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DATE: Public comments must be received by REA no later than: April 25, 1980.

ADDRESS: Submit written data, views or comments to the Director, Telephone Operations and Standards Division, Rural Electrification Administration, Room 1365-S, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Robert Peters, telephone (202) 647-3523.

SUPPLEMENTARY INFORMATION: Pursuant to the Rural Electrification Act, as amended (7 USC 901 et seq.), REA proposes to issue a File With to REA Bulletin 341-3. Interested persons may obtain copies of this proposed action from the address indicated above. All written submissions made pursuant to this action will be made available for public inspection during regular business hours at the above address.

On issuance of the File With to REA Bulletin 341-3, Appendix A to Part 1701 will be modified accordingly.

This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. A Draft Impact Analysis has been prepared and is available from the Director, Telephone Operations and Standards Division, Rural Electrification Administration, Room 1365-S, U.S. Department of Agriculture, Washington, D.C. 20250.

Dated: February 20, 1980.

Steven T. Shepherd,

Acting Administrator.

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Food Safety and Quality Service

7 CFR Part 2000

9 CFR Parts 300, 361

Prohibition of All New and Replacement Equipment and Machinery Containing Liquid Polychlorinated Biphenyls (PCBs)

AGENCY: Food Safety and Quality Service, USDA.

ACTIVE Proposed rule.

SUMMARY: This document would amend the Federal meat, poultry products, and egg products inspection regulations administered by the Agency by prohibiting the entry of new or replacement equipment and machinery

containing liquid polychlorinated biphenyls (PCBs) onto the premises of any official establishment or plant regulated under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. PCBs are a class of chemical compounds which are highly toxic and persistent in nature. This action is proposed because of a number of incidents of human food contamination from PCBs. The proposal is intended to reduce the likelihood of future PCB accidents and danger to human health and resultant losses of food due to adulteration.

DATE: Comments must be received on or before April 30, 1980.

ADDRESS: Written comments should be sent to: Executive Secretariat, Attn: Annie Johnson, Room 3607, South Agriculture Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250. Oral comments on the meat, poultry products, and egg products inspection regulations to Dr. W. O. Caplinger, (202) 447-5827. (See also comments under Supplementary Information.)

FOR FURTHER INFORMATION CONTACT: Dr. W. O. Caplinger, Acting Director, Facilities, Equipment, and Sanitation Division, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-5827.

SUPPLEMENTARY INFORMATION

Comments

Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in duplicate to the Office of the Executive Secretariat and should bear a reference to the date and page number of this issue of the Federal Register. Any person desiring opportunity for oral presentation of views on the meat, poultry products, and egg products inspection regulations must make such request to Dr. Caplinger so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented. All comments submitted pursuant to this notice will be made available for public inspection in the Office of the Executive Secretariat during regular business hours (7 CFR 1.27(b)).

Background

Polychlorinated biphenyls (PCBs) are a class of toxic industrial chemicals used for their highly stable, fire resistant, and heat transfer characteristics. They also have high resistance to the flow of electrical current.

PCBs have been used in the United States since 1929 in such applications as transformers and capacitor fluids, heat transfer fluids, hydraulic fluids, capacitors for motors driving refrigerator compressors, and capacitors in pumps and equipment that start under a heavy load.¹

Health Risks Due to PCB's

PCBs were not generally recognized as being toxic until after a widespread poisoning occurred in Japan in 1968 caused by the accidental introduction of PCBs into cooking oil. In that incident, 1,291 people were affected.

Prior to that incident, PCB's had caused reproductive problems in commercial fish. These problems were first reported in 1966, but it was not until 1970, after satisfactory analytical procedures had been developed, that PCB's were identified as the contaminant. The source of the PCB's was found to be contaminated coho salmon from Lake Michigan which were fed to the fish.

Research into the effects of exposure to PCB's since those early concerns has yielded data indicating that PCB's cause various kinds of health disorders in laboratory animals including reproductive failures, gastric disorders, skin lesions, and tumors.

Studies of human exposure to PCB's in the Japanese incident have indicated a high incidence of skin disorders, digestive disturbances, jaundice, throat and respiratory irritations, and severe headaches.

The effects of PCB contamination are cumulative. PCB's are extremely stable and chemically persistent; that is, they do not easily break apart into new chemical arrangements. Even when introduced into living organisms, PCB's do not readily metabolize, but tend to accumulate in the tissues of the host organism. Once introduced into the food chain, from whatever source, they will continue to be present in all resultant products as they move up the food chain. Thus, the human population is susceptible to PCB contamination from foods they consume.

¹ PCB's are or have been manufactured and used under a variety of trade names including Pyral (General Electric), Chloronate (All-Chloronate Inertex (Washington), Refluon (Vapor Service), Fluorobor (Pro Dairies), Therminol (Monsanto Chemical Co.), Aroclor (Monsanto Chemical Co.), MCP (Monsanto Chemical Co.), Pyralon (Monsanto Chemical Co.), Tardion (Monsanto Chemical Co.), and Karobor (Karochemical, Clapham (Bayer), Dynalene (Eastman), and Decachloro Biphenyl (Calfine).

PCBs in Today's Environment

The most significant sources of new PCB's in the environment include discarded consumer or industrial products containing PCB's, atmospheric fallout, and spills associated with the use or the transport of PCB's. In today's environment, PCB's are already widespread, as literally thousands of environmental and ecological samples from all over the world have been analyzed and reported to contain PCB. PCB's have been detected, frequently at high levels, in a large number of fish and bird species inhabiting widely separated geographic areas.

U.S. Regulatory Control of PCB's

PCB's are currently regulated by the Environmental Protection Agency (EPA) and by the Food and Drug Administration (FDA).

a. Environmental Protection Agency

The Toxic Substances Control Act (15 U.S.C. 2601 et seq.) requires the Environmental Protection Agency (EPA) to control the manufacture, processing, distribution in commerce, use, disposal, and marketing of PCB's. Section 4(e)(3) of that Act (15 U.S.C. 2606(e)(3)) provides that no person may manufacture any PCB after January 1, 1979, or process or distribute to commerce any PCB after July 1, 1979, except to the extent that EPA specifically exempts such activity. Implementation of the January 1, 1979, ban was subsequently postponed until 30 days after completion of EPA rulemaking on May 21, 1979 (44 FR 31834). The May 21 rule prohibits all manufacturing, processing, distribution in commerce, and use of PCB's after July 2, 1979, that are not specifically exempted by EPA.

The May 21 rule did provide certain exemptions. EPA authorized use of PCB's in a few "non-totally enclosed" systems, such as in hydraulic systems and heat transfer systems, and generally exempted the use of PCB's in "totally enclosed" systems, such as those found in transformers and capacitors.

EPA has, under the May 21 rule, established a 50 parts per million (ppm) "cut-off point" for defining the term "PCB." Any substance more dilute than this, unless otherwise specifically provided, is not considered a PCB. EPA's conclusion that this cut-off limit provides adequate protection for human health and the environment while defining a program that can be effectively implemented.

b. Food and Drug Administration

The Food and Drug Administration (FDA) similarly has taken steps to prevent the introduction of PCB's into the food supply. Specifically, current FDA regulations, which were promulgated in July 1973, restrict the industrial uses of PCB's in establishments that manufacture, handle, and store food intended for human consumption (21 CFR 110.46), and animal feed (21 CFR 308.46), and in establishments that manufacture food-packaging materials (21 CFR 108.18). These regulations provide that new equipment or machinery for handling or processing human food and animal feed and for manufacturing food packaging materials shall not contain PCB's. Establishments that manufacture, handle and store food intended for human consumption and animal feed, and establishments that manufacture food-packaging materials which had such equipment in place were also required by these regulations to replace any PCB-containing fluids in such equipment to the fullest extent practicable with good manufacturing practices, with fluid that did not contain PCB's, by September 4, 1973. The FDA regulations, however, specifically exempted electrical transformers and condensers containing PCB's in sealed containers because at the time there were no known suitable replacement fluids for such equipment, and their use in FDA regulated establishments was not expected to result in direct contact with materials being processed.

The Proposal

Since 1971, there have been at least eight separate incidents of PCB contamination of human food supplies, including chickens, turkeys, eggs, and cattle, as a result of PCB liquid leaking from industrial equipment. These accidents have resulted in PCB contamination of several million pounds of food with a loss of over \$10 million. No adverse human health effects have been directly attributed to any of these incidents. However, it is known that some PCB's have reached consumers.

A recent major industrial accident occurred in June 1979 in a meat slaughtering plant when PCB liquid leaked from a stored electrical transformer, a totally enclosed system. The PCB liquid was washed into the plant sewage system, separated in primary waste treatment, and sent with other inedible product for rendering into animal feeds. This, in turn, resulted in the contamination both of poultry feeds of animal origin intended for human consumption, including meat, poultry,

milk and eggs, and of secondary food products such as soup, cereal, etc. Millions of pounds of food were contaminated with PCB's as a result of this accident. Food and feed products implicated in the contamination incident were distributed to 19 States and two foreign countries. The cost from this accident alone will run into millions of dollars.

On December 20, 1979, there was a PCB leakage from a capacitor in a federally inspected hog slaughtering establishment in Iowa. Only the quick actions of plant officials and an FDA inspector in recognizing and containing the problem prevented another potentially massive contamination incident.

The Department has the most, poultry products, and egg products inspection acts, to inspect products and take other actions to prevent the distribution of adulterated products. Because of the persistent and highly toxic nature of this class of chemicals, PCB contamination of foods through industrial accidents appears to represent a substantial hazard to human health and environment. Furthermore, animal oil and such synthetic fluids as fluorocarbons, silicones, and others appear to be adequate industrial substitutes for PCB's. PCB substitutes are discussed at length in the *SWP Support Document Voluntary Environmental Impact Statement*, which is available from the Office of Toxic Substances, Environmental Protection Agency, Washington, D.C. 20460.

Consequently, FDA proposes to ban the introduction on the premises of official establishments and plants regulated by the Agency under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, of all new or replacement equipment or machinery containing liquid PCB's in excess of 50 ppm of the liquid medium.*

No exemption for PCB's contained in a "totally enclosed manner" is provided. The problem related to the presence of liquid PCB's in food processing establishments and the removal from all existing equipment and machinery are presently under study. Since PCB's in the solid state do not present the same leakage problems, an exempting them is presently being proposed. However, they will also be considered in connection with the study. The results of that study will determine future Agency action.

*The 50 ppm is the same as the definition amount determined by EPA in 40 CFR 706.5.

Options Considered

In its decision to propose regulatory action on the subject of PCB's, FSQS considered four options. The first option was to take no regulatory action. The second option was to propose the prohibition of the introduction of any new or replacement equipment containing liquid PCB's onto the premises of FSQS inspected meat, poultry products, and egg products processing plants. The third option was to take no regulatory action at the present time, but to conduct an extensive information and education program aimed at the managers of all plants under FSQS jurisdiction. The fourth option was to propose a requirement that would remove existing PCB-containing equipment as well as prohibit the introduction of any new or replacement equipment into any of the aforementioned food processing establishments.

The first option was rejected since it did not deal with the current hazards to human health which PCB's pose. The fourth option is seen as the eventual goal of the Agency. However, more information must be gathered on the economic and technical impact of this option before an effective proposal can be put forth. The second option was selected as the best alternative at present since it will entail a minimal economic impact on the regulated industry while being an important first step leading to the eventual regulation of all PCB's in those food plants inspected by FSQS. It was decided, however, to proceed with the information and education campaign contained in the third option. Using a booklet titled *Polychlorinated Biphenyls: An Alert For Food and Feed Facilities* (December 1979), which was prepared by the Environmental Protection Agency in cooperation with the Department of Agriculture and the Food and Drug Administration, FSQS is attempting to reach managers of all plants under its jurisdiction who have decision-making authority relating to electrical equipment containing PCB's.

IRLGC Liaison

PCB's are a toxic substance identified for regulatory coordination by the Toxic Substances Work Group of the Interagency Regulatory Liaison Group (IRLGC). During the development stage of this regulation, representatives of the EPA, the FDA, the Consumer Product Safety Commission (CPSC), and the Occupational Safety and Health Administration (OSHA) were consulted. FDA and EPA have separately reviewed and concurred in this proposal. It has

been agreed that any comments received as a result of this proposed rulemaking will also be shared with these agencies.

FSQS, EPA, and FDA are also concurrently and cooperatively developing broader rulemaking which would address the present use of PCB's by the food, feed, pesticide, and fertilizer industries. However, in view of the particular problems of this Agency in regulating meat, poultry, and egg products facilities under its jurisdiction, this action is deemed appropriate at this time.

Accordingly, the Federal meat, poultry products, and egg products inspection regulations would be amended as follows:

1. The following are the proposed amendments to 9 CFR:

PART 308—SANITATION

a. Section 308.5 of the Federal meat inspection regulations (9 CFR 308.5) would be amended by adding a new paragraph (g) to read as follows:

§ 308.5 Equipment and utensils to be easily cleaned; those for food products to be so marked; evaluation of equipment and utensils.

(g) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official establishment shall not contain liquid polychlorinated biphenyls (PCB's) in concentrations above 50 parts per million by volume of the liquid medium. This provision applies to both food processing and non-food processing equipment and machinery, and replacement parts for such equipment and machinery.

PART 361—POULTRY PRODUCTS INSPECTION REGULATIONS

b. Section 361.56 of the Federal poultry products inspection regulations (9 CFR 361.56) would be amended by designating the present text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 361.56 Maintenance of sanitary conditions and precautions against contamination of poultry products.

(b) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official establishment shall not contain liquid polychlorinated biphenyls (PCB's) in concentrations above 50 parts per million by volume of the liquid medium. This provision applies to both food processing and non-food processing equipment and machinery, and any

replacement parts for such equipment and machinery.

2. The following is the proposed amendment to 7 CFR:

PART 2000—INSPECTION OF EGGS AND EGG PRODUCTS (EPP) PRODUCTS INSPECTION ACT OF 1970

Section 2000.302 of the Federal regulations on the inspection of eggs and egg products (7 CFR 2000.302) would be amended by adding a new paragraph (c) to read as follows:

§ 2000.302 Equipment and utensils.

(c) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of an official plant shall not contain liquid polychlorinated biphenyls (PCB's) in concentrations above 50 parts per million by volume of the liquid medium. This provision applies to both food processing and non-food processing equipment and machinery, and any replacement parts for such equipment and machinery.

(Secs. 8, 9, and 21, 34 Stat. 1289, as amended, 21 U.S.C. 685, 686, and 687; Secs. 7, 14, and 15, 71 Stat. 647, as amended, 21 U.S.C. 685, 686, and 687; Secs. 2-20, 91 Stat. 1050 of imp. 21 U.S.C. 1051-1056, 45 FR 3555, 1980).

This proposal has been reviewed under the USDA criteria established to implement Executive Order 12064, "Improving Government Regulations," and has been classified "significant." An Approved Draft Impact Analysis is available from Dr. W. O. Coughlin, Acting Director, Facilities, Equipment, and Sanitation Division, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20258, (202) 447-5827.

Done at Washington, D.C., on February 23, 1980.

Carol Tucker Foxman,
Assistant Secretary for Food and Consumer Services.

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DEPARTMENT OF ENERGY

Office of Licensing Policy Development

10 CFR Parts 270 and 280

Licensee Consultation of Regional
Public Hearing on Final Rule Provisions
Share Meeting System

AGENCY: Department of Energy.

