Monsanto

FROM (NAME & LOCATION) Dept. of Medicine & Environmental Health - G.J. Levinskas, A2SG

DATE November 9, 1977 CC

SUBJECT PCBs

REFERENCE

file FDA.

TO
R.C. Isham - B1NB
E.T. Mollica - B2SB
A.M. Navarro - A3NB
R.A. Stohr - B2SC
D. Wood - B2SD
W. Easley - 1920
G. Roush, Jr. - A2SA

As a follow-up to our meeting on November 2, 1977, I am attaching copies of 4 items dealing with PCBs.

1) Food Chemical News, October 17, 1977, p. 8
We should get copies of the letters sent to FDA and EPA by the Audubon Society. If they are attacking our long-term studies on PCBs, we should know the specifics of their attack.

2) Fed. Register, vol. 38, July 6, 1973 pp.18096-18104 and vol. 42, April 1, 1977, pp. 17487-17494.
This discusses PCB toxicity and sets out the basis for the proposed tolerances. Nisbet's statement, or at least the portion cited above, is misleading because it fails to note FDA's consideration of human data in setting PCB tolerances. (See pp. 18097 and 17488).

3) Chem. Reg. Reporter, August 12, 1977, p. 752
A proviso in the Clean Air Act Amendments requires EPA to publish a list of environmental contaminants and to explain what is known about how they get into the environment. This is bound to reveal new sources of PCB contamination.

4) Chem. Reg. Reporter, July 22, 1977, p. 666
The attitude expressed by the EDF, that no type of exposure to PCBs can be termed insignificant, will be the basis for continuing controversy.

Subsequent to our meeting, Dave Wood told me that Warren Easley had been told by someone in EPA that they were satisfied with the data Monsanto had on PCBs, i.e., they were not challenging IBT's conduct of the studies. They did indicate that they disagreed with us on the interpretation of the data.

Recommendations:

On the basis of the preceding diverse items, I recommend:

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1) Warren Easley obtain copies of the Audubon Society letters to FDA and EPA.

2) Warren Easley attempt to get a written confirmation of the comments made to him by EPA regarding their views of our PCB studies. If he cannot get written confirmation, he should at least commit his recollection of that conversation to writing and send a copy of it to the person at EPA who made the remarks.

3) A rebuttal to the Audubon Society letter be sent to FDA and EPA after we have had an opportunity to review the remarks which have been made.

George J. Levinskas

/bkp

enc.

The Commissioner added: "Until we can generate a basic research establishment that provides useful shortcuts to what is now a hopelessly unimaginative and time-consuming process, until we can rebuild and improve the private-sector testing establishment, and until we can develop similar capabilities in the public sector to monitor and extend it, we will continue in the uncomfortable position of constantly having to pick up the pieces rather than preventing breakage."

The Commissioner said much of the current regulatory reform talk "amounts to a mindless request to 'Make 'em go away,'" commenting: "But to go away would be to pretend that in the food supply there simply aren't any public costs of private activity, and that's not true. What we need is an FDA so well equipped, so well able to offer advice, that unpleasant surprises don't happen."

RECONSIDERATION OF PCB TOLERANCES URGED BECAUSE OF IBT QUESTIONS

The Massachusetts Audubon Society has asked that the Food and Drug Administration "reconsider" its proposed revised temporary tolerances for polychlorinated biphenyls because of questions raised about studies conducted by Industrial Bio-Test Laboratories (See FOOD CHEMICAL NEWS, March 28, Page 2).

The Society, in letters to FDA and to the Environmental Protection Agency, urged that the temporary tolerance proposal be reconsidered and, "if judged necessary," that FDA "propose new tolerances or ... re-open the matter for public comment." The group said:

> "Although the discrepancies in the reports can be resolved only by a thorough re-examination of the pathological material, the data are already sufficient to show that the assumption of no-effect levels at 10 p.p.m., on which FDA's proposed temporary tolerances were based in 1973 and 1977, is no longer tenable."

The Society said "the IBT reports on toxicological studies with PCBs in rats and dogs contain discrepancies and inconsistencies which appear similar to those reported to have been identified by FDA and EPA in IBT reports on tests with other chemicals," adding that "the data in the IBT reports give prima facie evidence of toxic effects of PCBs in both rats and dogs at dietary levels as low as 1 p.p.m."

Audubon's Ian C. T. Nisbet said the 1973 temporary tolerances for PCBs were based "primarily on data from tests carried out at IBT," noting that the same data were cited in FDA's 1977 proposal to reduce the tolerances, "and appear to be the primary toxicological basis for the proposed tolerances."

Nisbet said he has "reviewed the IBT experiments with PCBs, on behalf of EPA, and found discrepancies similar to those reported to have been found in other IBT reports." Saying that his "findings have been reviewed and accepted by the Administrator of EPA," he wrote that, "The raw data in the IBT reports show serious toxicological effects at dose levels at and below those reported as 'no-effect' levels and utilized as such by FDA in establishing temporary tolerances."

E. P. Wheeler

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PART II

FEDERAL REGISTER

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

◻

POLYCHLORINATED BIPHENYLS

Contamination of Animal Feeds, Foods, and Food Packaging Materials and Availability of Supplement to Environmental Statement on Rulemaking

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H. D. Wheeler

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

POLYCHLORINATED BIPHENYLS (PCB's)

Contamination of Animal Feeds, Foods, and Food-Packaging Materials

In the FEDERAL REGISTER of March 16, 1972 (37 FR 5705) a notice of proposed rule making was published limiting the sources by which polychlorinated biphenyls (PCB's) may contaminate animal feed, food, and food-packaging materials during manufacturing, handling, and storage, and limiting the levels of PCB's that may be present in animal feed, food, and food-packaging materials as a result of unavoidable, environmental contamination. The notice provided for the filing of comments within 60 days after the date of publication and this was extended to July 16, 1972 by a notice published May 18, 1972 (37 FR 10003).

In response to the notice, ninety-three comments were received from members of industry, trade associations, consumer groups and individual consumers.

The following is a summary of the provisions contained in the notice and the comments on these provisions received by the Food and Drug Administration:

1. *Sections 3.93, 128.4, and 135.113.* The notice included provisions which would prohibit the use of PCB-containing materials and equipment in animal feed, in food, and in food-packaging material manufacturing, handling and storage establishments, in order to preclude direct, accidental PCB contamination of animal feed, food, and food-packaging materials.

a. One comment suggests that since most industrial chemicals can be interpreted to be "harmful or deleterious", the phrase should be deleted as a criterion for PCB replacement. The Commissioner concurs with deleting the phrase "harmful or deleterious". 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 (1) its toxicity, (2) 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, (3) possible signaling devices in the equipment to indicate a loss of fluid, etc., and (4) 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 fluid and operation basis. Accordingly, the appropriate amendments have been made in § 135.113(b) (1) (21 CFR 135.113(b)(3)), § 3.93(b)(2) (21 CFR 3.93(b)(2)), and § 128.4(b)(2) (21 CFR 128.4(b)(2)).

b. One comment argues that electrical capacitors and transformers should be exempt from the requirement that new equipment and existing equipment in establishments engaged in the processing of animal feed, human food, or packaging materials shall not contain PCB's, since no known substitute is available which offers the proper balance of characteristics (e.g., fire safety and design efficiency). In support of the comment, it is stated that both capacitors and transformers are constructed in sealed metal cases and are not normally installed in equipment or located in such a manner as to be in direct contact with the material being processed. The Commissioner of Food and Drugs agrees that there should be an exemption for the safe use of PCB's in electrical capacitors and transformers. The final order has been amended in § 135.113(c), § 3.93(c) and § 128.4(b) (3), to provide an exemption for electrical capacitors and transformers.

c. One comment contends that an effective date of 90 days following publication of the final order should be established since this time period would be required for the modification of existing plant equipment to accommodate PCB replacements. The Commissioner concludes that there is no justification for extending the effective date and the final order establishes an effective date of 30 days from the date of publication in the FEDERAL REGISTER.

d. One comment contends that with the replacement of PCB formulated heat exchange fluids with non-PCB fluids, some level of PCB residue is likely to remain in certain equipment. Therefore, the comment continues, the Food and Drug Administration should initiate studies for the purpose of establishing a finite allowable residual level. While it is true that some residue of PCB may remain in certain equipment, if the change is made in a responsible manner and in good faith there should not be significant concentrations of PCB remaining. Without additional data it is not possible to set any specific limit for PCB concentration in the equipment fluids. Furthermore, the Commissioner has determined that no reasons exists for FDA to initiate studies to determine the extent of residual levels of PCB's in heat exchangers or to specify by regulations finite tolerances for such residual material at this time.

2. *Section 121.2516.* The notice included an amendment to the existing food additive regulations (21 CFR 121.2516) so as to exclude from use in food-packaging materials pulp from reclaimed fibers containing poisonous and deleterious substances which may migrate to the packaged food.

a. One comment contends that the language of the amendment is incomplete since it does not establish a limit or tolerance for poisonous or deleterious substances, such as PCB's, which may ultimately be found in the packaged food product. The Commissioner disagrees because the purpose of § 121.2516 is to regulate the use of reclaimed fibers containing poisonous or deleterious substances for use in the manufacture of food-packaging materials and, to the extent necessary, to prevent contamination of the packaged food product with these substances. Therefore, the regulation precludes the necessity of establishing tolerances for the packaged food product. The Commissioner agrees, however, the clarification of the amendment is needed in order to be consistent with regulations which permit the presence of what could otherwise be regarded as poisonous or deleterious substances at levels that have been proved to be safe in food-packaging material. Therefore, the order is amended in § 121.2516 by adding the phrase "except as provided in regulations promulgated under Sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act."

3. *Part 122.* The notice included the proposal to establish temporary tolerances under Section 406 of the Federal Food, Drug, and Cosmetic Act for unavoidable PCB residues in animal feed, certain foods and food-packaging materials as a result of environmental contamination.

a. One comment recommends that a zero tolerance for PCB's in foods and feeds should be established. The Commissioner rejects this recommendation. Animal feeds, certain foods, and paper food-packaging materials contain PCB's which, under present conditions of environmental contamination, are unavoidable. Current toxicological information does not support the necessity of establishing zero tolerances for these articles in order to protect public health since human exposure to dietary sources of PCB's is usually sporadic, non-systematic, and occasional. The "finite" temporary tolerances being established will provide the assurance that significant PCB levels are not contained in food and that human exposure to PCB's from dietary sources will be maintained at safe and minimal levels. Zero tolerances therefore, are unwarranted and would unnecessarily deprive the consumer of a portion of his food supply and disrupt the Nation's food distribution system because a portion of fish, poultry, eggs, and milk and packaging used for food would be violative.

b. A consumer group's comment recommended lowering the PCB tolerances for human foods by a factor 5-10 while another comment recommended that the temporary tolerances should be based on toxicological data which would allow a level that is deemed safe rather than allow a level that can be reasonably achieved. The Commissioner disagrees with both recommendations. Section 406 of the Act, which is the authority for establishing the temporary tolerances for PCB's, states that where the addition of a poisonous or deleterious substance to food can not be avoided the Secretary shall promulgate regulations "limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health", and also specifically states that the Secretary in setting such a tolerance shall take into account the extent to which use of the substance "cannot be avoided". The fact

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that the tolerances are termed "temporary" in recognition that in the future, there should be less PCB contamination which cannot be avoided and the Commissioner is authorized to reduce the tolerance levels accordingly. The temporary tolerance levels are based on an analysis of animal and human toxicological data and data on the occurrence of PCB's in the food supply as follows:

(1) *Animal toxicological data.* Data from long-term animal studies are available to show that the no-effect level in rats and dogs (for PCB's with 42, 54, and 60 percent chlorination) is 10 parts per million (ppm). Employing a 100 to 1 safety factor, the "no-effect" level for man would be 0.5 microgram (mcg)/kilogram (kg) body weight/day based on data derived from dogs, or 2 mcg/kg body weight/day from rats. Therefore, based on long-term animal studies, the allowable level of PCB ingestion in man would be approximately 175 mcg/day for a 70 kg individual.

(2) *Human toxicological data.* Human intoxication with Kanechlor 400, a PCB manufactured in Japan with 48 percent chlorine was noted when a heat exchanger leaked fluid into rice oil and was consumed by Japanese families in 1968. About 1,000 people were eventually affected. Typical clinical findings included chloracne and increased pigmentation, visual impairment due to hypersecretion of the Meibomian glands, and systemic gastrointestinal symptoms that included abdominal pain and disturbances in liver function. A few babies were born with decreased birth weights and skin discoloration which slowly regressed as the children grew in size, although the growth rate of males appeared to be somewhat slower than normal. Adult patients had protracted clinical disease with very slow regression of symptoms and signs, suggesting slow metabolism and excretion of this PCB in humans, probably involving a long biological half-life. Exposure levels to the oil were calculated to approximate, on the average, 15,000 mg per day. The oil itself was reportedly contaminated at a level of about 2,000 ppm. This level was derived from the known organic chlorine content of rice oil related to the known organic chlorine content of Kanechlor 400. The average total dose of PCB's causing an effect in the Japanese was reported to be 2,000 mg. The human data published by Kuratsune, et al., Fukuoka Acta. Med. 23 117 (1971) established that the lowest level of PCB that produced an effect in man (using a 50 kg man) was 500 mg consumed over a period of 50 days at a rate of approximately 200 mcg/kg body weight/day. The effect level was based on overt symptoms rather than sensitive biochemical tests that might have demonstrated some effects at even lower levels. Employing a safety factor of 10 to 1 to go from an effect level in man to a permissible no-effect level in man allows for an ingestion of 20 mcg/kg body weight/day, or 1.4 mg/day for a 70 kg man based on a total period of exposure of 50 days (equivalent to the Japanese incident). Since PCB's probably have a long biological half-life in man, an alternative toxicological analysis of the human data may be based on the assumption that ingested PCB's would continue to accumulate in tissues for a long period of time. Since 2,000 mg was reported to be the average total dose causing an effect in the Japanese it is possible that 200 mg total dose of PCB's (applying a safety factor of 10 to 1 as above) may be tolerated over a much more protracted period of time without overt adverse effects if daily exposure is held to minimal levels. It would take 22 months of daily ingestion of 300 mcg of PCB's to arrive at a total dose of 200 mg. This would permit ingestion of 4 mcg/kg/day as derived from a 70 kg man. Since the lowest total dose producing an effect in man was 500 mg, a similar analysis leads to an allowable protracted ingestion of 1 mcg/kg/day as derived from a 70 kg man.

(3) *Dietary sources of PCB's.* The results of FDA total diet studies for fiscal years 1970–1972 show that quantitatively measurable residues of PCB's are equivalent to an intake of approximately 0.06 mcg/kg/body weight/day (or 4.2 mcg/day for a 70 kg man). Because of the sensitivity of the analytical methods used PCB's may be present at levels too low to be detected. If lower levels could be measured, the dietary intake of PCB's from the total diet studies would probably show an increase. It should be recognized, however, that in rare instances some people could have more systematic exposures to PCB's in foods than those expected by eating a moderately well balanced diet such as represented by the total diet samples. Hence, there is a need for minimizing potential human exposures. The total diet studies indicate that PCB's most frequently occur in the food composite consisting of meat, fish and poultry (experience has shown that most of the PCB residues in this composite are in fish and, to a lesser extent, poultry) and in the food composite consisting of grain and cereal products (experience has shown most of the PCB residues in this composite are derived from paper packaging materials). FDA's food surveillance activities have shown that PCB's also occur in dairy products, eggs, and packaged foods, in addition to packaged cereal products.

(4) *Temporary tolerances for PCB's.* Using the human toxicological data described above, FDA concludes that for the short term, based on the lowest total dose producing an effect and estimated biological half-life of PCB's, current levels of PCB's in the diet represent no immediate hazard. This is also true for the average total dose causing an effect in the Japanese for long-term exposure. However, based on the most sensitive "Japanese patient" (i.e., lowest total dose producing an effect), the possibility of potential long-term hazards necessitates reduction of the levels of PCB's in food as soon as possible. In the interim, temporary tolerances are necessary to limit human exposure to those foods that may contain PCB's resulting from environmental contamination which as a practical matter are unavoidable. Those foods for which temporary tolerances are being established, include milk and dairy products, poultry, eggs, fish, and infant and junior food products and young children consume a greater amount of food per pound of body weight and thereby have a proportionately greater exposure than do adults. A separate temporary tolerance for infant and junior foods, therefore, reflects the possibility that undue dietary exposure could result if consumption of certain PCB-contaminated foods comprise a major portion of this age group's diet. In order to maximize the overall dietary intake of PCB's, individual sources of PCB contamination must also be substantially minimized. It has been shown to occur in paper as a result of the PCB contamination of paper food-packaging materials. Limitations on the levels of PCB's in paper food-packaging materials are, therefore, necessary to minimize the amount of PCB's which may migrate to the packaged food. Since PCB's can be transmitted to and concentrated in edible portions of food-producing animals ingesting PCB-contaminated feed, animal feed represents another source of PCB's in the food supply. Limitations on the levels of PCB's in animal feeds and animal feed components are necessary, therefore, to minimize the frequency and magnitude of PCB residues in foods of animal origin.

The Commissioner concludes that the temporary tolerances being established will protect the public health from PCB's in food, but cautions that the temporary tolerances are not to be construed as "guidelines" permitting the consumption of foods containing these amounts of PCB's on a regular and consistent basis. Further, the temporary tolerances will be lowered as experience indicates that lower levels can be attained.

e. One comment recommends that FDA issue warnings to pregnant women who breast feed their babies to restrict their intake of fish to species that have been thoroughly monitored by FDA and found to be uniformly within the temporary tolerance. The basis for this recommendation is that consumption of PCB-containing fish and, for that matter other foods, may result in transfer and storage of PCB residues in human milk, which in turn, the comment contends, would present a hazard to breast fed babies. The Commissioner concludes that such a warning is not warranted. On the basis of available but limited scientific data, none of which is unpublished, it appears that PCB levels in human milk would generally be less than approximately 0.6a ppm (whole product basis). Analysis of available toxicological data involving multigeneration reproduction studies in rats indicates that this level presents no immediate hazard to nursing infants. Furthermore this level is substantially less than the level of 1 (0.5–1.0) ppm (fat basis) permitted in the milk of dairy cows. The temporary tolerance being established for milk is 2.5 ppm (fat basis), which is

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contained residues in excess of 5 ppm (fat basis) in the muscle (breast and thigh), discardable fat and liver of these animals. At a 0.2 ppm feeding level the concentration of the PCB residues in poultry was less than 5 ppm (fat basis). Data further indicate that continuous feeding of Aroclor 1254 at 0.5 ppm from day three to day forty-three post initial egg production can result in PCB residues only marginally less than 0.5 ppm in the eggs.

(2) Data from FDA surveillance programs and from industry reports indicate that PCB levels in finished animal feeds and in animal feed components are generally substantially less than the proposed tolerance limits. (a) Last year FDA conducted a survey of finished animal feeds for PCB's. The survey consisted of 1271 sample examinations representing various categories of animal feeds. The results show that 4.4 percent of the samples contained PCB residues. The highest reported level was 0.6 ppm PCB in feed intended for beef cattle. The average level for all samples tested was less than 0.1 ppm and the average level of the 56 samples that contained reportable levels of PCB's was less than 0.2 ppm. About 1 percent of the samples exceeded 0.2 ppm. (b) Animal feed components of animal and marine origin are expected to contain PCB's as a result of environmental contamination. During the past year, 32 samples of imported fishmeal were examined by FDA for PCB's. The results show that about 37 percent of the samples contained PCB residues. The highest level reported was 0.17 ppm. In addition, 153 fishmeal samples of domestic origin were examined during this period. The results show that about 48 percent of the samples contained PCB residues. The highest level reported was 2.1 ppm and the average was less than 1 ppm. (c) In the fall of 1971, industry conducted a survey of the PCB levels in rendered animal by-products used for feed ingredients such as hydrolyzed feather meal; meat and bone meal, fats and greases, and poultry by-product meal. The results of this survey which were published in "Feedstuffs," Issue of July 3, 1972, show that of the 628 samples tested, the highest level of PCB found was 1.9 ppm in fat and greases. The average PCB level for the samples tested was less than 1 ppm. Other data that the FDA has received on the levels of PCB's in rendered animal by-products essentially confirms the results of this industry survey. Therefore, on the basis of the above, the Commissioner concludes that available evidence requires and justifies a reduction in the PCB tolerances for animal feeds and animal feed components. The order is thus amended in § 122.10(a)(5) and (6) to establish temporary tolerances for PCB's in fat at 0.5 ppm and in animal feed components at 2 ppm.

c. One comment recommends that a tolerance of 5 ppm be established for PCB's in pet food. The Commissioner agrees in part with the comment. The proposal to establish a tolerance for animal feed was directed toward food-producing animals because the transmission of PCB's to the edible portion of animals ingesting PCB contaminated feed constitutes a potential hazard to human health. Further, the comment makes a reasonable recommendation since some pets may be able to safely consume levels of PCB's higher than 0.5 ppm. However on the basis of available toxicological information, there is insufficient data for FDA to establish a tolerance for PCB's in feed for all types of pets and for other non-food producing animals. For this reason, studies will be initiated to obtain this information and, if warranted, FDA will issue a proposal to limit the level of PCB's in this category of finished animal feed. In the interim, the order is amended so that the temporary tolerance in § 122.10(a)(5) is applicable to only food-producing animals.

7. *Section 122.10(a)(7).* The notice included the proposal to establish a temporary tolerance for PCB's in fish (edible portion) at 5 ppm.

a. One comment recommends that a temporary tolerance be established for shellfish. The Commissioner agrees with this recommendation because shellfish also have been found to contain PCB's as a result of unavoidable, environmental contamination and it is also in the interest of public health to limit the level of PCB's in this food. Therefore, § 122.10(a)(7) is amended to include shellfish under the temporary tolerance of 5 ppm.

8. *Section 122.10(a)(8).* The notice included the proposal to establish a temporary tolerance for PCB's in infant and junior foods at 0.1 ppm.

a. One comment states that the level proposed cannot be achieved because of trace quantities of PCB's in certain foods and in paper food-packaging materials. The Commissioner concurs with this statement because information indicates that this level of PCB's cannot be avoided and that current analytical methodology is insufficient to enforce a tolerance of 0.1 ppm. Therefore, the final order is amended by revising the temporary tolerance for PCB's in infant and junior foods to 0.2 ppm.

9. *Section 122.10(a)(9).* The notice included the proposal to establish a temporary tolerance for PCB's in food-packaging materials at 5 ppm.

a. One comment recommends that plastic and other non-paper food-packaging material be exempt from the temporary tolerance. The Commissioner agrees with this recommendation because there is no evidence to indicate that PCB's occur in plastic or other non-paper food-packaging materials as a result of unavoidable contamination. For this reason, no basis exists for establishing a tolerance under Section 406 of the Federal Food, Drug, and Cosmetic Act for these articles. Therefore, the coverage of § 122.10(a)(9) is revised to apply only to paper food-packaging material. This exemption means that no PCB's whatever may be present, either as a result of purposeful addition or industrial accidents, in plastic and other non-paper food-packaging materials. This is in the statement of General Policy or Interpretation under Part 3, which prohibits the use of PCB-containing equipment and materials, are applicable to those establishments engaged in the manufacture, handling, and storage of plastic and other non-paper food-packaging materials.

b. One comment contends that no authority exists under Section 406 of the Federal Food, Drug, and Cosmetic Act for the establishment of temporary tolerances for PCB's in food packaging materials. The Commissioner concurs with the establishment of temporary tolerances for PCB's in food-packaging material is consistent with the language and purpose of Sections 402(a)(2)(A) and 406 of the Federal Food, Drug, and Cosmetic Act.

c. One comment recommends the temporary tolerance be applied to the packaged food, rather than the food-packaging material. The Commissioner rejects this recommendation for the following reasons:

(1) Since the transfer of PCB's from packaging material to the food is dependent on time and conditions of exposure, tolerances based solely on the food would not provide adequate protection to the consumer. A packaged food analyzed at the time of packaging may be entirely free of PCB's, but by the time it reaches the consumer and is finally consumed it may have accumulated considerable quantities of PCB's if the packaging material is contaminated. A tolerance system in which analytical findings are so dependent on many variables such as time of sampling would not be reasonable or adequate. (2) In order to reduce non-compliance with a tolerance for packaged food, the level of PCB in the packaging has to be taken into account and limited to preclude the potential transfer of quantities of PCB's to the food that would cause the food to exceed its tolerance level. The fact that the level of PCB in packaged food is related to the level of PCB in the packaging, in effect, necessitate tolerance for both the food and its packaging. This would represent an obvious redundancy. (3) Establishing a tolerance for packaged food would be inconsistent with the intent and meaning of section 406 of the Federal Food, Drug, and Cosmetic Act. The packaged food does not contain unavoidable PCB residues. The principal source of the PCB contamination of packaged food is the paper food packaging material, which contain the unavoidable contamination. As such, the tolerance should deal with this article. Therefore, this source of food contamination should be limited so as to minimize the levels of PCB's that may migrate to the packaged food. (4) Failure to limit the level of PCB's in food-packaging materials would jeopardize the use of a known, avoidable source of PCB contamination of food.

d. One comment received from the dairy and related trade associations objects that the temporary tolerance for PCB's in food-packaging materials should be deleted or postponed until: (1) adequate control test procedures and analytical methods are developed to enable production and insure compliance.

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and (2) migration rates are established to take into account barrier effect type of food, and package weight to food weight ratio. In response, the Commissioner finds that (1) Although a trade association submitted data which they claimed indicates a lack of reliability in analyses of paperboard materials, the data failed to show that uniform test methods were employed by the participating laboratories or that these tests were performed by laboratories with demonstrated capabilities in trace residue analysis. Further, an interlaboratory study conducted under the auspices of another trade association using FDA analytical methodology, supports the conclusion that current methodology is adequately sensitive and reproducible from laboratory to laboratory in order to insure compliance with the tolerance. (2) It is recognized that migration rates (actual level of PCB in food resulting from the use of contaminated packaging) are affected by factors such as barriers, type of food, package weight to food weight ratio, and time and conditions of exposure. Since FDA's primary concern is not the fact that paper food-packaging materials contain PCB's, but the fact that PCB's can migrate to the food from the packaging, the use of barriers which prevent migration is an acceptable alternative to limiting the PCB content of paper food-packaging material. For this reason, the final order is amended in § 122.10(a)(9) to exempt paper food-packaging materials from compliance with the temporary tolerance if the paper food-packaging material is separated from the food by a functional barrier impermeable to PCB migration. Metal cans and glass bottles are obvious examples of what constitutes a functional barrier impermeable to PCB migration. Data from industry sponsored studies have shown that materials such as polyvinylidene coated paper and glassine can, to varying degrees, prevent or reduce PCB migration under test conditions which would favor migration. FDA would not object to the use of flexible materials and other materials as barriers provided there is no evidence of migration of PCB's to the food. At this time, however, there is insufficient information for FDA to list as part of the regulation these materials that are considered functional barriers. The other factors mentioned above which affect migration rates may also be important considerations and should be thoroughly studied. In the interim, the temporary tolerance for paper food-packaging materials and the exemption to this temporary tolerance are considered necessary to assure the consumer that packaged food is not being contaminated with PCB's to an avoidable degree.

6. One comment states that the establishment of temporary tolerances for PCB in paper food-packaging materials is unwarranted for public health reasons because available scientific evidence shows that Aroclor 1242 (predominant PCB found in paper) is not persistent and cumulative, and that PCB's are not a chronic toxicity problem. Although data indicates that some components of Aroclor 1242 are metabolized in biological systems more rapidly than the higher chlorinated Aroclors, there is no information available which describes the composition, toxicity, and fate of the metabolic products. The presence of Aroclor 1242 residues in human and other animal tissue and in the environment is not a sound basis from which to argue that no hazard exists from the ingestion of Aroclor 1242. The possibility exists that Aroclor 1242 is converted to alteration products which may be more toxic than the original compounds, but which are not detectable by current analytical methods. Further, available data from chronic feeding studies with rats and dogs fail to substantiate claims that Aroclor 1242 does not represent a toxic substance or that it differs in toxicity from the higher Aroclors. The Commissioner concludes that the temporary tolerance for paper food-packaging materials will apply to the term "PCB" irrespective of which Aroclor is present as the contaminant.

7. Several manufacturers and trade associations recommended that the temporary tolerance for PCB's in food-packaging materials be modified so that the tolerance is expressed as "0.265 mcg/square centimeter in that portion of the package from which migration to the food can reasonably be expected", rather than using "parts per million" terminology. The Commissioner believes that this would not be a practical alternative because, (1) Expressing the tolerance for the weight of PCB residues in terms of unit area of packaging material rather than unit weight of packaging material assumes that PCB's are uniformly distributed throughout the food package and that any area of the packaging material selected for PCB analysis would be representative of the entire package. It is generally recognized that this assumption is not valid. (2) The migration of PCB from package material to food is considered to be chiefly a vapor phase phenomenon which is related to the concentration of PCB's in the packaging material. It is therefore not possible to ascertain which portion of the package would be expected to contribute to the PCB contamination of the packaged food. For these reasons, it is necessary to take into account the paper food-packaging material in its entirety as a potential source for the PCB contamination of the packaged food. Therefore, expressing the tolerance in terms of weight of PCB's per weight of packaging material as "parts per million" is a practical means to measure the "average" PCB level in the packaging.

8. One comment recommends that FDA include in the final regulation PCB analytical procedures employed by FDA in determining the extent of compliance with the established temporary tolerance for paper food-packaging materials. The Commissioner concurs in part with the recommendation and FDA will provide upon request the analytical methods to be used for enforcing the temporary tolerances for PCB's in paper food-packaging materials and the other tolerances for which tolerances are established in § 122.10(a). Omitting the methodology from the regulation will permit earlier adoption of improved procedures as they are developed while having the analytical methods readily available to all interested parties.

9. One comment states that the temporary tolerance for PCB's for paper food-packaging materials will be detrimental to solid waste disposal programs, increase food packaging costs and result in an insufficient supply of packaging materials due to limitations of raw materials, and this will significantly affect the quality of the human environment. The underlying basis for this statement is the fact that PCB's may occur in recycled paper because of the inclusion of some types of carbonless copy paper containing 3-6 percent PCB's into waste-paper stocks used in the manufacture of recycled paper. The comment contends that the temporary tolerance will have an adverse effect on the recycled paper industry and thus will cause the above environmental consequences. In response, FDA prepared in accordance with the National Environmental Policy Act of 1969 an environmental impact statement on the proposed rule making. FDA issued a Draft Environmental Impact Statement on May 11, 1972, a Final Environmental Impact Statement on December 21, 1972, and a Supplement to the Final Environmental Impact Statement (published concurrently with this order). In these statements, FDA asserted that information on the toxicity of PCB's necessitates limiting the levels of PCB's currently present in certain foods as a result of environmental contamination, as well as levels of PCB's in certain unavoidable sources of food contamination, i.e., PCB contaminated paper food-packaging materials. FDA also asserted that the public health benefits derived from the rule making would outweigh any benefits that might be derived from industry-recommended alternative courses of action. These alternatives, which were considered and rejected by FDA as ineffective consumer protection measures, included: (1) The alternative of not regulating the PCB content of food-packaging materials. (2) The alternative of excluding Aroclor 1242 from the regulation; and (3) The alternative of regulating the packaged food rather than the packaging. FDA concluded in the statements that the rule making would have a significant beneficial effect on the quality of the human environment. FDA did, however, re-evaluate the proposed level of 5 ppm as the temporary tolerance for PCB's in paper food-packaging materials. Data from the FDA survey of PCB's in foods and food packaging showed that the food portion of the samples with 5-10 ppm in paper food packaging contained the same range of PCB levels (0.1-0.6 ppm) as the food portion of the samples with 0-5 ppm in paper packaging. Samples with more than 10 ppm in the packaging contained higher levels in the food, ranging up to 3.4 ppm. The Commissioner concluded that this was the only acceptable effective level available and stated in the Final Environmental Impact Statement that the temporary tolerance for PCB's in paper

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food-packaging materials would be changed to 10 ppm. This order amends § 122.101a)(3) to reflect this change. Data provided by industry shows that levels of PCB's in paper food-packaging materials have diminished during the past year to the point that 93 percent or more of this material will contain 10 ppm or less PCB's. Therefore, FDA concluded that the temporary tolerance of 10 ppm and the exemption to the tolerance for paper food-packaging materials separated from the packaged food by a functional barrier will protect the public, while minimizing or negating the impact of the rule making on recycling programs. Furthermore, FDA indicated in the Supplement to the Final Environmental Impact Statement that it will explore with other federal agencies measures for eliminating PCB-containing carbonless copy paper from existing inventories. If feasible, this action would reduce the primary source of PCB's found in paper food-packaging materials permitting FDA to reduce the temporary tolerance, and eventually to eliminate the need for regulating this unavoidable source of PCB's in food.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1784–1788 as amended; 21 U.S.C. 342(a), 346, 348, 371) and under authority delegated to the Commissioner (21 CFR 2.120) Parts 3, 121, 128, and 135 are amended and a new Part 122 is added, as follows:

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

1. The following new section is added to Part 3:

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

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's 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. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be persistent and hazardous contaminants in the environment, causing the contamination of certain foods. In addition, instances have occurred in which PCB's have incorrectly contaminated animal feeds as a result of industrial accidents (e.g., use or spillage of PCB fluids from electrical equipment). The accidents in these cases and the contamination of the animal feeds resulted in human consumption of contaminated meat, milk, and eggs. Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The extent of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (containing 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB's 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) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials.

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before August 6, 1973, 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 verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's next to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be accurately 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 or likely degradation in the environment to indicate a loss of persistence; 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 hazardous to be used on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

PART 121—FOOD ADDITIVES

2. In Part 121 § 121.2546(b) is amended by revising subparagraphs (1) and (2), as follows:

§ 121.2546 Pulp from reclaimed fibers.

* * * * *

(b) * * *

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is removed in the recovered pulp and that migrates to the food, except as provided for in regulations promulgated under sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act.

(2) Salvage from used paper and paperboard excluding that which (i) bears or contains any poisonous or deleterious substance which is removed in the recovered pulp and that migrates to the food, except as provided for in regulations promulgated under sections 406 and 409 of the act or (ii) has been used for shipping or handling any such substance.

* * * * *

PART 122—UNAVOIDABLE CONTAMINANTS IN FOOD AND FOOD PACKAGING MATERIAL

3. A new Part 122 is added as follows:

Subpart A—Definitions and Procedural and Interpretive Regulations

Sec.
122.1 Definitions and interpretations.
122.2—122.9 [Reserved]

Subpart B—Industrial Contaminants in Food and Food Packaging Material

122.10 Temporary tolerances for polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1784–1788 as amended; 21 U.S.C. 342(a), 346, 348, 371.

Subpart A—Definitions and Procedural and Interpretive Regulations

§ 122.1 Definitions and interpretations.

(a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in this part.

(b) Unavoidable natural environmental, or industrial contaminants in poisonous or deleterious substances added to raw food where such substance cannot be avoided by good manufacturing practice.

Subpart B—Industrial Contaminants in Food and Food Packaging Material

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

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals [illegible] of their widespread uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in

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the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated feed and feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts 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 by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts 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.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare Room 6-88, 5600 Fishers Lane, Rockville, MD 20852.

PART 128—HUMAN FOODS, CURRENT GOOD [illegible] ACTURING PRACTICE (CONTAINED IN [illegible] PROCESSING, PACKING OR HOLDING

4. In Part 128 by revising § 128.1 to read as follows:

§ 128.1 *Equipment and utensils.*

(a) *General.* All plant equipment and utensils should be (1) suitable for their intended use, (2) so designed and of such material and workmanship as to be adequately cleanable, and (3) properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(b) *Use of polychlorinated biphenyls in food plants.* Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including Aroclor (United States), Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and non-flammable chemicals. Industrial uses of PCB's 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. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment and causing the contamination of certain foods. In addition, 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 cause the contamination of food intended for human consumption (meat, milk, and eggs). Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food. The following special provisions are necessary to preclude accidental PCB contamination of food:

(1) New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's.

(2) On or before September 4, 1973, the management of food plants shall:

(i) Have the heat exchange fluid used in operating equipment or machinery for handling or processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate from the food plant any PCB-containing food-contact surfaces of equipment or utensils and any PCB-containing lubricants for equipment or machinery that is used for handling or processing food.

(iii) Eliminate from the food plant any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's (either as a result of normal use or as a result of accident, breakage, or other mishap).

(iv) The toxicity and other characteristics of fluids selected as PCB's 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 non-hazardous is to be made on an individual installation and operation basis.

(3) For the purposes of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

PART 135—NEW ANIMAL DRUGS

5. The following new section is added to Part 135, Subpart B:

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

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including, Aroclor (United States), Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's 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. Their unique physical and chemical properties and widespread uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition 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 cause the contamination of feed intended for human consumption (meat, milk, and eggs). Investigations by the Food and Drug Administration have revealed that heat exchange fluids for certain pasteurization equipment used in processing animal feed contain PCB's. Although heat exchange fluids in such equipment are considered to be in "closed systems", leakage has occurred that resulted in direct contamination of animal feed with PCB's and subsequently resulted in the transfer of PCB's to human food produced from animals consuming the contaminated feed. The use of certain [illegible] coatings on the [illegible] silos has resulted in the contamination of silage which has in turn caused PCB

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residues in the milk of dairy cows consuming the contaminated source. Since 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) The following special provisions are necessary to preclude accidental PCB contamination of animal feed:

(1) Coatings or paints for use on the contact surfaces of 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 feed in or around an establishment producing animal feed shall not contain PCB's.

(3) On or before Sept. 4, 1973, the management of establishments producing animal feed shall:

(i) Have the heat exchange fluid used in existing equipment or machinery for handling and processing 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. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices, be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any PCB-containing lubricants for equipment or machinery used for handling or processing animal feed.

(iii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such material is capable of causing animal feed to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iv) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement should be 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.; (d) and its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently non-hazardous is to be made on an individual installation and operation basis.

(c) For the purpose of this section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

(d) For the purpose of this section, the term "animal feed" includes all articles used for food or drink for animals other than man.

Any person who will be adversely affected by the provisions of §§ 121.254b and 122.10 of the foregoing order may at any time on or before August 6, 1973 file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-82, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the ground for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Objections may be accompanied by a memorandum or brief in support thereof. Six copies of all documents shall be filed. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date. This order will become effective for foods, feeds, and paper food-packaging materials initially shipped in commerce after Sept. 4, 1973 except as to any provisions of §§ 121.254b and 122.10 that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced in the FEDERAL REGISTER. In the event § 122.10 is stayed by valid objections, pending a final regulation the Food and Drug Administration will enforce the levels stated in § 122.10 by seizing pursuant to sections 301 and 304 of the Act any food, feed, or paper food-packaging material shipped in commerce containing higher than the specified level of PCB's as adulterated in violation of section 402 of the Act.

(Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1727-1763 as amended, 21 U.S.C. 342(a), 346, 346a, 371)

Dated: June 21, 1973.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.73-13549 Filed 7-5-73;8:45 am]

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

POLYCHLORINATED BIPHENYLS

Availability of Supplement To Final Environmental Impact Statement

The Commissioner of Food and Drugs published a notice in the FEDERAL REGISTER of December 21, 1972 (37 FR 28001) announcing that a statement entitled "Final Environmental Impact Statement—Rule Making on Polychlorinated Biphenyls" had been issued by the Food and Drug Administration.

Notice is hereby given that a statement entitled "Supplement to the Final Environmental Impact Statement—Rule Making on Polychlorinated Biphenyls" has been issued by the Food and Drug Administration. Copies of the supplement are available from the Office of the Assistant Commissioner for Public Affairs, Room 15B-42, or the Office of the Hearing Clerk, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to provisions of the National Environmental Policy Act of 1969 (Public Law 91-190) (sec. 102(2)(c), 83 Stat. 853, 42 U.S.C. 4332), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: June 21, 1973.

SAM D. FINE,
Associate Commissioner for Compliance

[FR Doc.73-13548 Filed 7-5-73;8:45 am]

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PCB file

SUPPLEMENTARY BACKGROUND

Regulations

Section 214.2(h)(4)(i) of the Immigration and Nationality Act, Service Regulations (8 CFR 214.2(h)(4)(i)), provides that the Immigration and Naturalization Service, in the case of a petition for the admission of aliens into the United States to perform certain temporary labor:

Under 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 * * *

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

Relationship of Proposed Rule to Previous Regulations for 20 CFR Part 655

On January 25, 1977, at 42 FR 4650, 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	$ .79
Maine	2.61
Massachusetts	2.60
New Hampshire	2.85
Rhode Island	2.42
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-0090]

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 18059), the Commissioner of Food and Drugs issued a final rule amending Part 109 (21 CFR Part 109) to deal with the problem of contamination of animal feeds, foods, and food packaging materials by PCB's. Among those 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 feed, which is [illegible] (see notice published in the FEDERAL REGISTER of August 24, 1976 (41 FR 35543)) pending completion of safety studies by Hearing Clerk Docket 76F-0106 and 76F-0107(e) of the act (21 U.S.C. 346 and 371(e)). In establishing these tolerances as "temporary" the Commissioner recommended 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 30 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 8169) the Commissioner issued a statement of policy regarding PCB's in certain fresh-water fish. The notice discussed the review of the temporary tolerances and stated that if, on the basis of this 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 (µg/kg) body weight per day was calculated. When rat data were used, the no-effect level in man was 3µg/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 effective through not always possible to rely on [illegible] than PCB's. In the case of PCB's, [illegible] contamination [illegible] Japan [illegible] Co. [illegible] PCB's. The [illegible] Yusho [illegible] Kanechlor 400 [illegible] PCB's containing 48 percent (by weight) chlorine. The 16 percent (by weight) chlorine-containing [illegible] 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 considered significant in establishing a temporary tolerance for human exposure to PCB's resulting from Americal [illegible].

The [illegible] determined were [illegible] 2,700 [illegible] of the [illegible] Kanechlor [illegible] that [illegible] 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 0.75 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 0.75 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 feed 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 tolerance [illegible] exposure of no more than [illegible] per day. [illegible] for a [illegible] of [illegible] per day.

[illegible] however, [illegible] established the temporary tolerance for [illegible] in the clear belief that it should be treated as an [illegible] and [illegible] statement of such change. The Chairman of the Interagency Committee to Coordinate Domestic 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 toxicity, human exposure to PCB's and sources of residues of PCB's and to [illegible] recommend [illegible] in such areas. This subcommittee, consisting of scientists from several government agencies concerned with PCB's, submitted its report to the Committee and it is referred to as the Interagency Committee 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 is dependent 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. These different patterns of toxicity is associated in part with a longer biological half-life and less susceptibility to metabolic alteration or detoxification 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 [illegible] mostly 5 [illegible] [illegible] chlorinated [illegible] [illegible] [illegible] PCB [illegible] [illegible] [illegible] of [illegible] chlorine [illegible] [illegible] [illegible] [illegible] served in the Yusho [illegible] [illegible] to the [illegible] [illegible] the observed effects, or whether such interaction occurred.

Different animal species vary in their susceptibility to the toxic effects of PCB's. However, evaluation of this susceptibility is complicated by [illegible] lack of information on the [illegible] portion of the PCB most responsible for studies and the relative [illegible] [illegible] of [illegible] PCB [illegible] [illegible] toxicity of the [illegible] PCB [illegible] [illegible] [illegible] [illegible]

[illegible] Aroclor 1254 (Reference 19). [illegible] Aroclor 1260 for 21 months developed [illegible] [illegible] [illegible]

[illegible] water from the major drainage basins of the United States, [illegible] occurrence of PCB's in [illegible] water and bottom sediments. The [illegible] due levels of PCB's in the surface water [illegible] or [illegible] to 0.1, with a maximum value level of 2.0 ppb (Reference 29).

In Wisconsin streams from cooling water intake [illegible] PCB's ranged from 11 to 70 parts per billion (ppb). Levels from paper manufacturing ranged from 0.4 to 25 ppb. Analysis of snow melt water from Wisconsin cities showed PCB residue levels of 0.17 to 0.71 ppb, suggesting that fallout of PCB's from the atmosphere is a source of PCB's in the waters of the State (Reference 29).

In Finland, [illegible] PCB's [illegible] 2 percent [illegible] 0.1 and 2 percent greater than 10.0 ppm. With such a disposal ruling either by incineration, landfill and crop or pasture application, the contamination 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 critical 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 chloroderma[illegible]" 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 on individual situations, they do not have any bearing on the [illegible] FDA [illegible] tolerances for PCB's in foods.

Petition To Reduce Tolerances

On November 21, 1973 the Environmental Defense Fund (EDF) and the Natural Resources Defense Council (NRDC) jointly submitted a petition (Docket No. 73P-0340) 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 urge certain inferences and conclusions, stating 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) 121 USC 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, [illegible] (at levels) or the continuing should cause removal of food from the [illegible] consumer. If measurable [illegible] residues were suddenly [illegible] to environmental contaminants present in the food supply, enforcement activities could significantly disrupt the food supply. Removing food containing detectable residue from the marketplace could lead to enforcement [illegible] present any significant risk to public health.

The Commissioner advises that while the statistical evaluation formulas for establishing risk probabilities, [illegible] Mantel-Bryan procedure, are valid and useful in some situations, they are not an appropriate tool for determining [illegible] safety [illegible].

The petitioners' [illegible] Japanese PCB poisoning episode in Japan and the results of some studies of 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 percentage 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 [illegible] whose consumption of PCB's in their diets is substantial relative to the general population, have not exhibited any adverse health effects (Reference 43).

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 markedly 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 judgements regarding allow-

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able but [illegible], all available data from all specific sources considered.

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

The Commissioner acknowledges that the temporary tolerances were established with the knowledge of 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 reported 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. Also, the Commissioner cannot agree with the petitioners' contention that the [illegible] tolerances are [illegible] 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 or the 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 areas in the petition which could have influenced the conclusion that the decrease in PCB levels is only "apparent." The petition reports fiscal year 1970 levels of PCB's, from the FDA Total Diet Survey as "three—60 ppm" in the feed composites. The highest finding in a Total Diet Survey food composite for the period was 0.07 ppm. The 60 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 the [illegible] 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 under section 406 have effectively reduced the PCB residue. The remaining contaminant problem as previously noted, is with fish, predominantly 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 no 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 these foods from the current 2 ppm to 1.5 ppm (fat basis).

The Commissioner has considered the current temporary tolerance of 5 ppm on fat of hogs for PCB residues in edible fat. For the reasons previously stated, he has concluded that it is desirable to lower further reduce the temporary tolerance for PCB's in this class of food to the lowest extent possible. Accordingly, the Commissioner considered proposing a tolerance of 1.5 ppm in the fat of pork, 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 hogs, the primary source of PCB's to which these animals are exposed, is established at 0.3 ppm—the level of detection. Data indicate that continuous feeding of poultry with finished feed contaminated with PCB, results in PCB residues in the discernible 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 tolerances. 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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[illegible] (0.1 ppm). As stated [illegible] the Commissioner [illegible] tolerance of 0.5 ppm [illegible] fish. [illegible] that [illegible] to reduce the tolerance [illegible] to 0.2 ppm [illegible] the tolerance for [illegible] will not be established.

The proposed reduction in the temporary tolerance for PCB's in fish is from 0.5 ppm to 0.2 ppm, the practical analytical limit for the determination of PCB's in fish. Although fish would be expected to contain PCB residues if the chemicals were consistently fed contaminated feed, the residues in fish resulting from 0.2 ppm PCB in the feed are not expected to exceed 0.2 ppm tolerance. Although, as noted, some fish may contain PCB's in the edible portion of fish at levels exceeding the temporary tolerance for PCB's in fish, the Commissioner has determined that PCB's in feed at the 0.2 ppm level will not be established.

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 on 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 foods taken from commercial markets and fish 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 1.0 ppm. In those species and locations where more data exist, the blended or whole fish is the 17 parts retained by consumers in the New Jersey area). However, the highest levels in these species were less than 5 ppm in whole fish and less than 0.5 ppm in edible portions. Bottom-feeding and long-lived contaminated fish tend to have higher PCB levels than other species (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, with [illegible] species [illegible] as high as 2 ppm. Carp, suckers, catfish, and yellow perch 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, (eliminating, 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 $18 million processed value.

The Commissioner notes that the economic loss for marine fish would be [illegible] the same as the 2 ppm level but the dollar loss for [illegible] be about 40 percent of [illegible] 2 ppm tolerance [illegible] according to the FDA economic assessment the current temporary [illegible] 5 ppm may be reduced to [illegible] maximum total loss for [illegible] (Reference 39). The commercial impact of a 5 ppm level would be much [illegible] that of 1ppm, and lands above 2 ppm would further decrease the [illegible] 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 considering whether any higher limits could be safely tolerated. An average per capita consumption level for fish and shellfish in this country, as reported to be [illegible] noted, 10 grams per [illegible] and a maximum [illegible] of 2 [illegible] grams [illegible] daily intake of PCB from commercial fish [illegible] would be about 38 micrograms. The FDA Total Diet Study data show that average PCB intake from all sources in the 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 16.4 milligrams. This low level of intake is less than one-fiftieth of the average cumulative dose (1,000 milligrams) of PCB's 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 the 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 was designed 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 150 pounds per year. In cooked fish, PCB residues ranged from 0.36 to 5.33 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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[illegible] investigations calculated that the [illegible] of PCBs in [illegible] to the general [illegible] would [illegible] per year and [illegible] from 1437 to 1154 [illegible] parts per [illegible]. No systematic adverse health effects could be demonstrated [illegible] to control. (Reference 46)

The 40 micro, [illegible] per day (168 micrograms per week) [illegible] given as an example previously, is based on a hypothetical 2 ppm [illegible] content in all fish. Although this level actually permits only [illegible] identified. 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 10 micrograms per day, providing an additional [illegible] safety.

[illegible] limit [illegible] can be considered adequate [illegible] PCB's [illegible] fish [illegible] PCB [illegible] 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 4.07 ppm, in cooked coho salmon from 0.48 ppm to 5.38 ppm, and in other cooked fish from 0.36 ppm to 2.66 ppm. These levels are decidedly lower than the mean levels of 22.81 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 a very large amount of fish taken from highly contaminated waters. Moreover, a 2 ppm tolerance would close only a relatively minor percentage of marginally and less than 10 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 PCBs, 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 408 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 may 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.

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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. 913 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 120, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14303)) 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 [illegible] food-packaging material [illegible] on the basis of [illegible] by a fatty food [illegible] migrate to [illegible] of PCB's.

[illegible] 42 FR 42794, Aug. 24, 1977, this [illegible] proposing § 109.30(a) (7), (effective) 12:10(a)(7)):

[illegible] § 109.30(a)(9) hereby stayed pending [illegible] of the objections and requests for hearing."

In the interim as stated in the final order (38 FR 1592), the Food and Drug Administration will enforce the temporary tolerance level established by § 109.30(a)(9) for [illegible] paper food-packaging material shipped in interstate commerce after September 4, 1973 containing levels lower than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Interested persons may, on or before [illegible], 1977, submit to the Hearing Clerk, Food and Drug Administration, [illegible] 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. Comments should be identified with the 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-0081]

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 [illegible] radiographic [illegible] is interested in receiving comments on the advisability of the above amendments and information and data bearing on the proposed amendments.

DATES: Comments concerning the proposed amendments are requested by April [illegible], 1977.

ADDRESSES: Individuals or organizations wishing to receive copies of the proposed 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-240), Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Comments concerning this proposal should be sent to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas B. Snope, 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 March 15, 1972 (37 FR 5261) and became effective on August 1, 1974. (The [illegible] effective date was published in the FEDERAL REGISTER of June 12, 1971 (36 FR 11444)).

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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The classification procedures appear in this report's Full Text section. Comments on the proposals will be accepted for 30 days after publication in the Federal Register.

Legislation

AIR ACT INCLUDES PROVISIONS FOR CHEMICALS REGULATION, RESEARCH

Authority to regulate radioactive materials, arsenic, cadmium, and polycyclic organic matter as air pollutants is contained in one of the provisions of Clean Air Act amendments signed by President Carter August 7.

The amendments, which were the result of a House-Senate conference committee agreement August 3, also provide for further study of the stratospheric ozone layer and of the relationship between environmental pollution and cancer and other diseases, and establish interagency committees to coordinate research in these areas.

Unregulated Pollutants

The amendments classify radioactive substances, including, but not limited to, naturally occurring radioactive materials, accelerator-produced isotopes, source material, special nuclear material, and byproduct material, as air pollutants — bringing the substances under the various regulatory provisions of the Act.

The Environmental Protection Agency is directed to list such radioactive substances as criteria pollutants under ambient air-quality standards (Section 108), or under hazardous-emission standards (Section 112) or new-source performance standards (Section 111) within two years unless the agency determines that the material does not contribute to air pollution that endangers public health.

EPA also is directed to take similar action against arsenic, cadmium, and polycyclic material within one year after enactment.

Before listing any radioactive pollutants under the Act, EPA must consult with the Nuclear Regulatory Commission and enter into an interagency agreement with the commission to minimize duplication of effort in the establishment and enforcement of emission limitations, standards of performance, and other requirements under the Act.

NRC could pre-empt an EPA or state or local emission standard if it finds after notice and public hearing that the standard would have an adverse effect on matters where NRC has jurisdiction to protect health and safety. The President then would have 90 days to overturn the NRC pre-emption.

Ozone Protection

The amendments direct EPA to conduct a continuing study of the stratospheric ozone layer and to provide Congress with an interim report by January 1, 1978, a final report within two years of enactment, and annual followup reports thereafter. The agency is required to contract with the National Academy of Sciences for a followup of its 1976 study on the depletion of the ozone layer.

EPA also is directed to chair an interagency committee to coordinate research on the protection of the ozone layer. Other members of the committee are to be representatives of the National Oceanic and Atmospheric Administration, National Aeronautics and Space Administration, Federal Aviation Administration, Department of Agriculture, National Science Foundation, National Cancer Institute and the National Institute of Environmental Health Sciences.

The amendments also include regulatory provisions directing EPA to promulgate regulations to protect the ozone layer if the agency finds that public health or welfare may be endangered. Such regulations are to fill in regulatory gaps, however, and are not to supersede any existing authority of other agencies.

The amendments provide also that any rulemaking begun by EPA under the Toxic Substances Control Act in this area should proceed as though the Air Act amendments were not enacted. EPA currently is receiving public comments on its proposed regulations for banning all nonessential uses of chlorofluorocarbons as aerosol propellants under Section 6 of TSCA (Current Report, August 5, p. 735).

Chemical Contaminants

The amendments require EPA to publish within a year of enactment a list of all known chemical contaminants in the U.S. resulting from environmental pollution which have been found in blood, urine, milk, and in other human tissue or body fluids. The list is to indicate approximate number of cases, range of levels found, and mean levels found. The agency then is to publish within 18 months of enactment an explanation of what is known about the manner in which the chemicals on the list entered the environment and human tissue.

EPA also is directed, in consultation with the National Institutes of Health, National Center for Health Statistics, and the National Center for Health Services Research, "if feasible," to conduct an epidemiological study to show the relationship between levels of chemicals in the environment and in human tissue. The study is to be made in the "appropriate areas" of the U.S. in order to determine any different results in such regions. Results of the study are to be reported to Congress "as soon as practicable."

The amendments additionally call for the establishment within three months of enactment of an interagency task force on environmental cancer and heart and lung disease. The task force is to be chaired by EPA and to include representatives of NCI, National Heart, Lung, and Blood Institute, National Institute for Occupational Safety and Health, and NIEHS.

The task force is directed to recommend a comprehensive research program to determine the relationship between environmental pollution and human cancer and heart and lung disease, recommend comprehensive strategies to reduce or eliminate the risks of such disease, recommend research and other measures for preventing or reducing the incidence of environmentally related diseases; and coordinate research and stimulate cooperation between EPA, the Department of Health, Education, and Welfare, and other agencies in this area.

The task force is to report to Congress one year after enactment of the amendments and annually thereafter on the problems and progress in this area.

Hazardous Design Standard

The amendments also revise Section 112 of the existing law to specify design, equipment or operational standards for the control of a source of hazardous emissions. This provision is applicable when an emission limitation is not possible or feasible to measure hazardous emissions or to control them through appropriate control devices.

Testing

AGENCIES HOPE TO DEVELOP ONE SET OF TESTING CRITERIA, BINGHAM SAYS

One area in which federal regulatory agencies are attempting to encourage cooperation and eliminate duplication of effort is in the development of a single set of testing stan-

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by chemical spills. He also said more frequent monitoring of industrial effluents and stricter enforcement of National Pollutant Discharge Elimination System permits are "sadly needed."

Arnold Leff, Cincinnati, Ohio, commissioner of health, said EPA has not dealt with the problem of water pollution that occurs in river valleys located in more than one EPA region, as is the case with the Ohio River valley. He said three separate regions are responsible for enforcing antipollution laws in that one river valley and added it would be "quite easy" to designate one region as the lead agency for law enforcement.

Jackson L. Higgins, mayor of Mt. Vernon, Ind., recommended more efficient monitoring and on-the-spot sampling of industrial effluents. He said all 150 industries located on the Ohio River should be required to list all the chemicals they have on their sites, so EPA "will not be troubled looking for an unknown chemical."

Hazardous Materials

MTB LISTS APPLICATIONS FOR EXEMPTIONS FROM MATERIALS TRANSPORTATION RULES

Applications for renewal of exemptions from hazardous materials transportation regulations, applications to become party to an exemption, and applications for exemptions were published by the Materials Transportation Bureau July 14 (42 FR 36337).

Comments in triplicate, including application numbers, should be sent to the Section of Dockets, Office of Hazardous Materials Operations, Department of Transportation, Washington, D.C. 20590. Comments on the applications for renewal and for becoming party to an exemption are due July 31 and comments on new applications are due August 15.

Mode indicators for new applications are. 1 — motor vehicle, 2 — rail freight, 3 — cargo vessel, 4 — cargo-only aircraft, 5 — passenger carrying aircraft.

The applications appear in the Full Text section of this report.

Polychlorinated Biphenyls

NO TYPE OF EXPOSURE TO PCBs IS INSIGNIFICANT, EDF TELLS EPA

Because of their persistence in the environment and highly toxic effects, no type of exposure to polychlorinated biphenyls can be termed as insignificant, according to Joseph Hyland of the Environmental Defense Fund.

At an Environmental Protection Agency hearing July 15 in Washington, Hyland told an agency panel that the use of PCBs in a "totally enclosed manner" is impossible.

EPA held the hearing to receive comments from the public prior to proposal of regulations for carrying out the phased ban on PCBs, the second phase of action against the chemicals under the Toxic Substances Control Act. Section 6(e) of TSCA provides that after January 1, 1978, PCBs may not be manufactured, processed, distributed in commerce, or used in other than a "totally enclosed manner." After July 1, 1979, no PCBs may be manufactured, processed, or distributed in commerce.

EPA currently is considering comments on its proposed regulations for the labeling and disposal of PCBs — the first phase of action against the chemicals under TSCA (Current Report, July 1, p. 603).

Resale Provisions

Herbert T. Gilky, director of public affairs, Air Conditioning and Refrigeration Institute, said his industry is concerned with the resale provisions of TSCA — when does one stop selling PCBs as such and start selling something that contains PCBs?

Gilky said that capacitors weighing three pounds or less which contain PCBs as a dielectric, are a small, but important part of air-conditioning units.

Hyland commented, however, that even exposure to sealed capacitors is significant through the production and disposal of the capacitors.

Hyland said that EDF is opposed to the further sale of existing stockpiles of PCBs and believes that such stockpiles should be incinerated. EDF also advocates strict restrictions on the disposal of PCB-contaminated sludge on land, he said.

PCB use should be restricted only to the servicing of existing equipment, Hyland said, and no further production of the chemicals should be permitted.

Government Stockpiles

Although the paper manufacturing process does not use PCBs, contamination from PCBs in recycled paperboard is posing a problem for the paper industry, according to an industry official.

Richard Wiechmann, director of environmental affairs for the American Paper Institute, told the EPA panel that PCBs were used as an encapsulating agent in ink at a concentration of about 3 percent. Although the practice was stopped in 1971, he said, the ink was used mainly on business forms used primarily by the Government for such uses as Internal Revenue Service W-2 forms. A problem now exists with the Government stockpiling the old forms and then recycling them, he said.

The contaminated business forms, which have a PCB content of about 30,000 parts per million (ppm), are recycled into paperboard, Wiechmann said. The Food and Drug Administration has set a tolerance of 10 ppm for PCBs in recycled foodboard, he said, and the paper industry has set up a quality control program to prevent contamination of the foodboard. No such program exists to prevent contamination of other forms of paperboard, however, he said.

Contaminated Waste Oil

Robert Magruder, Continental Forests Industries, Hopewell, Va., told the EPA panel that his company is concerned about its future use of PCB-contaminated waste oil.

Magruder said his company uses used crankcase oil, collected mainly from service stations in Maryland, North Carolina, and Virginia, in the operation of about one half of their steam generating units. Although the company has informed their collectors that they do not want the contaminated oil, he said, they have no way of assuring that the used waste oil will be free of contamination.

Magruder said that the impact of burning the contaminated waste oil is "minimal" and the process "almost qualifies as a PCB incinerator." Reprocessing the contaminated oil does not remove the PCBs, he said.

If the use of PCB-contaminated waste oil is banned after 1978 or 1979, Magruder said, the company will be forced to turn to more expensive oil, thereby increasing energy imports and eliminating a means of disposing of the PCB-contaminated oil at low cost.

Mining Operations

James Petrie, health specialist for the Interior Department's Mining Enforcement and Safety Administration, questioned whether the use of PCB-cooled electric motors in mining operations would be considered a "totally enclosed manner."

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