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 eliminating 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).

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.
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> "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 variability 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.

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.

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 percentage of the package would be expected to contribute to the PCB contamination of the 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

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.

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.

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

(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."

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.
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> "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."

§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."

Metal 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.

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.
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> "... 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."

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); (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

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.