SUPPLEMENTARY BACKGROUND:

BACKGROUND

Section 214.2(h)(3)(i) of the Immigration and Naturalization Service Regulations (8 CFR 214.2(h)(3)(i), issued under the Immigration and Nationality Act, requires, in support of a petition for the admission of an alien into the United States to perform certain temporary labor:

either a certification from the Secretary of Labor or his designated representative stating that qualified persons in the United States are not available and that the employment of the beneficiary will not adversely affect the wages and working conditions of workers in the United States similarly employed, or a notice that such a certification cannot be made, shall be attached to every nonimmigrant visa petition to accord an alien a classification under section 101(a)(15)(H)(ii) of the Act. * * *

Each year the Department undates its adverse effect rates so that, in light of current economic conditions, employers will be required to offer workers a wage which will not adversely affect the wages of U.S. workers.

RELATIONSHIP OF PROPOSED RULE TO PROPOSED REGULATIONS FOR 20 CFR PART 665

On January 25, 1977, at 42 FR 4670, the Department proposed comprehensive new regulations for the entire labor certification process for the temporary employment of aliens in the United States in agricultural and logging occupations. Those regulations, when eventually finalized, were proposed to be placed into a new Part 655 in 20 CFR, and to replace all the present regulations at 20 CFR 602.10, 10a, and 10b. The rule proposed in this document, however, is merely the annual update of the adverse effect rates. Because of the considerable interest shown by the public in the January 25 proposed comprehensive revision, the Department expects that it will be some time before the January 25 proposal will be finalized. The Department expects, however, that the new adverse effect rates proposed in this document will be finalized shortly after the end of the thirty-day comment period.

WHERE TO SEND COMMENTS

Comments on the proposed rule should be sent to the Assistant Secretary for Employment and Training, Attn: William B. Lewis, Administrator, United States Employment Service, Room 8000, 601 D Street, NW., Washington, D.C. 20213.

Accordingly, 20 CFR 602.10b, paragraph (a)(1), is proposed to be revised to read as follows:

§ 602.10b Wage rates.

(a)(1) Except as otherwise provided in this section, the hourly wage rates set forth below shall be offered and paid to agricultural workers. The Department has found that, unless these wage rates are offered and paid, the wage rates of similarly employed U.S. workers will be adversely affected.

State:	Rate
Connecticut	$2.75
Maine	2.84
Massachusetts	2.70
New Hampshire	2.97
Rhode Island	2.72
Vermont	2.93
New York	2.70
Maryland	2.43
Virginia	2.63
Florida (sugar cane only)	3.23

Signed at Washington, D.C. this 25th day of March, 1977.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

[FR Doc.77-9519 Filed 3-31-77;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 109]

[Docket No. 77N-0080]

POLYCHLORINATED BIPHENYLS (PCB'S)

Unavoidable Contaminants in Food and Food Packaging Materials; Reduction of Temporary Tolerances

AGENCY: Food and Drug Administration.

ACTION: Proposed reduction of temporary tolerances for polychlorinated biphenyls (PCB's).

SUMMARY: The Food and Drug Administration (FDA) is proposing to reduce the temporary tolerances for unavoidable residues of the industrial chemicals PCB's in several classes of food. Specifically, the agency is proposing to reduce the tolerances in milk and dairy products from 2.5 parts per million (ppm) to 1.5 ppm (fat basis); in poultry from 5 ppm to 3 ppm (fat basis); in eggs from 0.5 ppm to 0.3 ppm, and in fish and shellfish from 5 ppm to 2 ppm.

DATES: Comments on or before May 31, 1977.

ADDRESSES: Written comments on this proposal may be sent, in quadruplicate, to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Howard N. Pippin, Division of Regulatory Guidance (HFF-312), Bureau of Foods, Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, (202) 245-3092.

SUPPLEMENTARY INFORMATION: PCB's are a class of toxic industrial chemicals that are highly stable, heat resistant, and nonflammable. By late 1971, the unique physical and chemical properties of PCB's and their widespread, uncontrolled industrial application had resulted in their becoming a persistent and ubiquitous environmental contaminant. One consequence of the contamination of the environment with PCB's was the indirect contamination of certain foods.

REGULATORY HISTORY

In the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), the Commissioner of Food and Drugs issued regulations under Part 122 (21 CFR Part 122), to deal with the problem of contamination of animal feeds, foods, and food packaging materials with PCB's. Among these regulations are those establishing temporary tolerances for unavoidable PCB residues resulting from environmental contamination of milk and dairy products, poultry, eggs, fish and shellfish, infant and junior foods, and feed and feed components for food producing animals. There is also a temporary tolerance for PCB's in paper food-packaging material intended for or used with human food, finished animal feed and components intended for animal feeds, which is currently stayed (by order published in the FEDERAL REGISTER of August 24, 1973 (38 FR 22794)) pending completion of an evidentiary hearing under sections 406 and 701(e) of the act (21 U.S.C. 346 and 371(e)). In establishing these tolerances as "temporary" the Commissioner recognized that, in the future, unavoidable PCB contamination should decrease. The stated intention of the Commissioner has thus been to reduce the temporary tolerances as PCB contamination became less unavoidable.

At the National Conference on PCB's sponsored by the Environmental Protection Agency (EPA) on November 19 through 21, 1975, in Chicago, FDA announced that it had initiated a review of the appropriateness of the current temporary tolerances. (The proceedings from the National Conference have been published and a copy is on file in the office of the Hearing Clerk.) In a notice published in the FEDERAL REGISTER of February 26, 1976 (41 FR 8109), the Commissioner issued a statement of policy regarding PCB's in certain freshwater fish. The notice discussed the review of the temporary tolerances and stated that if, on the basis of the review, lowering of any of the temporary tolerances was warranted, the Commissioner would issue a proposal in the FEDERAL REGISTER to amend the existing PCB regulations.

TOXICITY OF PCB'S

The temporary tolerances established in 1973 were arrived at after evaluation of the best available toxicological data. Data from long-term (2-year) animal studies established that a no-effect level in rats and dogs for PCB's with three levels of chlorination (42, 54, or 60 percent) is 10 ppm. These animal data were used as a basis for estimating a no-effect level in man. When data derived from dogs were used, a no-effect level of 2.5 micrograms per kilogram (g/kg) body weight per day was calculated. When rat data were used, the no-effect level in man was 3g/kg body weight per day. Thus, for a 70-kilogram individual (approximately 155 pounds), an allowable level of PCB ingestion would be 175 to 210 micrograms per day.

When establishing tolerances for environmental contaminants, such as

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PCB's, it is preferable, though not always possible, to rely on human rather than animal data. In the case of PCB's, human data were available from the unfortunate "Yusho" poisoning incident in Japan in 1968 in which many individuals consumed rice oil contaminated with PCB's. The rice oil involved in the Yusho incident was contaminated with Kanechlor 400, a Japanese brand of PCB containing 48 percent (by weight) chlorine. The 48 percent (by weight) chlorine-containing PCB Aroclor 1248, an American product, is very similar to the Kanechlor 400. Consequently, the human data derived from the Yusho incident, though stemming from exposure to a Japanese PCB, were relevant and significant in establishing a temporary tolerance for residues resulting mostly from American-made PCB's.

The victims in the Yusho incident were calculated to have consumed an average of 15,000 milligrams per day (mg/day) of the rice oil contaminated with Kanechlor 400. At that time the rice oil was determined to be contaminated at levels of 2,000 to 3,000 ppm PCB's, the average level of PCB contamination in the oil being 2,500 ppm. The levels of PCB contamination of the oil were calculated by comparing the measured organic chlorine content of the rice oil with the known organic chlorine content of Kanechlor 400. Using the two average levels (consumption of rice oil and PCB level in the rice oil), the average daily intake of PCB's was estimated to be 37.5 mg/day. The average cumulative dose of PCB's that caused an overt effect in the Japanese victims was reported to be 2,000 milligrams. Based on the average daily intake of 37.5 mg/day, it would take 53 days of exposure for an individual to consume this amount. Actual periods of exposure no doubt varied around this figure. However, it was estimated that the maximum exposure at Yusho would have been 100 days.

Humans in the United States have not been exposed to PCB's at the concentrated levels that existed in the Yusho incident. General public exposure in the United States to PCB's has been sporadic. In developing temporary tolerances based on the data from the Yusho incident, a time period of 1,000 days of exposure to PCB's was used. As previously stated, this was not an analysis based on lifetime exposure. Rather, it was postulated that PCB levels in food would steadily decrease over the 1,000-day time period used in the calculation. The sporadic exposures in the United States were generally thought to result mainly from contaminated animal feed and, as measures were adopted to prevent future contamination, the PCB level in food was expected to be reduced. In calculating a total allowable exposure from the average overt dose in the Yusho incident, a safety factor of 1 to 10 was used and a total allowable exposure of 200 milligrams was calculated. Because of the sporadic nature of PCB exposure in the United States, the total exposure (200 milligrams) was spread out over the 1,000-day time period (over 10 times as long as Yusho exposure) providing a tolerable daily exposure of no more than 200 micrograms per day. Transforming this figure to body weight per day for a 70-kilogram adult produced a figure of 3 μg/kg body weight per day.

As indicated previously, FDA established the temporary tolerances for PCB's in 1973 with the clear intent that they should be lowered as experience indicated the appropriateness of such changes. The Chairman of the HEW Committee to Coordinate Toxicology and Related Programs established a Subcommittee on the Health Effects of PCB's and Polybrominated Biphenyls (PBB's), whose purpose was to assess new data developed since 1973 on the toxicology, human exposure to PCB's and sources of residues of PCB's, and to formulate recommendations about future research needs. This subcommittee, composed of scientists from several governmental agencies concerned with PCB's, reviewed all the currently available scientific literature and has released its final report. A copy of the report is on file in the office of the Hearing Clerk.

This information, as well as information obtained since the subcommittee report was published, has been evaluated by FDA. Three problem areas with PCB's are of major concern to FDA, namely, new toxicity data on PCB's, studies that indicate PCB's are carcinogenic, and the presence of PCB's in the environment resulting in widespread occurrence of residues in freshwater fish.

It is known that the toxicity of chlorinated biphenyls depends upon the degree of chlorination and the isomeric form. The low chlorinated biphenyls tend to have a higher acute toxicity compared to the higher chlorinated biphenyls, whose different pattern of toxicity is associated in part with a longer biological half-life and less susceptibility to metabolic alteration or degradation by the liver and other organs (Reference 2). Studies have shown that PCB's containing six or fewer halogen atoms are readily absorbed from the intestine. They are not excreted to an appreciable extent before being metabolized to more polar compounds, and long-term storage in the skin and adipose tissue occurs. However, tissues from animals and man containing PCB's from environmental exposure have residues resembling PCB mixtures with more than 50 percent chlorination, suggesting that PCB's with five or fewer chlorine atoms (less than 50 percent chlorination) are more readily metabolized than the PCB's with higher chlorination (Reference 3).

Evaluation of the toxicity of specific PCB's is further complicated by the finding that commercial preparations of PCB's contain, as impurities, some quantity of chlorinated dibenzofurans (Reference 4). Certain isomers of the chlorinated dibenzofurans are appreciably more toxic than a similar amount of chlorinated biphenyls (Reference 5). More recent information from the Yusho episode has brought new factors into consideration with the finding that the rice oil contained approximately 1,000 ppm PCB, chlorinated dibenzofurans at approximately 5 ppm, and unknown organic chlorinated substances, which so far are unidentified, at approximately 1,000 ppm (Reference 6). It is not known whether the chlorinated dibenzofuran contaminant or the unidentified source of organic chlorine is a crucial toxic substance producing the symptoms observed in the Yusho incident, whether exposure to the 1,000 ppm PCB produced the observed effects, or whether an interaction occurred.

Different animal species vary in their susceptibility to the toxic effects of PCB's. However, evaluation of this susceptibility is complicated by a general lack of information on the detailed composition of the PCB mixtures used in the studies and the relationship between the composition of a PCB mixture and the toxicity of that mixture. PCB's have been shown to cause effects on reproduction, hepatic porphyria (Reference 7) and other biochemical changes in the liver (Reference 8) and gastric mucosa (Reference 9) as well as liver tumors (Reference 10). In primates, the skin and the Meibamian glands are affected, in addition to the liver and gastric mucosa (Reference 11). In the rabbit, atrophy of the thymus has been reported (Reference 12). The levels causing these effects depend on the species and the compound tested. In rats, a dietary level of 20 ppm Aroclor 1254 depressed reproduction while a level of 500 ppm Aroclor 1260 was needed to reduce reproduction in the same strain of rats (Reference 13). Dietary levels of 5 ppm Aroclor 1254 have a marked effect on reproduction in the mink (Reference 14), and limited studies have shown that 2.5 ppm Aroclor 1248 affects reproduction in nonhuman primates (Reference 15).

Numerous biochemical systems are reported to be affected by PCB's. Hepatic porphyria has not been reported in the monkey, mink or human, but Aroclor 1254 or Aroclor 1242 and Aroclor 1016 have produced it in the rat (Reference 7). The female rat is more sensitive than the male and Aroclor 1016 is less active than either Aroclor 1254 or 1242 (Reference 7). Other biochemical changes reported in the liver include lipid accumulation induction of microsomal enzymes, including the hydroxylase and demethylase enzymes as well as an increase in cytochrome P-448 (Reference 16). Mitochondrial function is inhibited when rats are fed extremely high levels of PCB (1,000 ppm) but not at 100 ppm (Reference 17).

Histological and ultrastructural changes in the liver reflect the observed biochemical changes, and include hepatomegaly with a concomitant increase in smooth endoplasmic reticulum, atypical mitochondria and the formation of "fingerprints" in the hepatic cytoplasm. These changes are more pronounced at higher dose levels, and with Aroclor 1254 and 1260. The effects are less pronounced with Aroclor 1242 or 1016 (Reference 18).

Some of the new toxicity data relate to the carcinogenic effect of PCB's in mice and rats. In one strain of mice,

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neoplastic nodules (hepatomas, hyperplastic nodules) developed after dietary exposure to Aroclor 1254 (Reference 19). Female Sherman strain rats fed 100 ppm Aroclor 1260 for 21 months developed hepatocellular carcinomas as well as neoplastic nodules (hyperplastic nodules) of the liver (Reference 8).

However, several problems remain to be resolved before the risk of carcinogenesis following exposure to environmental PCB's can be fully evaluated. For example, the commercial PCB's fed to the animals in the carcinogenicity studies were found to contain low levels of toxic impurities, including chlorinated dibenzofurans. It has not been established what the role of the dibenzofurans is in the development of the carcinogenic lesions. In addition, the relatively high levels of commercial PCB's required to produce the carcinogenic response suggest the probability that liver damage may be required before the onset of carcinogenesis.

Recent experiments with monkeys indicate that adult monkeys suffered illness and female monkeys had reproductive disfunction when exposed to PCB's (Aroclor 1248) in amounts comparable to those experienced by patients in the Yusho poisoning incident (References 11, 20, 41, and 42). Infant monkeys suffered illness when nursing from their mothers whose milk contained PCB residues at a range of approximately 7 to 16 ppm on a fat basis (References 15 and 42). Surviving weaned infants recovered from the overt toxic effects (References 41 and 42), but behavioral abnormalities were noted (Reference 21).

Recent preliminary survey data indicate the presence of PCB residues in human breast milk at levels averaging 1.8 ppm (fat basis) (Reference 22). This may present as yet undefined risks to the nursing infant. It is known that residues of other halogenated hydrocarbons occur in breast milk and are thus ingested by nursing infants (Reference 23). Although such exposure is obviously not desirable, the immediate problem is to attempt to define more precisely the potential risks to infant health.

The relevance of the observations in the monkey studies to human infants nursing on mothers' milk containing PCB residues (average values to 3.5 ppm fat basis (Reference 24)) due to maternal exposure to PCB's largely from environmental sources is not known. In the monkey study these residues in the milk of the maternal monkeys resulted from their exposure to a commercial preparation of Aroclor 1248. This contains approximately 40 percent tetrachlorinated biphenyls, an appreciable amount of trichlorinated biphenyls (Reference 25), and unknown quantities of at least five different chlorinated dibenzofurans (Reference 26). Additionally, the maternal monkeys were toxic and hence toxicity effects in the offspring monkeys may not be purely due to the relatively low levels of PCB's received through monkey milk. It is not known if this overt toxicity, as well as the toxic effect of contaminants of Aroclor 1248 present in commercial samples, and not shown to be present in environmental samples, had additional adverse effects on the monkey fetus in utero or upon the nursing infant monkey.

Additional investigations are needed to evaluate the potential adverse effects on human infants nursing from mothers whose breast milk contains PCB residues. Because of the long biological half-life of PCB's in the mammalian body, it is desirable to limit the exposures of females to PCB residues in food to the extent reasonably possible in order to reduce the likelihood that PCB residues might occur both in body fat and in breast milk. The Commissioner is concerned about transfer of PCB residues to the fetus through the placenta or to the infant through breast milk. Fetal and infant exposure to PCB's should clearly be minimized until possible adverse effects are more clearly defined.

After assessing recent toxicological data, the Commissioner concludes that it is desirable to reduce human exposure to PCB's even further. While the data do not support establishment of a new allowable daily intake of PCB's, especially in light of the studies regarding carcinogenicity, the Commissioner concludes that the predicted level of exposure discussed below is tolerable.

Human Exposure To PCB's

Contamination of foods with PCB's results primarily from four broad sources: (1) Environmental contamination—in fish from contaminated lakes and streams; (2) industrial accidents—isolated incidents involving direct leakage and spillage of, or contact with, PCB fluids and other PCB-containing materials on animal feeds, feed ingredients, or food; (3) agricultural contamination—PCB migration to feed from silo coatings, causing subsequent contamination of milk; and (4) food packaging materials—migration to foods packaged in PCB-contaminated paper products. There were a number of other positive findings in foods which could not be traced to one of these broad sources before 1972; the sources of such occasional findings remain speculative. However, in recent years, essentially all positive findings of PCB's in the food supply have been attributable to one or more of these four sources.

The findings of the FDA Total Diet Study for fiscal years 1971 through 1975 show that PCB levels in all food classes of the total diet have declined to no detectable PCB occurrence in the composites and no calculable daily intake of PCB's, except in the meat-fish-poultry composites. About 40 percent of these meat-fish-poultry composites analyzed in fiscal year 1975 continued to contain detectable PCB's, although only traces have been detected in the most recent years (Reference 1).

It is important to stress that review of PCB levels in the diet must be an ongoing process. In analyzing the health implications of PCB residues in the diet, one must exercise caution because review of partial data for a given year or even complete data on a year-by-year basis may led to false conclusions concerning trends. For example, fiscal year 1976 findings show that milk and eggs infrequently contain PCB residues, i.e., less than 1 percent frequency rate. However, animal feed components contained detectable PCB residue (about 8 percent frequency rate) at a rate higher than in fiscal years 1974 and 1975, but lower than the approximate 13 percent rate for fiscal year 1973. Most of the feed component samples found positive in fiscal year 1976 were of animal and it is expected that such year-to-year variations will be encountered. This increased incidence did not cause an increase in dietary intake of PCB's. In fact, the rate of meat-fish-poultry composites found positive for PCB's in the first half of the fiscal year 1976 Total Diet Study dropped to a low of 5 percent and the first half of the 1976 meat and poultry sampling by the U.S. Department of Agriculture (USDA) showed a reduction to a low occurrence rate of 0.2 percent (Reference 27).

Since 1973, PCB's have not been found in the other total diet composite categories, notably not in dairy product composites and the composites of grain and cereal products. Based on the total diet study, there remains a continued low level occurrence (above 40 percent positive in fiscal year 1975 but only at trace levels) in the meat-fish-poultry composites. The fact that levels in these composites have declined to only traces further supports the inference that the meat and poultry and eggs rarely contain detectable PCB's and that the low level findings are primarily due to the fish in those composites. This would imply that the PCB levels in an "average" total diet may have decreased as much as they will until such time as there is a change in the levels for fish (Reference 1).

Evidence indicates that residue levels higher than those reported in foods other than fish in the studies discussed above would generally be due to avoidable sources of contamination such as isolated accidental spills or the use of PCB coating in dairy farm silos with the resultant contamination of the silage and milk. The Commissioner concludes that in light of these findings of reduced levels of PCB's in foods, it is appropriate to lower the tolerances for unavoidable residues of PCB's.

Section 406 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346) requires that the Commissioner consider the ways in which individuals may be affected by PCB's, other than through consumption of food.

Although human exposure to PCB's from air and water appears to be minimal, there is little question that such exposure does occur. Samples of ambient air collected in Florida, Mississippi, and Colorado show that PCB's were present at all locations. The average concentration at each of the three locations was approximately 100 nanograms

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per cubic meter of air. Studies of surface water from the major drainage basins of the United States report the widespread occurrence of PCB's in both surface water and bottom sediments. Main residue levels of PCB's in the surface water ranged from 0.01 to 0.05 micrograms per liter (μg/l), with a maximum residue level of 20.0 μg/l (Reference 28).

In Wisconsin, effluents from cooling water in aluminum foundries contained PCB's ranging from 11.5 to 335 parts per billion (ppb). Effluents from paper mills ranged from 0.01 to 25 ppb. Analysis of snow melt water from Wisconsin cities showed PCB residue levels of 0.17 to 0.24 ppb, suggesting that fallout of PCB's from the air may be an important source of PCB's entering the waters of the State (Reference 29).

In Michigan, testing of 900 samples of industrial effluents showed 22 percent had PCB residues greater than 0.5 μg/1, 8 percent greater than 1.0 μg/1, 6 percent greater than 10 μg/1 and 2 percent greater than 100μg/1. With sludge disposal taking place by incineration, landfill and crop or pasture application, the continuation of PCB's in the environment seems obvious (Reference 30).

At this time there is no evidence of deleterious effects resulting from inhalation of PCB's from the air; contamination of water results primarily in the intake of dietary PCB's from fish as discussed below in this preamble. However, surveillance of the food supply of the United States for PCB residues is maintained through ongoing FDA sampling programs. Should PCB contamination prove to be wider than is now thought, these surveillance programs will be helpful in the detection, evaluation, and resolution of any potential problem.

Reports of adverse human health effects resulting from PCB exposure have come from studies of occupational exposure as well as from human exposure through ingestion of contaminated rice oil in Japan. Some of the earliest reports of adverse health effects due to occupational exposure to PCB's in the United States were published in 1936 and described skin lesions and symptoms of systemic poisoning among workers who were reported to have inhaled chlorodiphenyls (Reference 31). Over the ensuing years numerous reports have described cutaneous eruptions as well as systemic manifestations among marine electricians, machinists, capacitor and transformer manufacturing workers, and others occupationally exposed to PCB's.

Researchers have reported dermatological ailments that include "brown chromodermatosis" of the dorsal joints of the hands and purple-like eruptions of the face and neck (References 32 and 33). However, one study, a health survey of workers in carbonless copy paper factories, 2 years after the use of PCB in such processes had ceased, showed neither dermal effects nor abnormalities of liver function, urine or blood tests. Blood levels of PCB's were reported as 0.01 to 0.02 ppm (Reference 34).

While the harmful effects of occupational exposure to PCB's may be significant in individual situations, they do not have an impact on the exposure that FDA regulates through tolerances for PCB's in foods.

Petition To Reduce Tolerances

On November 21, 1975, the Environmental Defense Fund (EDF) and the Natural Resources Defense Council (NRDC) jointly submitted a petition (Docket No. 75P-0346) seeking establishment of a zero tolerance for PCB residues in food, to be achieved by means of a phased reduction to zero of appropriately set temporary tolerances. The petition summarizes the recent studies and new data regarding the occurrence and the toxicology of PCB's and, on the basis of these data, the petitioners draw certain inferences and conclusions regarding the risk to human health presented by PCB's. The Commissioner's comments on the petitioners' conclusions are as follows:

1. The petitioners contend that it should be the express intention of the Commissioner, mandated by his responsibilities under the Federal Food, Drug, and Cosmetic Act, to establish zero tolerances for PCB residues in food. They state that this goal should be achieved by means of phased reduction of temporary tolerances which minimize the risk to the public health and which are "based on a level of risk which has been assessed using appropriate statistical models to account for the potential carcinogenic risk posed by any given residue level." The petitioners recommend use of the Mantel-Bryan or a comparable formula to establish risk probabilities for a carcinogen.

The Commissioner agrees that it is important to reduce human exposure to PCB's and that it is appropriate to reduce the tolerances for PCB's to the lowest practicable level; this has been the policy of FDA from the outset. However, he does not agree that "zero tolerances" are necessary or appropriate at this time. The phrase "zero tolerance" has been applied to the "no detectable residue" requirements of the exception to the Delaney anticancer clause in the act applicable to drugs and feed additives used in food producing animals (section 512(d)(1)(H) (21 U.S.C. 360b (d)(1)(H))). The absolute prohibition of the Delaney clause against the approval of food additives that cause cancer in man or laboratory animals does not apply to an environmental contaminant, such as PCB's, that is unavoidably present in food.

Section 406 of the act, under which the PCB tolerances are established, applies to substances whose presence in food cannot be avoided by good manufacturing practice. A tolerance that would totally prohibit such a substance in the food, when that substance cannot be avoided, would be inappropriate in the absence of a grave danger to health, for it would make all foods containing the substance unlawful per se. When an environmental contaminant is already present in food, FDA's responsibility is to decide what level(s) of the contaminant should cause removal of food from interstate commerce. If a nodetectable-residue requirement were automatically applied to environmental contaminants already present in the food supply, enforcement activities could significantly disrupt the food supply. Removing food containing any detectable residue from the marketplace could lead to enforcement action against food commodities not deemed to present any significant risk to public health.

The Commissioner advises that, while the statistical evaluation formulas for establishing risk probabilities, like the Mantel-Bryan procedure, are valid and useful in some situations, they are not an appropriate tool for determining a regulatory approach for unavoidable contaminants like PCB's.

2. The petitioners make direct comparisons between the 1968 human PCB poisoning episode in Japan and the results of some studies on the effects of low level exposure of nonhuman primates to PCB's. The implication in the petition appears to be that humans might suffer overt symptoms of PCB poisoning at the same levels (as low as 2.5 ppm in the whole diet) as did the monkeys.

As discussed elsewhere in this preamble, the Japanese patients were exposed not only to PCB's but also to the more highly toxic chlorinated dibenzofurans and to other chlorinated substances, some of which are as yet unidentified. The monkey studies represent tests of a commercial preparation of Aroclor 1248, which contains high percentages of trichlorinated and tetrachlorinated biphenyls, two of the more acutely toxic PCB constituents. Further, the commercial Aroclor 1248 also contained chlorinated dibenzofurans. While the effects seen in these monkeys were similar to the findings in the Japanese patients, such effects have not been noted in humans exposed to environmental PCB's in food in this country. Persons whose consumption of PCB's in their diet is substantial relative to the general population, have not exhibited any adverse health effects (Reference 40).

3. In discussing the validity of the tolerable daily intake published in the order establishing the temporary tolerances, the petitioners state that results from the recent nonhuman primate studies indicate that the rat and dog, on which that tolerable daily intake was partially based, are relatively insensitive to many of the toxic effects of PCB's. The petitioners imply that the tolerable daily intake published in 1973 is not valid in light of newly acquired data.

The Commissioner acknowledges that, compared to the monkey, the rat and dog may be relatively insensitive to PCB's; on the other hand, it is not known whether monkeys are unusually sensitive compared to humans. It is not yet possible to make a direct comparison of effects of PCB's from one kind of test animal to another or to humans. However, when judgments regarding allow-

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able intakes are made, all available data from all species are considered.

4. The petitioners contend that the existing temporary tolerances are insufficient to protect the public health.

The Commissioner advises that the temporary tolerances were consistent with the toxicological data available when they were established. Although he acknowledges that more recent toxicological data indicate that further reduction of PCB intake is desirable, the Commissioner is not aware of any consumers who have suffered deleterious effects by ingesting PCB's. As anticipated, except for fish, PCB residues in foods have only rarely reached or exceeded the tolerance levels. Current data do not indicate that even consumers of fish have actually experienced deleterious effects from contaminated fish. Thus, the Commissioner cannot agree with the petitioners' contention that the temporary tolerances have been insufficient to protect the public health.

Furthermore, PCB residues in food have declined significantly, so that a specific appraisal of human exposure to PCB's in light of recent data would not support the petitioners' contention. The remaining significant PCB residues occur predominantly in freshwater fish, most of which are sport fish or are in intrastate commerce and are therefore not subject to effective FDA control. The Commissioner believes that the temporary tolerances for PCB's in certain foods have provided significant protection to public health; the relevant question now concerns the additional steps indicated to further protect the public.

5. The petitioners stated that "PCB's continue to contaminate our food" and, further, that "The apparent decrease in the levels of PCB's * * * must be viewed with caution."

The Commissioner acknowledges that available data are incomplete, as are contamination data at any particular time. However, there are specific errors in the petition which could have influenced the conclusion that the decrease in PCB levels is only "apparent." The petition reports fiscal year 1973 levels of PCB's, from the FDA Total Diet Survey as "trace—6.0 ppm" in the food composites. The highest finding in a Total Diet Survey food composite for the period was 0.07 ppm. The 6.0 ppm was found in an individual cereal food, not in a composite. The fiscal year 1974 FDA and USDA data reported in the petition are for partial years only. There were approximately 7,000 samples examined by FDA in fiscal year 1974, which resulted in an overall 3.2 percent occurrence rate for PCB's instead of the 5.4 percent reported in the petition. Similarly, USDA examined over 1,000 samples of poultry with only 2 samples positive for PCB's estimated to be approximately 0.2 ppm and 1.25 ppm (fat basis). Additionally, the decline in PCB occurrence in foods, meats and animal feeds is shown to continue when fiscal year 1975 data are included (Reference 1).

In the discussion from which the petitioners conclude that PCB contamination of food is a continuing problem, the cited examples are of contamination incidents that occurred before FDA established the temporary tolerances in 1973. The current reduction in or absence of such problems, except in the case of fish, indicates that FDA regulatory activities and other events have effectively reduced the PCB problem. The remaining significant problem, as previously noted, is with fish, particularly freshwater fish.

The Commissioner concludes that the petition to establish zero tolerances should not be granted to the extent that the petition seeks to have all food containing any detectable level of PCB's removed from commerce. However, the Commissioner does conclude that it is desirable to reduce the tolerances for PCB's at this time as far as is reasonably possible.

Temporary Tolerances

Section 406 of the act states:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for the purpose of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health * * *. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

When the Commissioner established the temporary tolerances for PCB's, it was expected that PCB prevalence in the environment would soon decline and that, as a result, the levels of PCB's in foods and feeds would also decline. He stated that the tolerances would be reevaluated and reduced accordingly. As discussed above, except for fish, the levels of PCB's in the foods for which there are tolerances are now lower than they were when the temporary tolerances were established. Also, recent data regarding toxic effects of PCB's give rise to added concern regarding human exposure to PCB's. Therefore, the Commissioner has reviewed each temporary tolerance and proposes to reduce certain of them.

In addition to the factors specifically required by section 406 of the act to be considered in setting tolerances for unavoidable poisonous or deleterious substance in foods, the Commissioner must, as a practical matter, also consider the limits of the analytical methodology available for enforcement of such tolerances.

The current temporary tolerances for finished animal feed, feed components of animal origin, and infant and junior foods are already at the lowest level at which PCB's can be reliably determined in each of those products for enforcement purposes. It is therefore not possible at this time to lower these tolerances.

As little as 1.5 ppm PCB can be reliably determined in the fat of milk and manufactured dairy products (Reference 35), and the Commissioner proposes to lower the temporary tolerances for those foods from the current 2.5 ppm to 1.5 ppm (fat basis).

The Commissioner has considered the current temporary tolerance of 5 ppm on a fat basis for PCB residues in poultry. For the reasons previously stated, he has concluded that it is desirable to also further reduce the temporary tolerance for PCB's in this class of food to the greatest extent possible. Accordingly, the Commissioner considered proposing a tolerance of 1.5 ppm in the fat of poultry, the lowest level at which PCB can be reliably determined in these foods for enforcement purposes (Reference 35). However, under the provisions of section 406 of the act, the Commissioner also considered the extent to which the contaminant is unavoidable.

The current tolerance for PCB's in poultry feed, the primary source of PCB's to which chickens are exposed, is established at 0.2 ppm—the level of detection. Data indicate that continuous feeding of poultry with finished feed contaminated with PCB, results in PCB residues in the dissectible poultry fat at approximately 10 times the levels in the feed (References 36 and 37). The biomagnification factor of 10 is only approximate and varies from flock to flock. While it is unlikely that any flock would be consistently consuming feed containing PCB's at the tolerance of 0.2 ppm and allowing for other sources by which poultry may be exposed to PCB's, such as water and the environment, a tolerance level for poultry established at the level of detection (1.5 ppm on a fat basis) could be exceeded. The Commissioner found this tolerance unacceptable because it would be inconsistent to set tolerances on two products at levels such that the use of one product that complies with the applicable tolerance causes the second product to be illegal, unless other overriding considerations justify such a situation. Because the biomagnification factor of 10 is only approximate, and may vary from one lot of feed to another, from one flock to another, or from one bird to another, the Commissioner determined that a tolerance of 3 ppm (fat basis) is the lowest level that will make allowances for PCB residues resulting from feed contaminated at levels not exceeding the current feed tolerance. Accordingly, he considered whether this level would provide an acceptable margin of safety to the consumer.

Because the frequency of PCB residue occurrence in feeds is low, the likelihood of residues in poultry reaching the 3 ppm (fat basis) level is very small. Moreover, data regarding PCB residues in poultry confirm this and show that PCB contamination of poultry is very sporadic and infrequent. As such, this food is not a significant source of dietary PCB's. A tolerance of 3 ppm (fat basis) will continue to provide this assurance, while also providing adequate protection for the consumer. Therefore, the Commissioner proposes to reduce the temporary tolerance for poultry from 5 ppm to 3

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ppm (fat basis). As stated previously, the finished feed tolerance of 0.2 ppm cannot be reduced at this time because the analytical methodology necessary to enforce a lower tolerance is not available. The Commissioner advises that when such methodology becomes available so that the 0.2 ppm feed tolerance can be reduced, the tolerance for PCB residues in poultry will also be reevaluated.

The proposed reduction in the temporary tolerance for PCB's in eggs is from 0.5 ppm to 0.3 ppm, the practical analytical limit for reliable determination of PCB's in eggs. Although eggs would be expected to contain PCB residues if the chickens were consistently fed contaminated feed, the residues in eggs resulting from 0.2 ppm PCB in the feed are not expected to exceed a 0.3 ppm tolerance. As with poultry, eggs are not expected to contribute measurably to dietary PCB's, because the occurence of PCB's in feed is sporadic rather than consistent.

The temporary tolerance for PCB's in paper food-packaging material is currently stayed pending completion of an evidentiary hearing. When the hearing is completed or the issues resolved, the Commissioner will issue in the FEDERAL REGISTER a notice regarding the resolution and removal of the stay of the tolerance. At that time he will also propose to reduce the tolerance for PCB residues in paper food-packaging material in accordance with the reduction in the PCB levels which has occurred since 1973.

PCB's IN FISH

Although unavoidable PCB residues no longer occur regularly in the previously mentioned classes of foods, PCB contamination of the aquatic environment is sufficiently widespread that fish, mainly freshwater fish, in various locations of the United States contain significant amounts of the contaminant.

This conclusion is based on an extensive review of data FDA has compiled (Reference 39) from various sources including its own surveillance of fishery products taken from commercial markets and the testing programs conducted by the National Marine Fisheries Service by the U.S. Fish and Wildlife Service (PCB residue data from this source are not fully relevant because analyses were performed on whole fish, whereas the temporary tolerance is expressed in terms of the edible portion of fish), by the Michigan Department of Agriculture relative to Great Lakes fish, and by the New York Department of Environmental Conservation relative to Hudson River fish. These data show that with the exception of a few anadromous species (fish, such as salmon, that move from the ocean upriver to spawn), all ocean fish contain an average of considerably less than 1 ppm PCB. The average PCB levels for most species were less than 0.5 ppm for whole fish and the levels in edible portions (without heads, tails, scales, entrails) were lower still, the majority having an average of a few tenths of 1 ppm. The highest level of PCB's found in any ocean fish sample other than anadromous species was 1.8 ppm. Anadromous species had relatively high PCB levels, the highest in whole fish being 17 ppm (striped bass caught in the New Jersey area). However, the average levels in these species were less than 3 ppm in whole fish and less than 0.5 ppm in edible portions. Bottom-feeding and high-fat-containing fish tend to have higher PCB levels than other varieties (Reference 39).

A large number of freshwater fish, covering numerous species obtained from over 100 locations nationwide, have been analyzed for PBC's. Contamination appears to be geographically widespread, although in many species highest concentrations occur in the Great Lakes and in major rivers in the East and the Mississippi basin. Some Great Lakes' species, mainly coho salmon and lake trout, show PCB levels ranging as high as 30 ppm, while Hudson River species range as high as 178 ppm. Predator fish, such as walleye and bass, exhibit the highest PCB levels. Eels also contain high levels (Reference 39).

Because it is desirable to reduce exposure to PCB's in fish to the greatest extent possible, the Commissioner considered proposing a tolerance of 1 ppm, the lowest level which PCB's can be reliably determined in these foods for enforcement purposes (Reference 35). However, under the provisions of section 406 of the act, the Commissioner is required, in establishing a tolerance, to consider the extent to which the contaminant is unavoidable.

The Commissioner has determined that establishment of a tolerance at 1 ppm for fish sold in interstate commerce would have a substantially adverse impact on this country's commercial freshwater fishing industry and, to a lesser extent, the commercial marketing of saltwater species. He estimates that the loss to fresh and marine fisheries as a result of enforcing this legal limit would be a maximum total landed value of $18 million or $127 million after processing, (cleaning, canning, distributing, retailing etc.) (Reference 39). The Commissioner points out that because most commercial fishing is done by fairly small operators who may specialize in one or two species, the elimination of any species, even though it may account for only a fraction of the total catch, could be disastrous for them.

Accordingly, the Commissioner has examined the economic impact of proposing a tolerance for PCB's in fish at 2 ppm and has considered whether this level would provide an acceptable margin of safety to the consumer. For marine or saltwater fish, lowering the current temporary tolerance to 2 ppm would result in a loss of $1 million landed value, which would increase about seven times after processing. Thus, the total losses at a 2 ppm tolerance would be about $7 million (Reference 39). For freshwater fish the loss at the 2 ppm level would be more severe: about $7 million landed value or $49 million processed value.

The Commissioner notes that the economic loss for marine fish would be about the same at the 3 ppm level, but the dollar loss for freshwater fish would be about 40 percent of that estimated for a 2 ppm tolerance. He further notes that according to the FDA economic assessment, the current temporary tolerance of 5 ppm may be resulting in an $8 million maximum total loss for freshwater fish (Reference 39). The commercial impact of a 2 ppm level would be much less than that of 1ppm, and limits above 2 ppm would further decrease the potential commercial impact even more.

The Commissioner has evaluated the adequacy of a 2 ppm tolerance for fish from the standpoint of the protection of public health, while also assessing whether any higher limits could be safely tolerated. An average per capita consumption level for fish and shellfish in this country is reported to be approximately 19 grams per day. If all fish contained a maximum permitted PCB residue of 2 ppm, average daily intake of PCB's from commercial fish alone would be about 38 micrograms. The FDA Total Diet Study data show that average PCB intake from all sources in an average adult diet is about 8 micrograms per day, most of which is contributed by the fish in the meat-poultry-fish composite. Totaling these two figures (even though this counts both a theoretical maximum fish contribution and an average fish contribution) gives a maximum theoretical daily intake of about 45 micrograms PCB, or an annual intake of about 16.8 milligrams. This low level of intake is less than one-fiftieth of the average cumulative dose (1,000 milligrams) of PCB in rice oil which caused overt toxic effects in the Japanese poisoning episode. However, because of the presence of the previously discussed toxic impurities other than PCB's in the rice oil, it is likely that amounts of pure PCB's greater than those reported in this episode would be required to produce the reported toxic effects.

The amount of PCB's in environmental samples, such as fish, that is required to produce overt toxic effects is not known. A recently completed study has tried to assess some of the consequences of human exposure to PCB's as a result of high consumption of fish from contaminated areas. Data show that a group of Michigan sports fishermen consumed an average of 24 to 25 pounds of fish per person per year, with the highest individual exposure for a 2-year period reported as 180 pounds per year. In cooked fish, PCB residues ranged from 0.36 to 5.36 ppm. Although there was a wide range of PCB levels in blood for each quantity of fish consumed, there was a highly significant correlation between the reported quantity of Lake Michigan fish consumed and the concentration of PCB in the blood of study participants; the higher reported fish consumption was associated with higher PCB blood levels. The blood values ranged from a low of 0.007 ppm in the control group (fish consumption less than 6 pounds per year) to a high of 0.366 ppm in the exposed group (average fish consumption 24 to 25 pounds per year) (Reference 40).

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These investigators calculated that the amount of PCB's ingested by the exposed group could average 46.5 milligrams per year and ranged from 14.17 to 114.31 milligrams per year. No systematic adverse health effects could be demonstrated in the exposed group when compared to controls (Reference 40).

The 46 micrograms per day (16.8 milligrams per year) intake, given as an example previously, is based on a hypothetical 2 ppm PCB content in all fish, although this level actually occurs only sporadically. About 97 percent of the commercial fish consumed in this country are ocean fish, most of which contain no detectable PCB's, and average considerably less than 1 ppm PCB. This results in an average PCB intake from fish of substantially less than 19 micrograms per day, providing an additional margin of safety.

Actual PCB intake can be considered to be even lower in light of a study of PCB levels in cooked fish. Most of the PCB occurrence data are for raw fish and comparisons of PCB levels in raw versus cooked fish indicate that actual human exposure to PCB's from fish consumption is less than might be expected from the raw fish data. This is not unexpected, because preparation (trimming away fatty tissue) and cooking have been shown to decrease the concentration of PCB's. For example, the PCB level in cooked lake trout ranged from 1.03 ppm to 4.67 ppm; in cooked coho salmon from 0.48 ppm to 5.38 ppm; and in other cooked fish from 0.36 ppm to 2.06 ppm. These levels are decidedly lower than the mean levels of 22.91 ppm and 10.45 ppm reported in raw lake trout and coho salmon, respectively, for 1974 (Reference 40).

Thus, the Commissioner concludes that a tolerance of 2 ppm will provide adequate protection for all but those population groups that consume above average amounts of freshwater fish from contaminated waters. Moreover, a 2 ppm tolerance would eliminate a relatively minor percentage of marine fish and less than 25 percent of freshwater fish from commercial markets. On the other hand, although a tolerance higher than 2 ppm would be more economically desirable, such a tolerance would, based on the above analysis add to the risk for the so-called average consumer and those population groups who regularly consume freshwater fish. Therefore, in keeping with the agency objective to minimize dietary exposures to PCB's, the Commissioner concludes that a 2 ppm temporary tolerance for PCB residues in fish represents a proper balance of the safety and economic criteria of section 406 of the act.

The Commissioner does not consider it appropriate to change the temporary status of the tolerances for PCB's. The scientific community is actively studying PCB contamination and its effects on humans, and it is reasonable to expect that new data may justify a further downward revision of the tolerances; FDA will monitor these developments so that the Commissioner can take further action when it is appropriate.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

References

A copy of each reference document is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between the hours of 9 a.m. and 4 p.m., Monday through Friday.

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Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a), 406, 701(e), 52 Stat. 1046 as amended, 1049, 70 Stat. 919 as amended (21 U.S.C. 342(a), 346, 371(e))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that Part 109 (formerly Part 122, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) be amended by amending § 109.30 to read as follows:

§ 109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) * * *

(1) 1.5 parts per million in milk (fat basis).

(2) 1.5 parts per million in manufactured dairy products (fat basis).

(3) 3 parts per million in poultry (fat basis).

(4) 0.3 part per million in eggs.

(5) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other byproducts of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(7) 2 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 part per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

NOTE.—At 38 FR 22794, Aug. 24, 1973, the following appeared concerning § 109.30(a)(9) (formerly 122.10(a)(9)):

"* * * § 109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing."

In the interim, as stated in the final order (38 FR 18098), the Food and Drug Administration will enforce the temporary tolerance level established by § 109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Interested persons may, on or before May 31, 1977, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments (preferably in quadriplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107. A copy of the inflation impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: March 25, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-9432 Filed 3-25-77;11:49 am]

[21 CFR Part 1020]

[Docket No. 77N-0061]

DIAGNOSTIC X-RAY EQUIPMENT PERFORMANCE STANDARD

Intent To Propose Rules

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice of Intent.

SUMMARY: The agency is considering amending the Federal performance standard for diagnostic x-ray systems with regard to the x-ray field limitation and alignment requirements for general-purpose radiographic and fluoroscopic x-ray equipment. The amendments would clarify the requirements of the standard concerning positive beam limitation for radiographic x-ray systems, field limitation and alignment for spot-film devices, and field limitation for fluoroscopic x-ray systems. In addition, the agency is considering permitting the installation of certified beam-limiting devices that do not provide positive beam limitation on uncertified, stationary, general-purpose radiographic systems manufactured prior to the effective date of the standard if with such installation adequate radiation protection can be assured by alternate means. Data, views, and information are requested before proposing the amendments.

DATES: Comments concerning the amendments are requested by April 22, 1977.

ADDRESSES: Individuals or organizations wishing to receive copies of draft amendments or related documents distributed for review during the development of these amendments may have their names placed on the mailing list by writing to: Division of Compliance (HFX-440), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Comments concerning the proposed amendments should be sent (preferably in quadruplicate) to: Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas B. Shope, Bureau of Radiological Health (HFX-460), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, (301-443-3426).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration, under authority conferred by the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)), administers an electronic product radiation control program to protect the public health and safety. This authority provides for the development and administration of radiation safety performance standards for electronic products. A radiation safety performance standard for diagnostic x-ray systems and their major components was established in the FEDERAL REGISTER of August 15, 1972 (37 FR 16461) and became effective on August 1, 1974. (The extension of effective date was published in the FEDERAL REGISTER of June 12, 1973 (38 FR 15444)).

The Commissioner of Food and Drugs is considering amending Subchapter J of Title 21 of the Code of Federal Regulations by changing the performance standard for diagnostic x-ray equipment (21 CFR 1020.30 et seq). This notice of intent to propose rules is being issued to conform with the FDA policy of early public disclosure of rule making activities and to solicit comments from interested persons concerning the subject matter of the proposed amendments.

Since the promulgation of the performance standard for diagnostic x-ray systems, numerous questions have been received from manufacturers and others concerning the manner in which the current requirements of the standard concerning positive beam limitation are to be interpreted. As a result of these inquiries and the interpretations given by the agency in response to them, it may be desirable to amend § 1020.31(c)(2)

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