federal register

Friday
May 9, 1980

Part IV

Department of Agriculture

Food Safety and Quality Service

Department of Health, Education, and Welfare

Food and Drug Administration

Environmental Protection Agency

Restrictions on Use of Polychlorinated Biphenyls (PCB's)

PCB-ARCH-EXT0377995

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

7 CFR Part 2859

9 CFR Parts 308, 381

Prohibition of PCB-Containing Equipment or Machinery and Liquid Polychlorinated Biphenyls (PCB's) in Federally Inspected Meat Establishments, Poultry Product Establishments and Egg Product Plants

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Federal meat inspection regulations, the Federal poultry products inspection regulations, and the Federal regulations governing the inspection of eggs and egg products to establish a requirement that no equipment or machinery, other than capacitors containing less than 3 pounds of PCB liquid, and no separately maintained liquids in USDA inspected plants and establishments shall contain liquid PCBs in excess of 50 ppm. A 6-month disposal period would be allowed which would not start until disposal facilities become available. All equipment removal or flushing, and all handling or removal of PCB liquids, would be performed in accordance with the Environmental Protection Agency (EPA) regulations (40 CFR 761). PCBs are a class of chemical compounds which are highly toxic and are persistent in nature. These proposed regulations would supplement and extend the coverage of an earlier proposal (published in the Federal Register February 29, 1980 (45 FR 13471–13473) which would prohibit new or replacement equipment and machinery containing liquid PCBs in inspected plants and establishments.

DATE: Comments must be received on or before: July 7, 1980.

ADDRESS: Written comments should be sent to: Executive Secretariat, Attn: Annie Johnson, Room 3807, South Agriculture Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250. Oral comments on poultry products inspection regulations to Mr. Bartie Woods, (202) 447–5627. (See also comments under Supplementary Information.)

FOR FURTHER INFORMATION CONTACT: Mr. Bartie Woods, 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) 447–5627. The Draft Impact Analysis describing the options considered in developing this proposed rule and the impact of implementing each option is available on request from the above-named individual.

SUPPLEMENTARY INFORMATION: This proposed action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified "significant."

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 poultry products inspection regulations must make such request to Mr. Woods so that arrangements may be made for such views to be presented. A transcript will 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.

Background

Polychlorinated biphenyls (PCBs) constitute 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 United States since 1929 in such applications as transformers and capacitor fluids, heat transfer fluids, and hydraulic fluids.[1]

Health Risks Due to PCB's

The problem of PCBs as a potential food contaminant was first generally recognized after a poisoning incident in Japan in 1968 caused by the accidental introduction of PCBs into rice oil. In that incident, consumers of the contaminated rice oil developed adverse health effects.

Prior to that incident, PCBs had caused reproductive problems in commercial mink. Those problems were first reported in 1965, but it was not until several years later, after satisfactory analytical procedures had been developed, that PCBs were identified as the contaminant. The source of the PCBs was found to be contaminated coho salmon from Lake Michigan, which were fed to the mink.

Subsequent research into the effects of exposure to PCBs has shown that PCBs cause various kinds of health disorders in laboratory animals, including reproductive failures, gastric disorders, skin lesions, and tumors.

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

PCB's in Today's Environment

The most significant sources of PCBs in the environment include discarded consumer or industrial products containing PCBs, atmospheric fallout, and spills associated with the use or transport of PCBs. In today's environment, PCBs are already widespread, as thousands of environmental and ecological samples from all over the world have been analyzed and reported to contain PCBs. PCBs have been detected, frequently at high levels, in fish and bird species inhabiting widely separated geographic areas. Since 1971 there have been at least nine separate incidents of accidental PCB contamination of human food supplies, including chickens, turkeys, eggs and hogs. 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 of these foods containing PCBs have been consumed.

A recent major industrial accident occurred in June 1979 in a meat slaughtering establishment when, without anyone's knowledge, approximately 200 gallons of PCB liquid leaked from a stored electrical transformer into the plant drainage system. A portion of the liquid, along with plant waste, including fat, meat scraps, blood and other similar material, was then separated in primary waste treatment, and sent with other inedible products for rendering into animal feeds. This, in turn, resulted in the contamination both of primary foods of

[1] PCBs are or have been manufactured and sold under a variety of trade names including: Pyranol (General Electric), Chlorextol (Allis-Chalmers), Inerteen (Westinghouse), Noflamol (Wagner Electric), Phenochlor (Pro Delec), Therminol (Monsanto Chemical Co.), Aroclor (Monsanto Chemical Co.), MCS (Monsanto Chemical Co.), Pydraul (Monsanto Chemical Co.), Turbinol (Monsanto Chemical Co.), Santorac (Monsanto Chemical Co.), and Kanechlor (Kanegafuchi), Chlophen (Bayer), Dykanol (Cornell Dubilier), and Decachloro Biphenyls (Caffaro).

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animal origin intended for human consumption, including meat, poultry, milk and eggs, and of secondary food products such as soups and cakes. Millions of pounds of food were contaminated with PCBs 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 costs associated with 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 FSQS inspector in recognizing and containing the problem prevented another potentially massive contamination incident.

U.S. Regulatory Control of PCB's

PCBs are currently regulated by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Food Safety and Quality Service (FSQS) of the United States Department of Agriculture (USDA).

a. *EPA.* The Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) requires the Environmental Protection Agency (EPA) to control the manufacture, processing, and distribution in commerce, use, disoposal, and marketing of PCBs. Section 6(e)(3) of that Act (15 U.S.C. 2605(e)(3)) provides that no person may manufacture any PCB after January 1, 1979, or process or distribute in commerce any PCB after July 1, 1979, except to the extent that EPA specifically authorizes or exempts such activity. Implementation of the January 1, 1979, ban was subsequently postponed until 30 days after completion of EPA rulemaking on May 31, 1979 (44 FR 31514). Subsequently, the July 1, ban was also delayed slightly. However, the May 31 rule prohibits all manufacturing, processing, and distribution in commerce, and use of PCBs after July 2, 1979, that is not specifically authorized or exempted by EPA.

The May 31 rule did provide certain exemptions to bans. EPA generally exempted the use of PCBs in "totally enclosed" systems, such as those found in transformers and capacitors, and also authorized uses of PCBs in a few "non-totally enclosed" systems, such as in hydralic systems and heat transfer systems.

EPA has, under the May 31 rule, established a 50 parts per million (ppm) "cut-off point" for the applicability of its rule to PCB mixtures. Any mixture which is more dilute than this, unless otherwise specifically provided, is not regulated as a PCB. EPA concludes that this cut-off limit provides adequate protection for human health and the environment while establishing a rule that can be effectively implemented.

b. *FDA.* The Food and Drug Administration (FDA) similarly has taken steps to prevent the introduction of PCBs into the food supply. Specifically, current FDA regulations, which were promulgated in July 1973, restrict the industrial uses of PCBs in establishments that manufacture, handle, and store food intended for human consumption (21 CFR 110.40), and animal feed (21 CFR 500.45), and in establishments that manufacture food-packaging materials (21 CFR 109.15). 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 PCBs. 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 to replace by September 4, 1973, any PCB-containing fluids in such equipment, to the fullest extent possible with good manufacturing practices, with fluid that did not contain PCBs. The FDA regulations, however, specifically exempted electrical transformers and condensers which contain PCBs 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.

c. *USDA.* USDA, in its enforcement of the meat and poultry inspection acts, has since July 1970, rejected new PCB-containing equipment or machinery which is proposed for food processing uses. Similarly, no proposed new chemical compound which contains PCBs has been approved since 1970 to be used in food processing machinery or equipment. These case-by-case determinations have been made under the equipment evaluation and chemical compound evaluation systems. In these systems, lists are maintained of approved chemicals and equipment, including the uses for which they are approved. However, no attempt has been made to reevaluate or eliminate equipment or machinery which was approved before 1970. In addition, approval has not been denied for equipment or machinery which is not likely to contact food.

On February 29, 1980, USDA published a proposal which would prohibit the entry of new or replacement equipment or machinery containing liquid PCBs in excess of 50 ppm onto the premises of any establishment or plant inspected under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. The Department has the responsibility under these Acts to inspect products and take other actions to prevent the distribution of adulterated products. The action was proposed because of a number of incidents of human food contamination from PCBs, indicating that the present coverage needed to be reevaluated. That proposal, therefore, was intended to reduce the likelihood of future PCB accidents and the resultant danger to human health and losses of food due to adulteration.

This Proposal

This proposal represents the second step in attempting to eliminate essentially all potential sources of PCB contamination from meat, poultry product, and egg product plants and establishments. The first step—the proposed ban on new or replacement equipment and machinery containing PCBs—will be made final sometime in the next several months, if the proposal appears to be efficacious after a review of the comments. The second step is more complicated because it involves the disposal of PCBs now present in equipment in meat, poultry product, and egg product plants and establishments.

Under this proposal, all equipment or machinery containing PCBs (except capacitors with less than 3 pounds of PCBs) would have to be either removed from the plant or establishment, or drained and flushed so that they no longer contain PCBs in the liquid-medium at levels greater than 50 ppm by weight. In addition, any liquids with PCBs above 50 ppm that are on the premises for any reason would have to be removed.

After removal from the plant, both the equipment containing PCBs at a level of between 50 and 500 ppm of the liquid medium and the liquid containing PCBs between 50 and 500 ppm may be disposed of in an approved landfill pursuant to EPA regulations. If the PCB level is above 500 ppm, however, under EPA requirements, disposal must be generally accomplished by use of an approved incinerator. Although no such incinerators now exist, EPA has advised that there will be two of them in operation in the near future. The rule would, therefore, provide a 6-month disposal period which would not start until an incinerator for disposing of

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PCBs has been approved by EPA and placed in operation.

The 50 ppm cut-off for removal of PCBs has been proposed because the health hazards of exposure to PCBs are significantly greater at higher levels and because EPA has determined that PCBs are too widespread in the environment, including human and animal tissues, to establish a zero tolerance, or one that approaches zero. A cut-off point of 500 ppm was also considered, but the level of 50 ppm was proposed because it would appear to reduce the risk of human exposure by controlling an additional 1 million pounds of PCBs. It should be noted that EPA believes that the 50 ppm limit provides adequate protection for human health and the environment.

Small capacitors containing less than 3 pounds of PCBs would be exempted under the proposed regulation because there appears to be little chance of contamination of the food supply from such equipment. Not only does this equipment contain relatively small amounts of PCBs, but the PCBs are usually absorbed by paper or other material within the equipment, which minimizes spillage if a leak occurs. Since these capacitors appear to pose little risk, the benefit of requiring their removal appears to be outweighed by the cost of removing and replacing them.

Options Considered

The toxicity of PCBs and their persistence in the food supply following contamination has been well established. The possibility of contamination from PCBs in equipment located at food plants is also clear, and has been demonstrated in several recent incidents. FSQS has, therefore examined the options available for controlling these compounds at plants and establishments under its jurisdiction.

In its decision to propose regulatory action on PCBs, USDA considered four options:

Option 1. Take no new regulatory action. As stated above, USDA currently does take some actions with respect to PCBs. However, because of several recent PCB spills, the Department believes that stricter regulation is required to protect the public health. Therefore, this option is rejected.

Option 2. Take no new mandatory regulatory action but conduct an educational campaign. FSQS has concluded that this option is unworkable for two reasons. Some operators, who know they have PCB-containing equipment in their plants may elect to do nothing and continue to use equipment which poses the risk of contamination to food products and their immediate environment. Other operators, finding as a result of the campaign that they have PCB-containing equipment in their plants may elect to remove their equipment or liquid improperly, thus greatly increasing the hazard to food products and their immediate environment. However, an educational campaign appears to be a useful adjunct to Options 3 and 4, and will be used in this fashion.

Option 3. Ban liquid PCBs in all new or replacement equipment. This option greatly extends present controls for PCBs and would be the first USDA regulation to address PCBs specifically. It appears to be a logical first step, and has already been published on February 29, 1980, as a proposal. Because this measure appears to be feasible immediately in that it creates no disposal problem, it may be made a final rule after the comments are considered, even though eventually it would be made unnecessary if the rule considered in Option 4 were adopted.

Option 4. Ban any liquid PCB-containing equipment and machinery, other than capacitors containing less than 3 pounds of PCB liquid, and any other liquid PCBs in meat processing, poultry processing, or egg processing plants and establishments. This measure is more complicated than Option 3 but is a logical extention of it. It is the option of choice because it appears to be the most effective means to achieve a PCB-free food environment ultimately. Food contaminating spills of PCBs would have a much greater cumulative effect than would the impact of implementing this option.

IRLG Liaison

PCBs are toxic substances which have been identified for regulatory coordination by the Toxic Substances Work Group of the Ineragency Regulatory Liaison Group (IRLG). 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) have been 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.

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

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

a. Section 308.5 of the Federal meat inspection regulations (9 CFR 308.5) would be amended by changing the heading and amending the Table of Contents accordingly, and by adding new paragraphs (g), (h) and (i) to read as follows:

§ 308.5 Equipment and utensils to be easily cleaned, those for inedible products to be so marked; evaluation of equipment and utensils; PCB-containing equipment and liquids.

* * * * *

(g) No equipment or machinery, except capacitors containing less than 3 pounds of PCB liquid, on the premises of any official establishment, shall contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and non-food processing equipment and machinery.

(h) No liquid containing more than 50 parts per million polychlorinated biphenyls (PCBs) by weight shall enter or be held for any purpose in any official establishment.

(i) Any equipment removal or disposal, flushing procedure, or handling, removal, or disposal of liquid required by paragraphs (g) or (h) of this section shall be performed in accordance with the requirements of 40 CFR Part 761.

b. Section 381.56 of the Federal poultry products inspection regulations (9 CFR 381.56) would be amended by changing the heading and amending the Table of Contents accordingly, by designating the present text as paragraph (a) and by adding new paragraphs (b), (c) and (d) to read as follows:

§ 381.56 Maintenance of sanitary conditions and precautions against contamination of poultry products; PCB-containing equipment and liquids.

* * * * *

(b) No equipment or machinery, except capacitors containing less than 3 pounds of PCB liquid, on the premises of any official establishment, shall contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and non-food processing equipment and machinery.

(c) No liquid containing more than 50 parts per million polychlorinated biphenyls (PCBs) by weight, shall enter or be held for any purpose in any official establishment.

(d) Any equipment removal or disposal, flushing procedure, or handling, removal, or disposal of liquid required by paragraphs (b) or (c) of this section, shall be performed in accordance with the requirements of 40 CFR Part 761.

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

Section 2859.502 of the Federal regulations on the inspection of eggs and egg products (7 CFR 2859.502) would be amended by changing the headings, amending the Table of Contents accordingly, and by adding new paragraphs (c), (d) and (e) to read as follows:

§ 2859.502 Equipment and utensils; PCB-containing equipment and liquids.

* * * * *

(c) No equipment or machinery, except capacitors containing less than 3 pounds of PCB liquid, on the premises of any official plant shall contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and non-food processing equipment and machinery.

(d) No liquid containing more than 50 parts per million polychlorinated biphenyls (PCBs) by weight, shall enter or be held for any purpose in any official plant.

(e) Any equipment removal or disposal, flushing procedure, or handling removal or disposal of liquid, required by paragraphs (e) or (d) of this section shall be performed in accordance with the requirements of 40 CFR Part 761.

(Secs. 5, 8, and 21, 34 Stat. 1260, as amended, 21 U.S.C. 605, 608, and 621; Secs. 7, 14, and 18, 71 Stat. 441, as amended, 21 U.S.C. 456, 463, and 465; Secs. 2-29, 84 Stat. 1620 *et seq.*, 21 U.S.C. 1031-1056; 42 FR 35625, 35626)

Done at Washington, D.C., on April 29, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

[FR Doc. 80-13740 Filed 5-8-80; 8:45 am]
BILLING CODE 3410-DM-M

PCB-ARCH-EXT0377999

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 109, 110, 225, 226, 500, and 509

[Docket No. 80N-0128]

Current Good Manufacturing Practice Relating to Poisonous and Deleterious Substances In Food, Feed, and Food-Packaging Materials Plants

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend several of its regulations to prohibit or limit the amount of polychlorinated biphenyls (PCB's) in sealed electrical transformers and capacitors used or stored in or around food, feed, and food-and feed-packaging materials plants or storage facilities. FDA also proposes that certain raw materials used in human foods which are susceptible to PCB contamination be examined and analyzed as necessary to ensure that they comply with FDA tolerances for PCB's and other poisonous or deleterious substances. The purpose of this proposed action is for the protection of the public health.

DATES: Comments by July 7, 1980. The agency proposes that any final regulations resulting from this proposal be effective 180 days after the date of publication of the final regulations in the Federal Register or after an incinerator approved by the Environmental Protection Agency (EPA) is available, whichever is later.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1164.

SUPPLEMENTARY INFORMATION: PCB's are a class of chemicals that have been widely used in electrical transformers, capacitors, electromagnets, and heat transfer and hydraulic systems. They are useful in industrial applications due to their chemical stability, low flammability, high boiling points, and low electrical conductivity. PCB's were also used as plasticizers in the manufacture of paints, adhesives, and caulking compounds, as fillers for investment casting waxes, and as dye carriers in carbonless copy paper.

Although PCB's were first manufactured and commercially marketed for industrial uses in 1929, it was not until 1967 that their presence in the food supply was first detected. At that time and during the following years, FDA encountered a number of isolated industrial accidents resulting in PCB contamination of animal feed and human food. These accidents involved either the spillage or leakage of the chemical directly onto animal feed from manufacturing equipment, or animal feed otherwise coming in physical contact with PCB-containing materials. The consumption of the contaminated feed by food-producing animals resulted in the transfer of PCB's to human food (e.g., milk, meat, eggs).

At that time FDA's knowledge of the hazards of PCB's to human health was limited to primarily one incident that occurred in Yusho, Japan, in 1968 when very high levels of PCB's leaked from processing equipment and contaminated rice oil. The PCB-contaminated rice oil was sold as salad oil and, after several weeks, consumers were stricken with the so-called "Yusho" disease which ultimately was traced to the PCB's Among the many symptoms exhibited by the victims of this disease were chloracne (skin rash), discoloration of the gums and nailbeds, swelling of joints, and waxy secretions from glands in the eyelids.

The levels of PCB that produced those effects substantially exceeded the levels of PCB found at any time in the United States food supply. However, because PCB's accumulate in the fatty tissue of humans and animals, there was ample evidence indicating that prolonged exposure to PCB's, even at low levels, posed a potential health risk. Therefore, FDA concluded thast there was a need to limit consumer exposure to PCB's in their diet and, to accomplish this end, eliminate the use of PCB-containing equipment in food and feed establishments.

The agency then proposed in the Federal Register of March 18, 1972 (37 FR 5705) regulations for curtailing the direct contamination of foods, feeds, and food-packaging materials with PCB's. The proposed regulations were promulgated as a final rule in the Federal Register of July 6, 1973 (38 FR 18096). The regulations set forth restrictions on the industrial uses of PCB's in establishments that manufacture, process, pack, handle, and store food intended for human consumption (21 CFR 110.40) and animal feed (21 CFR 500.45) and in establishments that manufacture food-packaging materials (21 CFR 109.15) and feed-packaging materials (21 CFR 509.15). These regulations provide that new equipment or machinery for handling or processing human food, animal feed, and for manufacturing food- or feed-packaging materials shall not contain PCB's. The establishments in these industries that had such equipment in place were required to replace any PCB-containing fluids in such equipment with fluid that did not contain PCB's by September 4, 1973. The regulations, however, specifically exempted electrical transformers and condensers (capacitors), which hold PCB's in sealed containers because at that 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.

Toxicity data based upon laboratory animal studies received by FDA since 1973 have demonstrated a definite association between low-level PCB exposure and potentially more serious subchronic and chronic toxicities, including adverse reproductive effects, liver damage, and tumor production. One of these studies also has confirmed many of the adverse effects exhibited by the Yusho victims. FDA's current assessment of risk to human health from dietary exposures to PCB's is described in the preamble of FDA's final rule on the reduction of the tolerances for unavoidable PCB's in food which was published in the Federal Register of June 29, 1979 (44 FR 38330).

The industrial uses of PCB's are also subject to the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 et seq.), which requires EPA to regulate and control the manufacture, processing, distribution in commerce, use, disposal, and marketing of PCB's. Section 6(e)(3) of TSCA (15 U.S.C. 2605(e)(3)) provides that no person may manufacture in other than a totally enclosed manner any PCB after January 1, 1979, or process or distribute in commerce any PCB after July 1, 1979, except to the extent that EPA specifically authorizes or exempts any nontotally enclosed activity. EPA's implementing regulations of the statutory January 1, 1979, ban were delayed until 30 days after completion of its rulemaking (*see* the Federal Register of May 31, 1979; 44 FR 31514). In exercising its statutory exemption authority, the EPA May 31 rule provides certain exceptions to the ban, such as authorizing the uses of PCB's in some "nontotally enclosed" systems, as in hydraulic systems and heat transfer

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systems. Section 6(e) of TSCA statutorily exempts the use of PCB's in "totally enclosed" systems, as in transformers and capacitors.

The EPA rule also establishes a 50 parts per million (ppm) cut-off point for its applicability to PCB mixtures. Any mixture more dilute than this, unless otherwise specifically provided, is not regulated under this rule. EPA has determined that this cut-off limit provides adequate protection for human health and the environment while establishing a regulatory scheme that can be effectively implemented.

There recently have been a number of incidents in which the use or disposal of PCB's has resulted in contamination of food in the United States. At least two of these incidents were the result of PCB's leaking from damaged spare transformers and contaminating feed for poultry and livestock. The contaminated feed caused PCB's being carried into human food. One of the incidents was caused by a fire in a warehouse in Ponce, Puerto Rico, in 1977 when PCB's were released from transformers being stored in the warehouse. The warehouse served as a storage area for tuna fishmeal which was dried, rebagged, and shipped to manufacturers for use in the manufacture of animal and fish feeds. This resulted in over 2,000,000 pounds of finished feed and fishmeal being contaminated, more than 400,000 chickens being destroyed, and millions of eggs being withheld from consumer markets.

The second transformer incident ocurred in a Federally inspected meat-slaughtering and processing establishment in Billings, Montana, in 1979. A spare transformer was stored in a shed at the packing plant and an estimated 200 gallons of PCB-containing transformer oil leaked from the transformer into the plant's waste water system. Solids that were recovered from the plant's waste water system were rendered, and the rendered residues were included in a meat meal. This contaminated meat meal was then fed to poultry and livestock and caused the contamination of approximately 800,000 chickens, 3,800,000 eggs, 4,000 hogs, 800,000 pounds of assorted animal feeds and feed ingredients, and many bakery items in which contaminated eggs were used. Another incident of a potentially massive contamination was prevented when PCB leakage from a capacitor in a Federally inspected hog-slaughtering establishment in Iowa was recognized. Quick action by plant officials and a United States Department of Agriculture (USDA) inspector contained the problem.

As a result of the multi-agency involvment in PCB containment and the recent incidents of PCB leakage from electrical transformers and capacitors, FDA, as a member of the Interagency Regulatory Liaison Group (IRLG), joined in a cooperative effort with EPA and the Food Safety and Quality Service of USDA, to determine if any additional controls were necessary to further protect the public health from the use of PCB-containing equipment in or around food and feed facilities.

This interagency cooperation has resulted in a technical booklet entitled "Polychlorinated Biphenyls: An Alert for Food and Feed Facilities" (December 1979), which was prepared under the sponsorship of EPA and distributed by EPA, FDA, and USDA. This booklet was prepared to aid the food, feed, pesticide, and fertilizer industries in identifying potential problems with PCB's and to recommend that these industries institute a program for preventative action without delay. This cooperation has also resulted in the agencies' concluding that further mandatory controls are needed.

EPA intends to publish a proposal restricting the use of PCB's at agricultural chemical facilities.

USDA has published a proposal in the Federal Register of February 29, 1980 (45 FR 13471) to amend the Federal meat, poultry and egg products inspection regulations by prohibiting the entry of new or replacement equipment and machinery containing PCB's onto the premises of plants under their jurisdiction. USDA also intends to publish another proposal to prohibit PCB-containing equipment or machinery and liquid PCB's in Federally inspected meat, poultry, and egg product plants. Comments received as a result of the USDA proposals, the EPA proposal, and this FDA proposal will be shared among the members of IRLG.

Similarly, FDA believes that the use of PCB's should be prohibited in electrical transformers and capacitors used in or around FDA-regulated food, feed, and food-packaging materials plants and storage facilities even though such transformers and capacitors are sealed. This determination is supported by the recent potential health hazards caused by the leakage of PCB's from sealed transformers and capacitors. FDA is therefore proposing to revise the current regulations (21 CFR 109.15 (a)–(c), 110.40(b), 225.1(c), 226.1, 500.45 (a)–(c) and 509.15) to prohibit, with one exception, transformers and capacitors used or stored in or around such plants from containing PCB's. Under this proposal the plant has the option of either replacing the transformers and capacitors or replacing the PCB-containing fluid in such transformers with another fluid. The agency believes it is not feasible to replace PCB-containing fluids in capacitors. Therefore, the sole means of complying with these proposed regulations with respect to capacitors is to replace them with capacitors that do not contain PCB's.

FDA is also proposing the §§ 109.15 and 500.45 be amended to include the 50 ppm EPA cut-off point for regulating PCB's for the purpose of defining acceptable residual amounts of PCB's in retrofilled equipment, machinery, and other materials subject to the provisions of §§ 109.15 and 500.45. Use of this proposed 50 ppm cut-off point, for purposes of defining acceptable residual amounts of PCB's in retrofilled equipment, would replace the phrase "to the fullest extent possible commensurate with current good manufacturing practices" that now appears in §§ 109.15(b)(2) (i) and (ii) and 500.45(b)(3) (i) and (ii). This phrase was included in the existing regulations to guide establishments in retrofilling PCB-containing equipment or machinery. At that time the agency believed that if the exchange of fluids was perfomed in a careful and reasonable manner, there would be no significant concentrations of residual PCB's remaining in the retrofilled transformers. The proposed 50 ppm cut-off point would define "significant concentrations" and sets the maximum limits of PCB's remaining in the fluid after retrofilling such equipment. Under the proposal the retrofilling of such equipment shall be completed within the time limits established in the final regulations.

In addition, FDA is proposing to amend the current umbrella CGMP regulation (21 CFR 110.80) by adding a new paragraph (k) to require that raw materials that are susceptible to contamination with PCB's be examined and analyzed as necessary to ensure that the finished foods comply with current FDA tolerances, as required by § 109.30 (21 CFR 109.30), before these materials are manufactured into finished foods. The proposed amendments also include deletion of much of the detailed background information on the problem of PCB's presently set forth in §§ 109.15(a), 110.40(b), 500.45(a), and 509.15(a). Also, the phrase "in or around" would be used in a reasonable expectation " " ," that appears in current §§ 109.15(b)(2)(ii) and 500.45(b)(3)(iii). The phrase "in or around" is a more precise indicator for determining the location of the equipment that would be affected by the

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proposed regulations. Finally, the introductory phrase of § 500.45(b)(3) has been expanded to also include establishments that handle and store animal feed. This expansion would make the regulation consistent with the existing title of § 500.45.

Currently, there are approximately 285,000,000 pounds of fluids containing PCB's in use in transformers in the United States and 400,000,000 pounds in capacitors. FDA has made available a draft regulatory analysis pursuant to Executive Order 12044. However, the agency does not now possess sufficient data concerning the numbers, types, and locations of all transformers and capacitors in or around FDA-regulated food, feed, and food-packaging materials plants. FDA requests that comments submitted to the agency in response to this proposal incude information conerning the presence of PCB-containing fluids in transformers and capacitors used in or around FDA-regulated food, feed, and food-packaging materials plants and storage facilities; the numbers, types, and locations of PCB-containing transformers and capacitors used or stored in or around such facilities; a reasonable time estimate for replacing all transformers and capacitors containing PCB's or to eliminate the PCB-containing fluids from transformers in or around such plants and storage facilities; and an estimate of the cost involved. FDA also solicits comments as to alternatives to the replacement of the transformers and capacitors or the PCB-containing fluids to assure that such food, feed, and food-packaging materials will not become contaminated from PCB's because of transformer or capacitor failure or other accident. Such alternatives may include: (1) Protection of the transformer or capacitor by installing an adequate catch basin and guard around the equipment; (2) removal of the equipment from inside to outside the plant buildings to a site where there could be no reasonable expectation of contamination from a leak or spill; and (3) daily inspection of each piece of PCB equipment for leaks or other imminent hazards. The relative economic impact of these alternatives will be incorporated in the final regulatory analysis. FDA proposes to exempt capacitors containing less than 3 pounds of fluid from the regulations. These small capacitors are not included because most of the PCB's they contain are in a nonliquid, nonmobile state.

As stated in 21 CFR 109.15(b)(2)(iii) and 21 CFR 500.45(b)(3)(iv), "The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this ... determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis."

The handling, storage, and disposal of PCB-containing liquid must be carried out in accordance with the EPA regulations (40 CFR Part 761). Although the amended regulations as proposed specify that establishments must remove or replace PCB-containing transformers and capacitors on or before 180 days after the date of publication of a final regulation, this effective date is contingent upon the availability of an incinerator approved by EPA for disposal of PCB fluids.

All supporting data and information (inculding EPA's current regulations on PCB's) and a copy of FDA testimony to Congress regarding this proposal are on file with the Hearing Clerk, FDA, and may be seen from 9 a.m. to 4 p.m., Monday through Friday.

FDA has determined pursuant to 21 CFR 25.24(d)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. This concludion is based in part on knowledge that the handling, storage, and disposal of PCB-containing liquid must be carried out in accordance with EPA regulations (40 CFR Part 761).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs: 402(a), 406, 409, 701(a)), 52 Stat 1046 as amended, 1049 as amended, 1055, 72 Stat. 1785–1788 as amended (21 U.S.C. 342(a), 346, 348, 371(a)), and the Public Health Service Act (sec. 361, 58 Stat. 703 (42 U.S.C. 264)), and the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 109—UNADVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

1. In Part 109, § 109.15 is amended by revising paragraphs (a) and (b)(2)(i); by revising (b)(2)(ii), redesignating it as (b)(2)(iii), and adding new (b)(2)(ii); by redesignating (b)(2)(iii) as (b)(2)(iv); and be revising paragraph (c) to read as follows:

§ 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) are a class of toxic chemicals whose uses include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Incidents have occurred in which PCB's have directly contaminated the food supply as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). Because PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accident, which can in turn cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) • • •

(2) The management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verfiy the absence of PCB's in such formulations by other appropriate means. Any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Replace or remove PCB-containing transformers and capacitors (except capacitors containing less than 3 pounds of fluid) used or stored in or around such establishments or replace the PCB-containing fluid in the transformers with another fluid.

(iii) Eliminate any other PCB-containing equipment, machinery, and materials in or around the establishment.

• • • • • •

(c) PCB's as used in this section, as they relate to transformer, capacitors, and other manufacturing equipment, means substances and combination of substances that contain 50 parts per

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million (on a dry weight basis) or greater of PCB's.

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKAGING, OR HOLDING HUMAN FOOD

2. Part 110 is amended:

a. In § 110.40 by revising paragraph (b) to read as follows:

§ 110.40 Equipment and procedures.

* * * * *

(b) *Use of polychlorinated biphenyls in food plants.* Restrictions on the industrial uses of polychlorinated biphenyls (PCB's) provided in § 109.15 of this chapter shall also be applicable to the industrial uses of PCB's in the production, processing, handling, and storage of human food. Equipment, utensils, machinery, and electrical transformers and capacitors that are used or stored in or around a food or food-packaging material plant or storage facility shall not contain PCB's except for capacitors containing less than 3 pounds of fluid.

b. In § 110.80 by adding new paragraph (k) to read as follows:

§ 110.80 Processes and controls.

* * * * *

(k) Raw materials susceptible to contamination with polychlorinated biphenyls (PCB') shall be analyzed as necessary to ensure that the finished foods comply with current Food and Drug Administration tolerances for unavoidable or deleterious substances as required by § 109.30 of this chapter before these materials are manufactured into finished foods. Compliance with this requirement may be accomplished by purchasing these materials under a supplier's guarantee or certification, or may be verified by analyzing these materials for PCB's

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

3. In Part 225, § 225.1 is amended by adding new paragraph (c) to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(c) The provisions in § 500.45 of this chapter concerning restrictions on the use of PCB's are also applicable to this part.

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED PREMIXES

4. In Part 226, § 226.1 is revised to read as follows:

§ 226.1 Current good manufacturing practice.

The criteria in §§ 226.10 through 226.115, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or holding of a medicated premix conform to or are operated or administered in conformity with current good manufacturing practice to ensure that a medicated premix meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this part permit the use of precision, automatic, mechanical, or electronic equipment in the production of a medicated premix when adequate inspection and checking procedures or other quality control procedures are used to ensure proper performance. The provisions in § 500.45 of this chapter concerning restrictions on the use of PCB's are also applicable to this part.

PART 500—GENERAL

5. In Part 500, § 500.45 is amended by revising paragraphs (a), (b)(1) and (2), introductory text of (b)(3), and (b)(3)(i); by revising and combining (b)(3)(ii) and (iii) and redesignating them as (b)(3)(iii); by adding new (b)(3)(ii); and by revising paragraph (c) to read as follows:

§ 500.45 Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed.

(a) Polychlorinated biphenyls (PCB's) are a class of toxic chemicals whose uses include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, plasticizers, and in formulations of lubricants, coatings, and inks. Incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food intended for human consumption (e.g., meat, milk, and eggs). Because PCB's are toxic chemicals, the PCB contamination of food as a result of these and other incidents represent a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of animal feed.

(b) * * *

(1) Coatings or paints for use on the contact surfaces of animal feed storage areas may not contain PCB's or any other harmful or deleterious substances likely to contaminate feed.

(2) New equipment or machinery for handling or processing animal feed in or around an establishment producing animal feed shall not contain PCB's.

(3) The management of establishments producing, handling, or storing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing animal feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. Any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Replace or remove PCB-containing transformers and capacitors (except capacitors containing less than 3 pounds of fluid) used or stored in or around such establishments or replace the PCB-containing fluid in the transformers with another fluid.

(iii) Eliminate from the animal feed producing establishment any other PCB-containing equipment, machinery, and materials in or around the establishment.

(c) PCB's as used in this section, as they relate to transformers, capacitors, and other manufacturing equipment, means substances and combination of substances that contain 50 parts per million (on a dry weight basis) or greater of PCB's.

* * * * *

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD PACKAGING MATERIALS

6. In Part 509, § 509.15 is revised to read as follows:

§ 509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Restrictions on the industrial uses of polychlorinated biphenyls (PCB's) provided in § 500.45 of this chapter shall also be applicable to the industrial uses of PCB's in the production, handling, and storage of feed-packaging material intended for animal food. Equipment, utensils, machinery, and electrical transformers and capacitors that are used or stored in or around a feed- or food-packaging material plant or storage facility shall not contain PCB's except for capacitors containing less than 3 pounds of fluid.

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Interested persons may, on or before July 7, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

It is hereby certified that the economic effects of this proposal have been considered in accordance with Executive Order 12044 and that a Draft Regulatory Analysis is on file with the Hearing Clerk, Food and Drug Administration.

Dated: April 30, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-13743 Filed 5-8-80; 8:45 am]

BILLING CODE 4110-03-M

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