Monsanto

FROM (NAME & LOCATION): Cumming Paton - G. O.

DATE: July 23, 1973

SUBJECT: PCBs

REFERENCE:

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The FDA has published their regulations concerning PCBs in food, animal feed, and packaging plants and tolerance levels for PCB in food and food packaging. The EPA is wrestling with establishing effluent standards for toxic pollutants as part of the Federal Water Pollution Control Act. I attach the relevant sections from the Federal Register.

TNGS 009028

PLAINTIFF'S EXHIBIT
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11-1-07-0

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The key features are:

1. FDA Regulations

   (a) FDA has exempted PCBs in electrical capacitors and transformers from the regulations (page 18096).

   (b) The effective date for these regulations is September 4, 1973 but certain procedures have to be taken by August 6.

   (c) The temporary tolerances established for PCBs in foodstuffs range from 0.2 to 5.0 ppm and in paper food packaging 10 ppm.

2. EPA

   (a) EPA is proposing a list of toxic pollutants which includes PCB.

   (b) It is apparently EPA's intention to establish effluent standards for each of these toxic pollutants as part of the Federal Water Pollution Control Act.

I also attach an article from Food News which comments on and interprets the FDA regulations on PCBs.

You may find these articles useful for reference if the topic is brought up at Therminol, Pydraul or dielectric accounts. If you have any questions please refer them to Bill Papageorge or George Fague (Pydraul/Therminol) or Paul Benignus (dielectrics). In their absence feel free to contact me. If publications of these government proposals and regulations may lead to fluid conversions by customers, please let us know.

Cumming Paton

/pep
Attachments

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PCB TEMPORARY TOLERANCES TO BE ENFORCED EVEN IF STAYED

The Food and Drug Administration on July 6 finalized temporary tolerances for polychlorinated biphenyls in food, feed and packaging materials (See FOOD CHEMICAL NEWS, March 20, 1972, Page 38) -- making it known that the tolerances will be enforced even if they are stayed because of objections filed within 30 days

The regulations setting the temporary tolerances will become effective in 60 days, unless they are stayed. However, the agency said: "In the event §122.10 is stayed by valid objections, pending a final regulation the FDA 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 §402 of the Act."

§301 spells out prohibited acts which make products adulterated or misbranded, and §304 provides for seizure.

The 93 comments filed on the proposed PCB regulations were reviewed by FDA (See FOOD CHEMICAL NEWS, April 10, 1972, Page 12; April 24, 1972, Page 9; May 1, 1972, Page 15; May 8, 1972, Page 12; May 15, 1972, Page 42; May 22, 1972, Page 17; May 29, 1972, Page 9; June 5, 1972, Page 10; July 3, 1972, Page 26; July 24 Page 39; Aug. 7, Page 21; Oct. 2, Page 11; Feb. 5, Page 24; Feb. 12, Page 16; and March 5, Pages 8 and 27).

FDA noted that one comment urged 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 agency concluded "that there is no justification for extending the effective date..."

Tolerance in Paper Raised from 5 p.p.m. to 10 p.p.m.

In finalizing the proposals, FDA raised from 5 p.p.m. to 10 p.p.m. the tolerance for PCBs in paper, concluding that "the temporary tolerance of 10 p.p.m. and the exemption to this tolerance for paper food packaging materials separated from the packaged food by a functional barrier will protect the public, while minimizing or preventing the impact of the rule making on recycling programs."

In re-evaluating the proposed 5 p.p.m. tolerance for paper, FDA said its survey "showed that the food portion of the samples with 5-10 p.p.m. in paper food packaging contained the same range of PCB levels (0.1-0.6 p.p.m.) as the food portion of the samples with 0-5 p.p.m. in paper packaging." Samples with more than 10 p.p.m. in packaging contained levels up to 3.7 p.p.m., FDA said.

The expected raise in tolerance for paper from 5 p.p.m. to 10 p.p.m. was previewed in the agency's final Environmental Impact Statement (See FOOD CHEMICAL NEWS, Dec. 25, Page 5). The reasoning for the change was spelled out in more detail in the lengthy preamble to last week's regulations, and in a Supplemental EIS (See FOOD CHEMICAL NEWS, June 11, Page 3).

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FDA adopted the suggestion made in a comment that "plastic and other non-paper food-packaging material be exempt from the temporary tolerance." The agency said "there is no evidence to indicate that PCBs occur in plastic or other non-paper food-packaging materials as a result of unavoidable contamination.' It added:

> "This exemption means that no PCBs whatever may be present, either as a result of purposeful addition or industrial accidents, in plastic and other non-paper food-packaging materials. The provisions in the Statement of General Policy or Interpretation..., 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."

Explaining the exemption "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," FDA said "the use of barriers which prevent migration is an acceptable alternative to limiting the PCB content of paper food-packaging material." The agency said:

> "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 PCBs to the food. At this time, however, there is insufficient information for FDA to list as part of the regulation those materials that are considered functional barriers. The other factors...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 PCBs to an avoidable degree."

An industry comment, FDA said, urged that the tolerance for packaging materials be scrapped or at least postponed until (1) quality control test procedures and adequate analytical methods are developed, and (2) migration rates are established taking into account barrier effects, types of foods, and ratios of package weight to food weight. Turning down this plea, FDA said it has found that:

Although a trade association submitted data which they claimed indicates a lack of ability in analyses of paperboard material, the data failed to show that uniform test methods were employed by the participating laboratories or that these tests were performed in laboratories with demonstrated capabilities in trace residue analysis.

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Further, an inter-laboratory 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 PCBs but the fact that PCBs can migrate to the food from the packaging, the use of barriers which can prevent migration is an acceptable alternative to limiting the PCB content of paper food packaging material."

Noting a contention that there is no authority under §406 for setting the temporary tolerance for packaging materials, FDA concluded it is authorized by the section on poisonous and deleterious substances.

FDA rejected a suggestion that the temporary tolerance apply to the packaged food rather than the food-packaging material, saying:

"(1) Since the transfer of PCBs 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 PCBs, but by the time it reaches the consumer and is finally consumed it may have accumulated considerable quantities of PCBs if the packaging material is contaminated. A tolerance system in which the analytical findings are so dependent on many variables such as time of sampling would not be reasonable or adequate;

"(2) In order to achieve 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 PCBs 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 its packaging, in effect, necessitates tolerances 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 §406 ... 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 contains 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 PCBs that may migrate to the packaged food.

"(4) Failure to limit the level of PCBs in food-packaging materials would perpetuate the use of a known, avoidable source of PCB contamination of food."

One comment requested an exemption for Aroclor 1242 on the grounds that it is not persistent and cumulative, and would not present a chronic toxicity problem.

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FDA declined the exemption, saying that, "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 fat of the metabolic products."

The agency said that the absence of Aroclor 1242 residues in human and 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." It added that, "The possibility exists that Arochlor 1242 is converted to alteration products which may be more toxic than the original compounds, but which are not detectable by current analytical methods."

FDA also said that data from chronic rat and dog feeding studies "fail to substantiate claims that Aroclor 1242 does not represent a toxic substance or that it differs in toxicity from the higher Aroclors." The agency concluded that the temporary tolerance should apply to PCBs "irrespective of which Aroclor is present as the contaminant."

A number of firms suggested that the tolerance be 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 in terms of p.p.m. FDA rejected this approach saying that the change would assume "that PCBs 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." The agency said "it is generally recognized that this assumption is not valid."

FDA also said that since "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 PCBs in the packaging material," it would not be "possible to ascertain what portion of the package would be expected to contribute to the PCB contamination of packaged food." Therefore the agency said it must "take into account the paper food-packaging material in its entirety," and that use of p.p.m. is "a practical means to measure the 'average' PCB level in packaging."

Accepting a suggestion that it make known its analytical procedures for PCBs in packaging materials, FDA said it "will provide upon request the analytical methods to be used for enforcing the temporary tolerances for PCBs in paper food-packaging materials and the other articles for which tolerances are established ..." The agency did not include the methodology in the regulations, so it may more easily adopt improved procedures "as they are developed."

Noting comments that the regulation may deter recycling of paper, FDA said the problem arises because "of the inclusion of some types of carbonless copy paper containing 3-5% PCBs into wastepaper stocks used in the manufacture of recycled paper."

FDA said "it will explore with other federal agencies measures for eliminating PCB-containing carbonless copy paper from existing inventories," adding that such action "would reduce the primary source of PCBs found in paper food-packaging ..."

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materials permitting FDA to reduce the temporary tolerance, and eventually to eliminate the need for regulating this unavoidable source of PCBs in food."

In the Supplemental EIS, FDA said it has "contacted the Environmental Protection Agency and requested its assistance in exploring possible procedures" for implementing the EPA's suggestion regarding the carbonless copy paper. EPA had urged FDA action against this product, but FDA responded that it lacks jurisdiction.

In the EIS, FDA said the raising of the tolerance to 10 p.p.m. and the exemption for paper packaging used with barriers would reduce any adverse effects on the paper recycling programs. Also, the agency said "recycling mills are not being placed at a competitive disadvantage," since virgin paper products as well as recycled products have been shown to contain PCBs, and "the entire paper industry will have to bear added costs of implementing quality control procedures."

PCB tolerances for Feed, Feed Components Reduced

FDA reduced the tolerance for PCBs in finished animal feeds from 0.5 p.p.m. to 0.2 p.p.m., and in animal feed components from 5 p.p.m. to 2 p.p.m. The agency said that "available evidence requires and justifies" the reduction of the temporary tolerances.

The agency explained that data from its feeding studies showed that the proposed 0.5 p.p.m. tolerance in feed "is incompatible with the temporary tolerances for poultry." White leghorn hens were exposed to a diet containing 0.5 p.p.m. of PCBs for 8 weeks, and they contained residues in excess of 5 p.p.m. on a fat basis in the muscle, dissectable fat, and liver. At a 0.2 p.p.m. feeding level, the PCB concentration was less than 5 p.p.m.

"Data further indicate that continuous feeding of Aroclor 1254 at 0.5 p.p.m. from day three to day forty-three post initial egg production can result in PCB residues only slightly less than 0.5 p.p.m. in eggs," FDA said.

The agency said that data from its surveillance programs and from industry reports "indicated that PCB levels in finished animal feeds and in animal feed components are generally substantially less than the proposed tolerance limits." An FDA survey of finished animal feeds last year showed that 4.4% of the 1,274 samples contained PCB residues. The highest reported level was 0.6 p.p.m. in feed intended for beef cattle. FDA said the average level for all samples tested was less than 0.1 p.p.m. and the average level of the 56 samples that contained reportable levels of PCBs was less than 0.2 p.p.m. About 1% of the samples exceeded 0.2 p.p.m.

Noting that feed components of animal and marine origin "are expected to contain PCBs as a result of environmental contamination," the agency said that during the past year 32 samples of imported fishmeal were examined, and about 37% contained PCB residues. The highest level reported was 0.47 p.p.m.

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FDA examined 153 domestic fishmeal samples, finding that about 48% contained PCB residues, with the highest level 2.1 p.p.m. and the average less than 1 p.p.m.

An industry survey of PCB levels in rendered animal by-products used for feed ingredients -- hydrolyzed feather meal, meat and bone meal, fats and greases, and poultry by-production meal -- showed the highest PCB level found was 1.6 p.p.m. in fat and greases, FDA said. The average PCB level for the 438 samples tested was less than 1 p.p.m. Other data confirms the results of the 1971 industry survey, the agency said.

Concentrates, Supplements, Premixes Under "Feed Component" Tolerance

One comment, FDA said, urged that the term "finished animal feed" be changed to "complete animal feed," since some finished feeds are further mixed with ingredients of plant origin before feeding. FDA retained the term "finished animal feed," but clarified the regulation to make this temporary tolerance "applicable to finished animal feeds, except feed concentrates, supplements, and premixes."

The agency explained that "certain finished animal feeds, such as feed concentrates, premixes, and supplements often contain high levels of PCBs because they consist of a high percentage of animal-derived ingredients," but added that at time of use these are mixed with plant-derived ingredients which are not expected to contain PCBs. Therefore, FDA said, "the final ration for the animal would not contain excessive levels of PCBs."

FDA rejected a suggestion that a tolerance of 1.0 p.p.m. be set for feed components which are not of animal or marine origin, saying "there is no need at this time to establish a separate tolerance," since "there has been no reported finding of PCBs(other than that which may be due to avoidable contamination during processing, handling or storage) in animal feed components such as grains and by-products of grains..."

In response to a suggestion that the term "animal feed components" be made to include "fishmeal and concentrates, premixes, and supplements," FDA amended the temporary tolerance to make it apply to "animal feed components of animal origin (including fishmeal and other marine by-products) and animal feed concentrates, premixes and supplements."

Proposed Tolerance for PCBs in Pet Food Deleted

FDA made it clear that the temporary tolerance for animal feed does not apply to pet food, and at the same time declined to establish a suggested 5 p.p.m. tolerance for residues in pet food. The agency said that "studies will be initiated to obtain ... information and, if warranted, FDA will issue a proposal to limit the level of PCBs in this category of finished animal feed." The tolerance for feed was amended so that it applies only to food-producing animals.

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Therefore, there is no PCB tolerance for pet food. In discussions with the paper industry, FDA-ers have insisted that if there were no tolerance for PCBs in food-packaging paper, there would be an automatic "zero tolerance." However, the lack of a tolerance for PCBs in pet food obviously is not being interpreted in that way.

FDA said its original proposal for a tolerance in animal feed was directed toward food-producing animals, and that "some pets may be able to safely consume levels of PCBs higher than 0.5 p.p.m." The agency added, however, that "on the basis of available toxicological information, there is insufficient data for FDA to establish a tolerance for PCBs in feed for all types of pets and for other non-food producing animals."

Tolerance for Infant and Junior Foods Revised

The agency changed from 0.1 p.p.m. to 0.2 p.p.m. the temporary tolerance for PCBs in infant and junior foods. Noting a comment that the 0.1 p.p.m. level "cannot be achieved because of trace quantities of PCBs in certain foods and in paper food-packaging materials," FDA concurred "because information indicates that this level of PCBs cannot be avoided and that current analytical methodology is insufficient to enforce a tolerance of 0.1 p.p.m."

Explaining the need for the separate tolerance for infant and junior foods, FDA said, "Infants and young children consume a greater amount of food per kilogram of body weight and thereby have a proportionately greater exposure than do adults." It added "that undesirable exposures could result if combinations of certain PCB-contaminated foods comprise a major portion of this age group's diet."

The 5 p.p.m. tolerance for fish was amended to also include shellfish. Noting that there was a suggestion that a tolerance be set for shellfish, FDA agreed and said that: "shellfish also have been found to contain PCBs as a result of unavoidable, environmental contamination..."

FDA rejected a suggestion that its "action level" for PCBs in poultry of 5 p.p.m. in the edible tissues be retained. The agency made the temporary tolerance 5 p.p.m. (fat basis).

Noting there has been PCB contamination of poultry at levels in excess of the temporary tolerance because of use of feed contaminated with PCBs as a result of industrial accidents, FDA said "there is no justification for establishing a tolerance level that accounts for avoidable sources of contamination." The 5 p.p.m. tolerance on a fat basis "takes into account that this level of PCB is generally unavoidable because some poultry feeds contain unavoidable PCB residues that will transfer to and concentrate in the fat of poultry," the agency added.

Declining to change the "fat basis" tolerance for an "as is" basis tolerance, FDA said "that although the dietary intake of PCBs resulting from contaminated poultry was considered on an 'as is' basis (whole tissue) in the development of the temporary tolerance level, expressing the temporary tolerance on a fat basis is preferred since PCBs are fat soluble and fat derived from poultry can be used as a separate food

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(e.g., soups, gravies, etc.)." The fat basis tolerance, the agency said, assures that "poultry contains acceptable levels of PCBs, irrespective of whether the whole tissue is consumed or the fat is consumed as a separate food."

FDA Retains "Fat Basis" Tolerance For Milk

Discussing the 2.5 p.p.m. tolerance for milk and dairy products, FDA rejected a suggestion that the temporary tolerance be raised to the 5 p.p.m. existing "action level." The agency said the 2.5 p.p.m. tolerance on a fat basis "takes into account current toxicological data and the level of PCB residues that is currently considered unavoidable." A recent FDA survey showed only one sample of milk out of 520 tested contained more than 2.5 p.p.m. PCB in the fat, the agency said, adding: "Evidence also indicates that higher levels may be generally attributed to avoidable sources of contamination, such as the use of PCB coatings in dairy farm silos..."

Rejecting a suggestion that the PCB tolerance be expressed on an "as is basis," FDA said "butterfat is generally considered the most valuable constituent of milk," and that "PCBs are fat soluble, and in the manufacture of various dairy products from milk, remain at a nearly constant concentration in the fat." The "fat basis" tolerance, the agency continued, is "necessary to govern the level of PCBs in such products in preparing some other type of food," noting that butter made from milk containing levels of PCBs below tolerance would also be acceptable.

FDA said the "temporary tolerances will be lowered as experience indicates that lower levels can be attained." The agency stressed that "the temporary tolerances are not to be construed as 'guidelines' permitting the consumption of foods containing these amounts of PCBs on a regular and consistent basis."

In the Federal Register preamble, FDA described the test data on PCBs, and concluded that for the short term, based on the lowest total dose producing an effect and estimated biological half-life of PCBs, current levels of PCBs in the diet represent no immediate hazard."

Even in the Japanese incident where there was toxicity and illness, FDA said it was the "long-term exposure" rather than the "average total dose" that caused the problem. 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 PCBs in food as soon as possible," FDA said.

"In the interim, temporary tolerances are necessary to limit human exposure to those foods that may contain PCBs resulting from environmental contamination, which as a practical matter are presently unavoidable," the agency continued.

Long-term animal studies show that the no-effect level in rats and dogs is 10 p.p.m., FDA said, using a 100-to-1 safety factor to set a no-effect level for man. FDA said that, 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."

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Discussing the Japanese incident, which affected about 1,000 people after a heat exchanger leaked PCB fluid into rice oil, FDA said exposure levels to the oil averaged about 15,000 mg per day. The oil was reportedly contaminated at a level of 2,000 p.p.m. Japanese data indicated 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."

Applying a 10-to-1 safety ratio "to go from an effect level in man to a permissible no-effect level in man" results in a 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, FDA said The agency added:

> "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 dosage PCBs (applying a safety factor of 10-to-1...) may be tolerated over a much more protracted period of time without overt adverse effect if daily exposure is held to minimal levels. It would take 22 months of daily ingestion of 300 mcg of PCBs to arrive at a total ingestion 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."

FDA said its total diet studies for fiscal years 1970-1972 showed PCB residues are equivalent to an intake of approximately 0.06 mcg/kg/body weight/day, or 4.2 mcg/day for a 70 kg man. If lower levels had been able to be measured, the agency added, the dietary intake would probably have been larger. FDA added:

> "It should be recognized, however, that in rare instances some people could have more systematic exposures to PCBs 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 exposure.
>
> "The total diet studies indicate that PCBs 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 PCBs also occur in dairy products, eggs, and packaged foods, in addition to packaged cereal products."

FDA rejected proposals in comments that (1) PCB tolerances for food should be lowered by a factor of 5-19, and (2) "that the temporary tolerances should be based on toxicological data which would allow a level that is deemed safe rather than a level that can be reasonably achieved."

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§406 provides for temporary tolerances where a poisonous or deleterious substances cannot be avoided, and "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,'" FDA said. It added that, "The fact that the tolerances are termed 'temporary' is 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 agency also rejected a recommendation that there be a zero tolerance for PCBs in food and feed. FDA noted that PCBs are now unavoidable, that the "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 PCBs is usually sporadic, non-systematic, and occasional."

The temporary tolerances, FDA said, will assure that "human exposure to PCBs from dietary sources will be maintained at safe and minimal levels." The agency added that zero tolerances "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."

As proposed, the Food Additive Order for pulp from reclaimed fiber was amended to bar use of poisonous and deleterious substances, but FDA added to §121 2546 the phrase "except as provided in regulations promulgated under §406 and §409 of the ... Act." FDA said the amendment was needed for "clarification" 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 proved to be safe in food-packaging materials."

The agency declined to accept a suggestion that tolerances be set for poisonous and deleterious substances in packaged food products under §121.2546. FDA said the Order is designed 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."

Electrical Capacitors and Transformers Exempted

FDA exempted from its PCB regulations "the safe use of PCBs in electrical capacitors and transformers." A comment argued that these should be exempt from the requirement that equipment in establishments engaged in processing of feed, food or packaging materials must not contain PCBs, "since no known substitute is available which offers the proper balance or characteristics (e.g., fire safety and design efficiency)."

It was noted 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.

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In discussing replacements for PCBs, FDA deleted from the regulation a bar against use of "harmful or deleterious" materials. A comment had noted that most industrial chemicals can be interpreted to be "harmful or deleterious." FDA spelled out criteria for replacements, as follows:

> "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 non-hazardous is to be made on an individual installation and operational basis."

A portion of the Supplemental EIS was devoted to the problem of replacements for PCBs. FDA said, in part:

> "Industry should be more cognizant of the serious repercussions that can result from the indiscriminate use of toxic chemicals and from accidents of this type, such as adverse effects on human health and the environment, adverse publicity, criminal and civil penalties, and substantial financial losses. In addition to these considerations, there is information which indicates that less toxic, biodegradable PCB replacements have been developed and are being used for heat transfer systems and other industrial applications that have caused past environmental problems.
>
> "... FDA can only speculate that some PCB replacements or substitutes may present future environmental problems. However, it is known with certainty that the continued use of PCBs by the regulated industries presents a definite hazard to man and his environment. Therefore, FDA's action to restrict the use of this contaminant in feed, food, and food-packaging manufacturing establishments is clearly more beneficial to the quality of the human environment than allowing the continued use of PCBs."

One comment urged FDA to clarify the term PCBs to distinguish between PCB compounds of different chemical composition. The agency agreed that this clarification is needed in its analytical methodology, but disagreed "that the tolerances for PCBs should distinguish between PCB compounds of different chemical composition..." FDA said "toxicological data do not support the need to establish separate tolerances for each Aroclor," and that "the temporary tolerances will apply to the term 'PCB' irrespective of which Aroclor or mixture of Aroclor is present as the contaminant."

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There was a suggestion that FDA "initiate studies for the purpose of establishing a finite allowable residual level," noting that even when PCB heat exchange fluids are replaced, some level of PCB residue is likely to remain in certain equipment. FDA said some residue is possible, but that "if the change is made in a reasonable manner and in good faith there should not be significant concentrations of PCB remaining."

Additional data would be needed to set specific limits for PCB concentration in equipment fluids, FDA said, adding that "no reason exists for FDA to initiate studies to determine the extent of residual levels of PCBs in heat exchangers or to specify by regulations finite tolerances for such residual material at this time."

FDA also turned down a recommendation for issuing warnings to pregnant women who breast feed their babies to restrict their intake of fish to species that have been monitored and found to be uniformly within the temporary tolerance for PCBs. Concluding that "such a warning is not warranted," FDA said that "on the basis of available but limited monitoring data, most of which is unpublished, it appears that PCB levels in human milk would generally be less than approximately 0.05 p.p.m. (whole product basis)."

Toxicological data, including that from multigeneration reproduction tests in rats, indicate that this level "presents no immediate hazard to infants," FDA said. It also noted that 0.05 p.p.m. "is substantially less than the level of PCBs FDA will permit in the milk of dairy cows," which equals 0.1 p.p.m. on a whole product basis.

The Supplemental EIS responded to comments filed on the Draft EIS by the Agriculture Department, EPA, the Commerce Department, and the American Paper Institute. FDA had been urged to consider the economic issues involved. The agency said in the Supplemental EIS that "although not explicitly stated," it "conducted a form of a cost/benefit analysis" and concluded "that the health benefits derived outweigh any adverse economic consequences that may result."

The finalized regulations consist of: (1) §3.93, a statement of general policy or interpretation on use of PCBs in establishments manufacturing food-packaging materials. (2) The revision of the §121.2546 Food Additive Order for pulp from reclaimed fiber: (3) A new Part 122 of the regulations on unavoidable contaminants in food and food-packaging material, in which the temporary tolerances were established; (4) A revision of the equipment and utensils portion of the §128 umbrella Good Manufacturing Practice regulations for food to rule out use of PCBs; and (5) A new §135.113 New Animal Drug regulation barring use of PCBs in plants.

Temporary Tolerances for PCBs Established under new §122

The §122 temporary tolerances are: (1) 2.5 p.p.m. in milk (fat basis); (2) 2.5 p.p.m. in manufactured dairy products (fat basis); (3) 5 p.p.m. in poultry (fat basis); (4) 0.5 p.p.m. in eggs; (5) 0.2 p.p.m. in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes); or (6) 2 p.p.m. in animal feed components of animal origin for food-producing animals, including fishmeal and other by-products of marine origin and in finished animal feed

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concentrates, supplements, and premixes; (7) 5 p.p.m. in fish and shellfish (edible portion); (8) 0.2 p.p.m. in infant and junior foods; and (9) 10 p.p.m. in paper food-packaging material, except for that separated from the food by a functional barrier which is impermeable to migration of PCBs.

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USDA PLANS TO REVISE MEAT PATTIES PROPOSAL

The Agriculture Department is planning to revise the proposed standard for "meat patties," "patties with meat," and "meat patty mix" (See FOOD CHEMICAL NEWS, July 2, Page 6).

The Department's revisions may require issuance of a new proposal before publication of a final order. Changes are likely to include new names and different product categories, and provision for protein efficiency ratio (PER) values to be determined by extender suppliers. The proposal's PER testing requirement drew numerous objections from patty makers who complained about the expense of PER analysis.

Processors' comments continued to urge USDA to: (1) Establish product categories, similar to the approach followed in the hot dog order; (2) Drop the PER testing requirement, or impose it on extender suppliers; and (3) Eliminate the proposal's provision for percentage ingredient labeling.

Swift and Company suggested Agriculture adopt three product categories:

(1) Hamburger, ground beef, chopped beef, consisting of meat, seasoning, with a 30% maximum fat content; (2) Meat patties or, meat patty mixes, containing 60% meat with the 30% fat maximum, 13.5% minimum protein and a PER not less than 90% of that for hamburger or chopped beef; (3) Patties and patty mixes made with meat, poultry products, meat by-products, binders, extenders or added water, seasonings.

The firm said it was against percentage ingredient labeling because a need for this disclosure had not been demonstrated. "As long as products are formulated to USDA specifications under USDA supervision, there is no need for such percentage ingredient labeling," Swift asserted.

Ranch Hand Foods, Inc. offered a suggestion for two categories of patties made with extenders:

(1) Meat patties or meat patty mixes having a minimum of 13.5% protein and containing added poultry, meat by-products, binders or extenders with a minimum PER of 1.8 compared to casein at 2.5 as determined by the AOAC method, "Biological Evaluation of Protein Quality;" and (2) Patties with meat or patty mixes with meat having a 13.5% protein minimum.

These patties would be made from a raw mix consisting of chopped meats, either fresh or frozen or both, combined with binders, extenders, poultry by-products, meat by-products, or added water, or fat, or any combination thereof, and optional seasonings. The percentage of meat would be shown in the ingredient statement on the label.

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PART II



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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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 DIPHENYLS (PCB's)

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

In the FEDERAL REGISTER of March 18, 1972 (37 FR 5,33[illegible] 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 [illegible] chemicals can be interpreted [illegible] "poisonous or deleterious", [illegible] should be deleted as a criterion. The Commissioner [illegible] and thus the phrase [illegible]. The toxicity [illegible] of fluids selected [illegible] replacements must be [illegible] so that the least [illegible] enforcement is [illegible] consideration with [illegible] such limit, consideration [illegible] its toxicity; (2) [illegible] quantity of food [illegible] ingested, (3) [illegible] 123 provide [illegible] and (4) its [illegible] and tolerance to [illegible] threat to the [illegible]. The final point as to whether [illegible] should be established by non-[illegible] is to be made on an individual [illegible] consideration basis [illegible] the agency [illegible] has been made in § 135.113(b)(3) [illegible] (b)(2)(i), § 3.93(b)(2) [illegible] (b)(2)(i), and § 128.4(b)(2) [illegible] § 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 future 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 reasonable 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 prescribe by regulations finite tolerances for such residual material at this time.

2. *Section 121.2516.* The notice included a supplement 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 reasonably 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 materials. 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, [illegible] and [illegible] packaging used for food would be [illegible].

b. [illegible] comment group [illegible] comments [illegible] PCB [illegible] for [illegible] foods by a factor [illegible] [illegible] [illegible]

the tolerances are termed "temporary" is 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 2.5 micrograms (mcg) PCB's per kg body weight/day based on rat data, or 3 mcg/kg body weight/day from dog data. 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 toxication 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 hyperplasia of the Meibomian glands, and female 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 receded as the children grew in size, though 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 man, probably involving a long biological half-life. Exposure levels to the toxic material is approximate, on average, to 1.5 mg per day. The oil was experimentally contaminated at a level of about 2,000 ppm. This level was chosen as the known organic chlorine level of the oil related to the known organic chlorine content of Kanechlor 400. The average total dose of PCB's ingested in the Japanese was estimated to be 2,000 mg. The human data published by Kuratsune, et al., Fukuoka Acta Medica, 62:117 (1971) established the lowest level of PCB that produced an effect in man using a 50 kg [illegible] consumed over a period [illegible] of approximately [illegible] body weight/day. [illegible] was based on overt [illegible] than chloracne. Moreover, it has been demonstrated that even lower levels, [illegible] to 1 or 10 to 1 to [illegible] level in man to allow an [illegible] of 25 mcg/kg body weight/day for a 70 kg [illegible] a total period of exposure of 5 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 dosage 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 effect 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 ingestion 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 considers 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. The [illegible] true for the average total dietary exposure to the Japanese for [illegible] exposure. However, based on the most sensitive "Japanese patient" [illegible] producing an effect, [illegible] of potential long-term hazards [illegible] reduction of PCB levels in food as soon as [illegible] 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 presently unavoidable. These foods, for which temporary tolerances are being established, include milk and dairy products, poultry, eggs, fish, and infant and junior food. Infants and young children consume a greater amount of food per kilogram of body weight and thereby have a proportionately greater exposure than do adults. A separate temporary tolerance for infant and junior food, therefore, reflects the possibility that undesirable exposures could result if combinations of certain PCB-contaminated foods comprise a major portion of this age group's diet. In order to minimize the overall dietary intake of PCB's, individual sources of PCB contamination must also be appropriately minimized. PCB's have been shown to occur in processed food 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 [illegible]. The Commissioner concludes that [illegible] warnings is not warranted. On the basis of [illegible] and limited available data [illegible] much as [illegible] it appears that PCB levels in human milk are [illegible] be less than approximately 0.05 ppm (whole product basis). At levels of available tolerance monitoring [illegible] studies do not indicate [illegible] pre-existing [illegible] immediate hazard to [illegible] health, at the level of PCB's FDA [illegible] in the milk of dairy cows. The temporary tolerance being established for milk is 2.5 ppm fat basis, which [illegible]

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quivalent to 0.1 ppm (whole product da). Therefore, a public warning as ommended is not supported by the entific facts available at this time.

1. One comment recommends clarifi- tion of the term "PCB's" so as to tinguish between PCB-compounds of ferent chemical composition. The is for this comment is the fact that B's are mixtures of chlorinated bi- enyl compounds. Each component of PCB mixture is a specific chemical mpound having the basic biphenyl ucture and one to ten chlorine atoms. ere are 209 different chlorinated bi- enyl compounds which component of nufactures and sold in the United ates under the registered trade name of oclor, followed by a four digit number g., 1242; 1254; 1260; etc.). The term oclor signifies that the product con- sts of chlorinated biphenyls, chlori- ated terphenyls, or a mixture of these mpounds. The first two digits of the umerical part of the trade name indi- te the molecular type (1200 signifies lorinated biphenyl), while the last two gits give the weight percent of chlorine (2 signifies 42 percent chlorine). Since e physical and chemical properties of ch Aroclor vary, the analytical be- avior of each Aroclor will also vary. For CB residue analysis, it is customary to termine the amount of PCB residue und by comparing the residue to a nown quantity of the Aroclor it most early matches when separated into multicomponents on a gas chromato- raph. Therefore, the Commissioner grees that clarification of the term PCB" is necessary for the analysis of od, animal feed and paper food-pack- ging materials for PCB residues. The ompilation of FDA analytical methods o be used for enforcing the PCB toler- nce that is available upon request con- ains instructions regarding this aspect f the tetrachloride extraction. The Commissioner does not agree, however, that the clearances for PCB's should distinguish etween PCB-compounds of different hemical composition because toxicologi- l data do not support the need to stablish separate tolerances for each Aroclor. Therefore, the temporary toler- nces will apply to the term "PCB" ir- espective of which Aroclor or mixture of Aroclor is present as the contaminant.

4. *Section 122.10(a)(1) and (2).* The notice included the proposal to establish a temporary tolerance for PCB's in milk and dairy products at 2.5 ppm (fat basis).

a. One comment recommends that there FDA's previous action level for PCB's in milk and dairy products, which was set at 5 ppm (fat basis), was stated to be adequate for protecting public health, the temporary tolerance for milk and dairy products should be kept at the same level. The Commissioner concludes that there is no justification for lowering the PCB tolerance until additional data and/or level of PCB's which is presently considered unavoidable. A recent FDA survey revealed that only one sample of milk in 520 tested contained more than 2.5 ppm PCB in the fat, i.e., 0.2 percent of the total samples. Evidence also indicates that higher levels may be generally attributed to avoidable sources of contamination, such as the use of PCB coatings in dairy farm silos which caused PCB contamination of silage for dairy cows with subsequent transmission of PCB's to the milk of these cows.

b. One comment recommends the PCB tolerance be expressed on an "as is" basis because the fat content of dairy products varies and these foods are consumed "as is". The Commissioner rejects this recommendation. The butterfat is generally considered the most valuable constituent of milk. PCB's are fat soluble, and in the manufacture of various dairy products from milk, remain at a nearly constant concentration in the fat. The fat basis tolerance is therefore necessary to govern the level of PCB's in such products in preparing some other type of food. For example, butter (about 80 percent fat) made from milk containing levels of PCB's below tolerance would also be acceptable since the PCB concentration in the fat would be unchanged.

5. *Section 122.10(a)(3).* The notice included a proposal to establish a temporary tolerance for PCB's in poultry at 5.0 ppm (fat basis).

a. One comment recommends that since FDA's previous action level for PCB's in poultry, which was set at 5 ppm on the edible tissue, was stated as adequate for protecting public health, the temporary tolerance should be kept at that same level. The Commissioner rejects this recommendation. PCB contamination of poultry at levels in excess of the temporary tolerance being established has been attributed to the use of animal feed contaminated with PCB's as a result of industrial accidents, e.g., leakage of PCB's onto feed components. The Commissioner concludes that there is no justification for establishing a tolerance level that accounts for avoidable sources of contamination. The temporary tolerance of 5 ppm (fat basis) takes into account that this level of PCB is generally unavoidable because some poultry feeds contain unavoidable PCB residues that will transfer to and concentrate in the fat of poultry. Furthermore, current toxicological data supports this tolerance level.

b. One comment recommends that the tolerance for poultry be expressed on an "as is basis" since this would more closely relate to the total PCB intake from this food than would a tolerance established for poultry on a "fat basis". In response, the Commissioner finds that although the dietary intake of PCB's residues from contaminated poultry was considered on an "as is" basis (whole product) in the development of the temporary tolerance level, experience in the determination of tolerances on a fat basis for pesticide residues PCB's are fat soluble and fat tissue of fowl can be used as a separate food (e.g., livers, gizzards, etc.). The fat basis tolerance, therefore, provides the assurance that poultry contains acceptable levels of PCB's, irrespective of whether the whole tissue is consumed or the fat is consumed as a separate food.

6. *Section 122.10(a)(5) and (6).* The notice included the proposal to establish temporary tolerances for PCB's in finished animal feeds at 0.5 ppm and animal feed components (including fishmeal) at 5 ppm.

a. One comment recommends that the term "finished animal feed" be changed to "complete animal feed" since some finished feeds are further mixed with grains, by-products of grain, and other feed ingredients of plant origin before feeding. The Commissioner agrees that certain finished animal feeds, such as feed concentrates, premixes, and supplements, often contain high levels of PCB's because they consist of a high percentage of animal-derived ingredients. At time of use, however, these articles are mixed with plant-derived ingredients which are not expected to contain PCB's. Thus, the final ration for the animal would not contain excessive levels of PCB's. The Commissioner concludes that for purposes of the PCB tolerance for animal feeds, clarification of the term "finished animal feed" is needed rather than a change in terminology. Therefore, the order is amended in § 122.10(a)(5) (21 CFR 122.10) so that the temporary tolerance for PCB's is applicable to finished animal feeds, except feed concentrates, supplements, and premixes.

b. One comment recommends a PCB tolerance of 1.0 ppm be established for animal feed components which are not of animal or marine origin. Since there has been no reported finding of PCB's (other than that which may be due to avoidable contamination during processing, handling, or storage) in animal feed components such as grains and by-products of grains, the Commissioner concludes there is no need at this time to establish a separate tolerance for PCB's in this category of animal feed component.

c. One comment recommends that the term "animal feed components" be qualified by the expression "including fishmeal and concentrates, premixes, and supplements". The Commissioner agrees with this recommendation and the order is amended in § 122.10(a)(6) so that the temporary tolerance for PCB's is applicable to animal feed components of animal origin including fishmeal and other marine by-products and animal feed concentrates, premixes and supplements.

d. The Commissioner finds that although there was no comment to oppose the proposed tolerance level of 0.5 ppm for finished animal feeds and 5.0 ppm for animal feed components, current information indicates a lowering of the tolerance levels is warranted for the following reasons:

(1) Data from FDA conducted feeding studies show that the proposed temporary tolerance 0.5 ppm for finished animal feeds is incompatible with the temporary tolerances for poultry. White Leghorn hens exposed to a diet containing 0.5 ppm PCB's (Aroclor 1254) for 8 weeks

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contained residues in excess of 5 ppm (fat basis) in the muscle (breast and thigh), discernible fat, and liver of these animals. At a 0.2 ppm feeding level, the concentration of the PCB tissue residues in poultry was less than 5 ppm (fat basis). Data further indicate that continuous feeding of Aroclor 1254 at 0.6 ppm from day three to day forty-three of initial egg production can result in PCB residues only slightly less than 0.5 ppm in the eggs.

c. Data from FDA surveillance programs and from industry reports indicate that PCB levels in finished animal feeds and in animal feed components are generally less than the proposed tolerance. In addition, the Food and Drug Administration conducted a survey of finished animal feeds for PCB's. The survey consisted of 274 samples of formulations representing [illegible] of animal feeds. The results showed that 44 percent of the samples contained PCB residues. The highest reported level was 9.6 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. Animal feed components 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 0.47 ppm. In addition, 53 fishmeal samples of domestic origin were examined during this period. The results show that about 43 percent of the samples contained PCB residues. The highest level reported was 2.1 ppm and no level was less than 1 ppm. (c) In the fall of 1971, Fido Dry conducted a survey of the PCB level 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 288 samples tested, the highest level of PCB found was 0.6 ppm in fat and grease. The average PCB level for the samples tested was less than 1 ppm. Other data submitted by [illegible] received on the level of PCB's in rendered animal products [illegible] primarily concerns the results of [illegible]. However, in the [illegible] the Commissioner concludes that available evidence continues [illegible] PCB [illegible] animal feed components. The order is thus amended in § 122.10(a)(5) and (6) to establish temporary tolerances for PCB's in [illegible] at 0.2 ppm and in animal fat [illegible] at 2 ppm.

e. One comment recommends that a tolerance of 5 ppm be established for PCB's in [illegible] the Commissioner [illegible] The proposal to establish a tolerance for animal feeds 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)(6) 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 since 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 to establish a tolerance under Section 406 of the Federal Food, Drug, and Cosmetic Act for the articles. Therefore, the wording of § 122.10(a)(9) is revised to apply only to paper food-packaging materials. This exemption includes all PCB's which [illegible] paper and [illegible] paper-board, [illegible] paper food-packaging materials. For reasons 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 concludes that the establishment of temporary tolerances for PCB's in food-packaging materials is consistent with the law and the intent and purpose of Sections 406(a), 406(b)(2)(A), and 406 of the Federal Food, Drug, and Cosmetic Act.

c. One comment recommends that a 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 achieve 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 the 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 primary source of the PCB contamination in packaged food is the paper food-packaging material, which contains the unavoidable contamination. As such, the tolerance should deal with this material. Therefore, the source of food contamination should be limited so as to minimize the levels of PCB's that migrate to the packaged food. (4) Exclusive to limit the level of PCB's in food-packaging materials would jeopardize the use of a known, safe, and useful source of PCB contamination of food.

d. One comment received from industry and food related trade associations recommended that the temporary tolerance for PCB's in food-packaging materials (molded articles or packaged materials) [illegible] quantitative test procedures and adequate analytical methods are developed for [illegible] production and future compli-

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(2) migration rates are established ; take into account barrier effects, type f food, and package weight to food eight ratio. In response, the Commissioner finds that: (1) Although a trade association submitted data which they aimed indicates a lack of reliability in nalyses of paperboard material, the ata failed to show that uniform test ethods were employed by the particiating laboratories or that these tests ere performed by laboratories with emonstrated capabilities in trace re due analysis. Further, an interlaboratory study conducted under the auses of another trade association using DA analytical methodology, supports ie conclusion that current methodology adequately sensitive and reproducible om laboratory to laboratory in order o insure compliance with the tolerance. 2) It is recognized that migration rates actual level of PCB in food resulting rom the use of contaminated packagng are affected by factors such as barriers, type of food, package weight to ood weight ratio, and time and conditions of exposure. Since FDA's primary oncern is not the fact that paper foodackaging materials contain PCB's, but ie fact that PCB's can migrate to the ood from the packaging, the use of barers which prevent migration is an acceptable alternative to limiting the PCB ontent of paper food-packaging materil. For this reason, the final order is mended in § 122.10(a)(9) to exempt aper food-packaging materials from ompliance with the temporary tolerance the paper food-packaging material is eparated from the food by a functional arrier impermeable to PCB migration. etal cans and glass bottles are obvious xamples of what constitutes a functional barrier impermeable to PCB migration. Data from industry sponsored tudies have shown that materials such s polyvinylidene coated paper and glass an can, to varying degrees, prevent or educe PCB migration under test conditions which would favor migration. FDA ould not object to the use of flexible aterials and other materials as barers provided there is no evidence of igration of PCB's to the food. At this me however, there is insufficient inormation for FDA to list as part of the egulation those materials that are considered functional barriers. The other actors mentioned above which affect igration rates may also be important onsiderations and should be thoroughly valuated. In the interim, the temporary olerance for paper food-packaging aterials and the exemption to this olerance are considered necessary to assure the consumer that packaged foods will not be contaminated with CB's to an undue degree.

6. One comment states that the establishment of temporary tolerance for PCB in paper food-packaging materials is unwarranted for public health reasons because substantial scientific evidence shows that Aroclor 1242 contaminant PCB absorption is not permanent and cumulative, and thus will not present a human toxicity problem. Although data indicate 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 absence 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 tem "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 this recommendation and FDA will provide upon request the analytical methods to be used for enforcing the temporary tolerance 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 easier 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 thus 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 3–5 percent PCB's into wastepaper 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 exempting 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 its 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 dogs and beef [illegible] showed that the food portion of samples with 6–10 ppm in paper food-packaging contained the estimated PCB level of 0.1–0.6 ppm in the food portion of the samples with 3–5 ppm in paper packaging. Samples with more than 10 ppm in the paper packaging contained higher levels in the food, but not over 1.7 ppm. The Commissioner concluded that this was the only acceptable alternative available and stated in the Final Environmental Impact Statement that the temporary tolerance for PCB's in paper

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polychlorinated biphenyl materials would be changed to 10 ppm. (This order amends § 180.1021 (b) to reflect this change.)

Data worked up by industry shows that levels of PCB's in paper food-packaging materials have diminished during the past year to the point that 95 percent or more of this material will contain 10 ppm or less PCB's. It appears that the level of PCB contamination will be further reduced by a time limitation that will protect the public while encouraging the industry to complete its program for removing PCB's presently in the environment. In view of the Food Division's statement that it will explore with industry groups methods for controlling PCB-containing packaging materials from existing inventories, if possible, this action would [illegible] of PCB's found in packaging materials pending the temporary tolerance and eventually to eliminate the need for retaining this unavoidable source of PCB's in food.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1048, 1055–1056 as amended; 70 Stat. 919 and 72 Stat. 948, 76 Stat. 1264–1265 as amended; 21 U.S.C. 342, 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) [illegible] a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanechlor (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 [illegible] for heat and electric insulating fluids, hydraulic fluids, [illegible] and flame retardants. They have also been used in [illegible] and other coatings, and have found [illegible] in carbonless copy paper. In addition, methods have been found in which PCB's have unwittingly contaminated [illegible] PCB's [illegible] industrial chemicals, [illegible] PCB's have been found in [illegible] materials. Reclaimed fibers containing carbonless copy paper contains 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 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 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 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 examined so that the least [illegible] replacement fluid [illegible] this degree of reduction with [illegible] fluid, consideration should be given to [illegible] the [illegible] that could be spilled into a given quantity of [illegible] before it would [illegible] falling into [illegible] as odor [illegible] possible excessive [illegible] to indicate a loss [illegible] and (b) its origin and [illegible] and technology to service and [illegible] in the food chain. The [illegible] to another [illegible] to readily identify non-[illegible] to be made on raw materials [illegible] and operation books.

(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:

§ 121.2516 Pulp from reclaimed fibers.

(b) [illegible]

(1) Industrial waste from the manufacture of paper and paperboard products, excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided 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 bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided 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, 1048, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948, 76 Stat. 1264–1265 as amended; 21 U.S.C. 342, 346, 348, 371.

Subpart A—Definitions and Procedural and Interpretive Regulations

§ 122.1 Definitions and interpretations.

(a) The definitions and [illegible] of terms contained in [illegible] Federal Food, Drug, and [illegible] shall be applicable to such [illegible] in this part.

(b) Unavoidable natural, environmental, or processing contaminants [illegible] which cannot be avoided by [illegible] practices.

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. Because of their widespread, uncontrolled industrial application, PCB's have become persistent and ubiquitous contaminants

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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 animal 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 fish meal and other by-products of marine origin, in feed in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 6 parts per million in fish and shellfish (edible portion). The edible portion of fish does not include head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and [illegible]

(9) [illegible] million in paper food-[illegible] intended for or used [illegible] animal feed [illegible] intended for animal [illegible] that do not comply to [illegible] [illegible] to migrate [illegible] PCB's. [illegible] Department of Health, Education, and Welfare, Room 6-[illegible], Parklawn Building, 5600 [illegible].

PART [illegible] ENVIRONMENTAL CONTROL [illegible] PCB's [illegible] PROCESS [illegible] PCB's IN FOOD [illegible]

4. In [illegible] by adding § 120.4 to read as follows:

§ 120.4 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: Arocior (United States); Phenoclor (France); Colphen (Germany); and Kanneclor (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 [illegible] equipment or machinery for heating or reheating food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's [illegible] [illegible] [illegible]

residues in the milk of dairy cows consuming the contaminated silage. 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 cooking 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 food manufacturing practices from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such materials could cause 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 6-88, 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 grounds 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 seizure 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. 1040 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948, 72 Stat. 1785-1788 as amended; 21 U.S.C. 342(a), 346, 348, 371)

Dated: June 21, 1973.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.73-13540 Filed 7-5-73;8:45 am]

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ARTMENT OF HEALTH, UCATION, 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 28201) 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 6-86, 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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graph (a)(2) of this section and such other pertinent information as may be available, that:

(i) Existing facilities, qualified staff, and other resources available to the applicant during the fiscal year in question, either directly or through affiliation agreements and contractual arrangements, are adequate and appropriate for assisting the Federal Government in such drug abuse treatment and rehabilitation programs as may be available for persons who are in the catchment area, or that the applicant has reasonable prospects for obtaining, during the fiscal year in question, such additional resources as may be necessary for the provision of such assistance; and

(ii) Utilization of the applicant's existing or anticipated resources for assisting the Federal Government in such drug abuse treatment and rehabilitation programs as may be available for residents of the area would not necessitate curtailment of drug abuse treatment and rehabilitation services provided or to be provided directly by the applicant or curtailment of other mental health services provided or to be provided by the applicant.

(3) *Assurance.* Upon a determination that it is feasible for the applicant to assist the Federal Government in treatment and rehabilitation programs for drug addicts and other persons with drug abuse and other drug dependence problems in accordance with paragraph (c)(2) of this section the Secretary shall provide a written notification to the applicant which shall briefly state the basis for the Secretary's determination. The notification will be accompanied by a form for providing the required assurance. The applicant shall promptly execute the assurance and return it to the Secretary. The assurance imposes a continuing obligation upon the applicant not to refuse a request from an agency or department of the Federal Government to enter into an agreement under which the applicant's facilities may be used, to the maximum extent practicable, in drug abuse treatment and rehabilitation programs provided by such departments or agencies for persons who are in the catchment area served by the applicant.

Provided, however, That the Secretary may, upon a written request from the applicant which shall be supported by pertinent information, determine that it is not feasible for the applicant to comply with its assurance in a particular fiscal year or that it is not practicable for the applicant to enter into a specific agreement which has been proposed by a department or agency of the Federal Government.

[FR Doc.73-13779 Filed 7-5-73;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 129]

WATER POLLUTION PREVENTION AND CONTROL

Proposed List of Toxic Pollutants

Notice is hereby given that the Acting Administrator, Environmental Protection Agency, proposes to establish a list of toxic pollutants in accordance with section 307(a)(1) of the Federal Water Pollution Control Act, as amended, (33 U.S.C.A. section 1317(a)) (Supp. 1973), (the Act) which provides in part:

> The Administrator shall, within ninety days after the date of enactment of this title, publish (and from time to time thereafter revise) a list which includes any toxic pollutant or combination of such pollutants for which an effluent standard (which may include prohibition of the discharge of such pollutants or combination of such pollutants) will be established under this section.

The proposed list consists of the following pollutants:

LIST OF TOXIC POLLUTANTS

1. Aldrin (1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4,5,8 - endo-exodimethanonaphthalene) Dieldrin (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4-endo, exo-5,8-dimethanonaphthalene)
2. Benzidine and its salts (para-para'-diaminobiphenyl)
3. Cadmium and all cadmium compounds
4. Cyanide and all cyanide compounds
5. DDD(TDE) 1,1 - dichloro - 2,2 - bis(para-chlorophenyl)-ethane DDE (dichlorodiphenyldichloroethylene) 1,1 - dichloro-2,2-bis (para-chlorophenyl)-ethylene DDT (dichlorodiphenyltrichloroethane) 1,1,1 - trichloro-2,2-bis(para-chlorophenyl)-ethane
6. Endrin (1,2,3,4,10,10 - hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a - octahydro-1,4-endo-endo-5,8-dimethanonaphthalene)
7. Mercury and all mercury compounds
8. Polychlorinated biphenyls (PCB's)
9. Toxaphene (chlorinated camphene)

Evaluation of other water pollutants is continuing and the list will be revised from time to time as data become available and as the Administrator deems appropriate. The pollutants included on this initial list are toxic in very low concentrations. The single exception is the industrial chemical, benzidine, which was included because of its ubiquity and known carcinogenic properties.

The term "toxic pollutant" is defined in section 502(13) of the Act as "those pollutants or combinations of pollutants, including disease causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunction in reproduction) or physical deformations in such organisms or their offspring." Thus, the definition is broad and potentially applicable to a large number of substances.

From other provisions of the Act, however, it is clear that the Congress intended that the Administrator be selective in determining which of the potentially large number of candidate substances actually should be listed at various times.

These other provisions include section 101(a)(3), which declares that "it is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited" and section 307(a)(1), which states, in part, that the Administrator in publishing the required list of toxic pollutants, "shall take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms." In addition, as indicated above, section 307(a)(1) provides that the Administrator shall revise the list from time to time.

Furthermore, when section 307(a) is viewed in the context of the Act as a whole which includes a number of specific provisions for preventing and controlling water pollution, it seems apparent that the Administrator's mandate under section 307(a) is to focus on those water pollutants which pose the most serious hazards to man and other organisms inhabiting or consuming water. It is also apparent that the Administrator has a mandate to establish priorities for dealing with such pollutants i.e., to take action initially with respect to those pollutants which, based on available evidence, appear to pose immediate problems and therefore require abatement more rapidly than can be achieved under other provisions of the Act.

In accordance with this mandate, pollutants chosen for inclusion on the initial list meet the following criteria:

1. There is evidence that, either directly or through transformation or bioaccumulation, they are toxic, as defined by section 502(13), at extremely low concentrations in water; and

2. They are discharged in significant amounts from point sources; and

3. Point source discharges are known to have resulted in incidents involving the types of adverse effects cited in section 502(13), and/or

4. There is a significant potential for the occurrence or recurrence of such incidents as a result of point source discharges; and

5. Control testing under section 304(a) is necessary because the presence and occurrences of abatement under other provisions of the Act are not consistent with the nature and extent of the problems identified by the above criteria; and

6. Adequate data are available to establish an effluent standard meeting the requirements of the Act.

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The Environmental Protection Agency invites all interested parties to submit comments on this proposal. Comments shall be submitted in writing, preferably in triplicate, to Dr. C. H. Thompson, Office of Air and Water Programs, Environmental Protection Agency, Washington, D.C. 20460. All relevant comments received on or before August 6, 1973 will be considered. Comments received by the Agency will be available for inspection during normal business hours at the Office of Public Affairs, 401 M Street, S.W., Washington, D.C. 20460. Following consideration of comments, the list will be republished, with any modifications which the Administrator deems appropriate, and will then constitute the list required by section 307(a).

Dated: July 3, 1973.

ROBERT W. FRI,
Acting Administrator.

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