contents (food) injurious to health," and because FDA has jurisdiction as well over food which " bears***any***deleterious substance" (Sec. 402 (a) (1) , (6) of the FDC Act, 21 U.S.C. 342 (a) (1) , (6)).

E. Technical Assistance. The Food and Drug Administration will provide, upon the request of CPSC, technical assistance, such as evaluation of sealing efficiency of home canning lids, where FDA

determines that it has the technical and laboratory capability to provide such assistance. Results of all evaluations will be reported to CPSC.

F. Future Jurisdictional Questions. Each agency will fully cooperate with the other in administrative, regulatory, and technical matters, and will continue to discuss and reach understandings in future jurisdictional questions. This agreement may be modified by mutual consent of both parties, and may be terminated by either party upon a thirty (30) day advance written notice to the other. Any modification or notice of termination will be published in the FEDERAL REGISTER.

Approved and Accepted
for the Consumer Product Safety Commission
Signed by: S. John Byington
Chairman, CPSC
Date: July 23, 1976

Approved and Accepted
for the Food and Drug Administration
Signed by: Sherwin Gardner for
Alexander M. Schmidt, M.D.
Commissioner of Food and Drugs
Date: July 26, 1976