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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

MONS 061956

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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 5535) 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 16, 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, 128.6, 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] can be interpreted as "functional or deleterious", [illegible] deleted as a criterion. The Commissioner [illegible] using the phrase "replacements". The toxicity [illegible] of fluids selected [illegible] replacements must be [illegible] so that the least [illegible] replacement is [illegible] consideration with [illegible] to (1) its toxicity, (2) [illegible] quantity that could be [illegible] given quantity of food [illegible] consumed, taking into [illegible] (3) provide [illegible] the equipment to [illegible] (4) PCB's etc., and (5) [illegible] and relevant to [illegible] related there to the [illegible] as to whether [illegible] is reasonably [illegible] as to be made on an individual [illegible] operation basis [illegible] The appropriate [illegible] in § 135.113(b)(2), § 128.6(b), § 3.93(b)(2), § 128.6(b)(2), and § 128.6(b)(2)).

b. One comment argues that electrical capacitors and transformers should be exempt from the requirement that new equipment and existing equipment in establishments engaged in the processing of animal feed, human food, or packaging materials shall not contain PCB's, since no known substitute is available which offers the proper balance of characteristics (e.g., fire safety and design efficiency). In support of the comment, it is stated that both capacitors and transformers are constructed in sealed metal cases and are not normally installed in equipment or located in such a manner as to be in direct contact with the material being processed. The Commissioner of Food and Drugs agrees that there should be an exemption for the safe use of PCB's in electrical capacitors and transformers. The final order has been amended in § 135.113(c), § 3.93(c) and § 128.6(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 specify by regulations finite tolerances for such residual material at this time.

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

a. One comment contends that the language of the amendment is incomplete since it does not establish a limit or tolerance for poisonous or deleterious substances, such as PCB's, which may ultimately be found in the packaged food product. The Commissioner disagrees because the purpose of § 121.2516 is to regulate the use of reclaimed fibers containing poisonous or deleterious substances for use in the manufacture of food-packaging materials and, to the extent necessary, to prevent contamination of the packaged food product with these substances. Therefore, the regulation precludes the necessity of establishing tolerances for the packaged food product. The Commissioner agrees, however, the clarification of the amendment is needed in order to be consistent with regulations which permit the presence of what could otherwise be regarded as poisonous or deleterious substances at levels that have been proved to be safe in food-packaging 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-systemic, 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 certain of fish, poultry, [illegible] and food packaging used for food would be [illegible].

b. [illegible] comment strongly [illegible] objects to the PCB [illegible] for [illegible] foods by a factor [illegible] [illegible] which [illegible] be [illegible] level [illegible] the Commissioner [illegible] amendments, [illegible] of [illegible] the authority [illegible] the temporary tolerances for [illegible] that where the [illegible] [illegible] to [illegible] the [illegible] [illegible] that the [illegible] [illegible] to which use of the [illegible] cannot be avoided". The fact

MONS 061957

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

(1) *Animal toxicological data.* Data from long-term animal studies are available to show that the no-effect level in rats and dogs for PCB's with 42, 54, and 60 percent chlorination is 10 parts per million (ppm). Employing a 100 to 1 safety factor, the "no-effect" level for man would be 5 micrograms (mcg) (microgram (mcg) = 1/1,000 mg) per kg body weight/day based on data derived from dogs, or 3 mcg/kg body-weight/day from rats. Therefore, based on these two animal studies, the allowable level of PCB ingestion in man would be approximately 175 mcg/day for a 70 kg individual.

(2) *Human toxicological data.* Human intoxication with Kanechlor 400, a PCB manufactured in Japan with 48 percent chlorine was noted when a heat exchanger leaked fluid into rice oil and the oil was consumed by Japanese families in 1968. About 1,000 people were eventually affected. Typical clinical findings included chloracne and increased pigmentation with impairment due to hypersecretion of the Meibomian glands, and female gastrointestinal symptoms that included generalized pain and disturbances in liver function. A few babies were born with decreased birth weights and skin discoloration which slowly regressed as the children grew in size, although the growth rate of males appeared to be somewhat slower than normal. Adult patients had protracted clinical course with very slow regression of symptoms and signs, suggesting slow catabolism and excretion of this PCB in humans probably involving a long biological half-life. Exposure levels to the toxic oil have been estimated to approximate, on average, 1.6 mg per day. The oil was subsequently contaminated at a level of about 2,000 ppm. This level was established from the known organic chlorine content of rice oil related to the known average chlorine content of Kanechlor 400. The average total dose of PCB's consumed in the Japanese was estimated to be 2,000 mg. This human data is cited by Kuratsune, et al., Fukuoka Acta Medica 62:213-223 (1971), established the lowest level of PCB that produced an effect in man (using a 50 kg person) consumed over a period of approximately [illegible] days. [illegible] level was based on overt [illegible] symptoms. Higher [illegible] that have shown [illegible] lower levels, [illegible] to 1 to [illegible] man to a per[illegible] level in man would be [illegible] of 20 mcg/kg/day, both [illegible] or 1.4 mg/day for a 70 kg [illegible] for a total period of exposure of 3 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 1970–1973 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 calculated biological half-life of PCB's, current levels of PCB's in the diet represent no immediate hazard. This is true for the average total dosage and effect in the Japanese for human exposure. However, based on the most sensitive "Japanese patient" data, based on dose producing an effect, the long-term possibility of potential long-term hazards requires reduction of the levels of PCB's 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. Those 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 contaminations 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 should be appropriately minimized. PCB's have been shown to occur in packaged 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.

c. 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, may present a hazard to breast fed [illegible]. The Commissioner considers [illegible] a warning to nursing mothers on the basis of the [illegible] limited [illegible] may [illegible] it [illegible] that PCB levels in human milk [illegible] be less than [illegible] 0.05 ppm (whole product basis) [illegible] years of available [illegible] and [illegible] voluntary monitoring reports [illegible] studies do not indicate [illegible] present no immediate hazard to [illegible] The temporary tolerance level is set [illegible] basis of the [illegible] PCB's [illegible] fat in the milk of dairy cows. The temporary tolerance being established for milk is 2.5 ppm (fat basis), which [illegible]

MONS 061958

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

1. One comment recommends clarifiion 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 bienyl 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 bienyl compounds. Each component of nufacturers' mixtures sold in the United ates under the registered trade name of oclor, followed by a four digit number e., 1242; 1254; etc.). The term oclor signifies that the product conts of chlorinated biphenyls, chlorited terphenyls, or a mixture of these mponents. The first two digits of the merical part of the trade name indite the molecular type (1200 signifies lorinated biphenyl, while the last two gits give the weight percent of chlorine 42 signifies 42 percent chlorine). Since e physical and chemical properties of ch Aroclor vary, the analytical beavior 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 osely matches when separated into multicomponents on a gas chromatoraph. Therefore, the Commissioner grees that clarification of the term PCB" is necessary for the analysis of od, animal feed and paper food-packing aterials for PCB residues. The mplementation of FDA analytical methods o be used for enforcing the PCB tolerance that is available upon request contains instructions regarding this aspect f the recommendation. The Commissioner does not agree, however, that the clearances for PCB's should distinguish etween PCB-components of different hemical compositions because toxicological data do not support the need to stablish separate tolerances for each Aroclor. Therefore, the temporary tolerances will apply to the term "PCB" irrespective 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 these FDA previous action level for PCB's in milk and dairy products, which was set at 5 ppm (fat basis), was stated as adequate for protecting public health. The 5 ppm tolerance for milk and dairy products would be kept at the same level. The Commissioner concludes that there is no justification for lowering the present 5 ppm level to 2.5 ppm for milk & dairy products. The present 5 ppm level is adequate to protect public health since PCB's are fat soluble and fat content of milk 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 contained from contaminated poultry fat were considered on an "as is" basis, whole body, the development of the temporary tolerance level, expressed on the basis of fat tolerance on a fat basis is appropriate since PCB's are fat soluble and fat derived from poultry can be used as a separate food (e.g., sauces, gravies, 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 grains, and other feed components 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 object to the proposed tolerance levels of 0.5 ppm for finished animal feeds and 5.0 ppm for animal feed components, current information he states 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. While liver from hens exposed to a diet containing 0.5 ppm PCB's (Aroclor 1254) for 8 weeks

MONS 061959

contained residues in excess of 5 ppm (fat basis) in the muscle (breast and thigh), discontinue 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 0.5 ppm from day three to day forty-three post initial egg production can result in PCB residues only slightly less than 0.5 ppm in the eggs.

[illegible] data from FDA surveillance programs and from industry reports indicate that PCB levels in finished animal feeds and in animal feed components are generally substantially less than the proposed tolerances. (2) Last year FDA conducted a survey of finished animal feeds for PCB's. The survey consisted of 274 samples of formulations representing [illegible] of animal feeds. The [illegible] 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 these samples exceeded 0.2 ppm. [illegible] feed components of animal origin are expected to contain PCB's as a result of environmental contamination. During the past year, 32 samples of imported fishmeal were examined by FDA for PCB's. The results now that about 31 percent of the samples contained PCB residues. The highest level reported was 0.47 ppm. In addition, 93 fishmeal samples of domestic origin were examined during this period. The results show that about 29 percent of the samples contained PCB residues. The highest level reported was 2.1 ppm and the average was less than 1 ppm. (c) In the fall of 1971, FDA jointly conducted a survey of the PCB levels in rendered animal by-products used for feed ingredients such as hydrolyzed feather meal; meat and bone meal; fats and greases; and poultry by-product meal. The results of this survey which were published in *Pesticides*, Issue of July 3, 1972, show that of the 458 samples tested, the highest level of PCB found was 1.6 ppm in fat and grease. The average PCB level for the samples tested was less than 1 ppm. Other data that the Bureau received on the level of PCB's in rendered animal [illegible] confirm the results of the above survey. Therefore, on the basis of the above evidence the Commissioner concludes that [illegible] PCB in the animal feed components. The order is thus amended in § 122.10(a)(5) and (6) to establish temporary tolerances for PCB's in fish (edible portion) at 5 ppm and in animal feed components at 2 ppm.

c. One comment recommends that a tolerance of 5 ppm be established for PCB's in fish. The Commissioner does not agree with this recommendation because the proposal was directed toward food-producing animals because the transmission of PCB's to the edible portion of animals ingesting PCB contaminated feed constitutes a potential hazard to human health. Further, the comment makes a reasonable recommendation since some pets may be able to safely consume levels of PCB's higher than 0.5 ppm. However, on the basis of available toxicological information, there is insufficient data for FDA to establish a tolerance for PCB's in feed for all types of pets and for other non-food producing animals. For this reason, studies will be initiated to obtain this information and, if warranted, FDA will issue a proposal to limit the level of PCB's in this category of finished animal feed. In the interim, the order is amended so that the temporary tolerance in § 122.10(a)(5) is applicable to only food-producing animals.

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

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

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

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

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

a. One comment recommends that plastic and other non-paper food-packaging material be exempt from the temporary tolerance. The Commissioner agrees with this recommendation because there is no evidence to indicate that PCB's occur in plastic or other non-paper food-packaging materials as a result of unavoidable contamination. For this reason, no basis exists 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 action includes that no PCB's whatsoever have been added to the paper as a result of processing conditions or handling practices, in the manufacture of paper food-packaging materials. Those persons in the Statement of General Policy or Interpretation under Part 3, which prohibits the use of PCB-containing equipment and materials, are applicable to those establishments engaged in the manufacture, handling, and storage of plastic and other non-paper food-packaging materials.

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

c. One comment recommends that temporary tolerance be applied to the packaged food, rather than the paper or 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 onerous recommendation. (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 the avoidable PCB residues. The principal source of the PCB contamination of packaged food is the paper food-packaging material, which acts as the transfer vehicle. As such, the tolerance should deal with this vehicle. Therefore, the source of food contamination should be limited so as to minimize the levels of PCB's that may migrate to the packaged food. (4) Failure to limit the level of PCB's in the packaging materials would perpetuate the use of a known, avoidable source of PCB contamination of food.

d. One comment received from industry and related trade associations objects to the temporary tolerance for PCB's in food-packaging materials because of the [illegible] or packaged foods; (2) quality control test procedures and adequate analytical methods are developed for [illegible] production and future compli-

MONS 061960

(3) migration rates are established take into account barrier effects, type food, and package weight to food eight ratio. In response, the Commissioner finds that: (1) Although a trade sociation 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 interlaborary study conducted under the auses of another trade association using DA analytical methodology, supports e conclusion that current methodology adequately sensitive and reproducible om laboratory to laboratory in order insure compliance with the tolerance. 2) It is recognized that migration rates actual level of PCB in food resulting rom the use of contaminated packagig are affected by factors such as barers, type of food, package weight to ood weight ratio, and time and condions of exposure. Since FDA's primary oncern is not the fact that paper foodackaging materials contain PCB's, but e fact that PCB's can migrate to the od from the packaging, the use of barers which prevent migration is an acptable 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 udies have shown that materials such s polyvinylidene coated paper and glass ars, 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 conidered functional barriers. The other actors mentioned above which affect igration rates may also be important onsiderations and should be thoroughly udied. In the interim, the temporary olerance for paper food-packaging aterials and the exemption to this olerance are considered necessary to protect the consumer that packaged foods will not become contaminated with PCB's to an unavoidable degree.

e. One comment states that the establishment of temporary tolerance for PCB paper in food-packaging materials is unwarranted for public health reasons because overall scientific evidence shows that PCB's are not persistent and cumulative, and thus will not present a health or toxicity problem. Although data indicates that some components of Aroclor 1242 are metabolized in biological systems more rapidly than the higher chlorinated Aroclors, there is no information available which describes the composition, toxicity, and fate of the metabolic products. The 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.

f. 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 "0.205 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.

g. 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 tolerances for PCB's in paper food-packaging materials and the other tolerances for which tolerances are established in § 122.10(a). Omitting the methodology from the regulation will permit easier adoption of improved procedures as they are developed while having the analytical methods readily available to all interested parties.

h. 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 waste-paper stocks used in the manufacture of recycled paper. The comment contends that the temporary tolerance will have an adverse effect on the recycled paper industry and thus will cause the above environmental consequences. In response, FDA prepared in accordance with the National Environmental Policy Act of 1969 an environmental impact statement on the proposed rule making. FDA issued a Draft Environmental Impact Statement on May 11, 1972, a Final Environmental Impact Statement on December 21, 1972, and a Supplement to the Final Environmental Impact Statement (published concurrently with this order). In these statements, FDA asserted that information on the toxicity of PCB's necessitates limiting the levels of PCB's currently present in certain foods as a result of environmental contamination, as well as levels of PCB's in certain unavoidable sources of food contamination, i.e., PCB contaminated paper foodpackaging materials. FDA also asserted that the public health benefits derived from the rule making would outweigh the 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 regulations; and (3) The alternative of retaining the packaged food rather than the packaging. FDA concluded in the statements that the rule making would have a significant, beneficial effect on the quality of the human environment. FDA did, however, re-evaluate the protocol level of 5 ppm as the temporary tolerance for PCB's in paper food-packaging materials. Data from the FDA survey of PCB's in foods and feeds [illegible] showed that the food packaging samples with 6–10 ppm [illegible] paper contained [illegible] PCB levels of 0.1–0.6 ppm in the [illegible] tion of the samples with more than 10 ppm in the packaging contained higher [illegible] levels, but not [illegible] ppm. The Commissioner concluded that this was the only reasonable alternative available and stated in the Final Environmental Impact Statement that the temporary tolerance for PCB's in paper

MONS 061961

applications, [illegible] materials would be changed to 10 ppm. (This order amends § 121.3[illegible] to reflect this change.) Data provided by industry shows that levels of PCB's in paper food-packaging materials [illegible] diminished during the past year to the point that 92 percent or more of this material will contain 10 ppm or less PCB's. Therefore, FDA concluded that the temporary tolerance of 10 ppm could be [illegible] to this tolerance for [illegible] materials [illegible] from the food by a [illegible] will protect the public [illegible] the impact of the FDA [illegible] on recycling programs [illegible] FDA indicated in the [illegible] to the Final Environmental Impact Statement that it will explore with other [illegible] measures for eliminating PCB-containing carbonless [illegible] from existing inventories [illegible] this action would [illegible] of PCB's found [illegible] materials permitting [illegible] to reduce the temporary tolerance and eventually to eliminate the need for permitting this unavoidable source of PCB's in food.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055–1056 as amended by 76 Stat. 919 and 72 Stat. 948, 76 Stat. 1784–1788 as amended; 21 U.S.C. 342, 346, 346a, 371) and under authority delegated to the Commissioner (21 CFR 5.10), Parts 3, 121, 128, and 135 are [illegible] and a new Part 122 is added, as follows:

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

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

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

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and 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 as [illegible] heat exchange [illegible] transfer [illegible] hydraulic [illegible] lubricant and [illegible] plasticizer [illegible] have entered PCB's into the environment, where they [illegible] contaminate food. In addition, incidents have occurred in which PCB's have directly contaminated [illegible] as a result of [illegible] PCB [illegible] Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (containing 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB 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 replacement must be considered [illegible] so that the least potentially hazardous replacement is used. In addition, the device in which such fluid is to be used, the application should be tested to [illegible] possibility that the environment under which the fluid is to be used could be spilled onto a large quantity of food before it would be noticed, leading into account its odor and [illegible] such possible spoilage detection [illegible] to evaluate a [illegible] and the environmental [illegible] may to survive and be [illegible] through the food chain. The [illegible] to another [illegible] should be made on an individual [illegible] and operation basis.

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

PART 121—FOOD ADDITIVES

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

§ 121.2516 Pulp from reclaimed fibers.

* * * * *

(b) * * *

(1) Industrial waste from the manufacture of paper and paperboard products, excluding that which bears or contains any poisonous or deleterious substance which is 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 or 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, 1049, 1055–1056 as amended by 76 Stat. 919 and 72 Stat. 948, 76 Stat. 1785–1788 as amended; 21 U.S.C. 342, 346, 346a, 371.

Subpart A—Definitions and Procedural and Interpretive Regulations

§ 122.1 Definitions and interpretations.

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

(b) Unavoidable natural, environmental, or industrial contaminants include any poisonous or deleterious substance added to any food [illegible] such [illegible] cannot be avoided [illegible] manufacturing practice.

Subpart B—Industrial Contaminants in Food and Food-Packaging Material

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

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, unrestricted industrial application, PCB's have become persistent and ubiquitous contaminants

MONS 061962

...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-pack-...aging 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 en-...vironmental 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 prac-...ticable time. For the purposes of this ...paragraph, the term "polychlorinated ...biphenyls (PCB's)" is applicable to mix-...tures 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) 0.5 parts per million in milk (fat ...basis).

...(2) 0.5 parts per million in manufac-...tured 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 ma-...rine origin used in finished animal feed ...concentrates, supplements, and premixes ...intended for food producing animals.

...(7) 5 parts per million in fish and ...shellfish (edible portion). The edible por-...tion of fish does not include scales, viscera, ...and inedible bones.

...(8) 2 parts per million in infant and ...[illegible]

...[illegible] million in paper food-...[illegible] used for or used ...[illegible] animal feed ...[illegible] used for animal ...[illegible] not [illegible] to ...[illegible] [illegible] ...[illegible] [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 existing equipment or machinery for handling and processing feed sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices, be replaced with a heat exchange fluid that does not contain PCB's.

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

(iii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the animal feed producing establishment any other PCB-containing materials, whenever there is a reasonable expectation that such 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 §§ 121.354b 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 states 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 §§ 121.354b and 122.10 that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced in the FEDERAL REGISTER. In the event § 122.10 is stayed by valid objections, pending a final regulation the Food and Drug Administration will enforce the levels stated in § 122.10 by seizing pursuant to sections 301 and 304 of the Act any food, feed, or paper food-packaging material shipped in commerce containing higher than the specified level of PCB's as adulterated in violation of section 402 of the Act.

(Secs. 402(a), 406, 409, 701, 52 Stat. 1046 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 73 Stat. 940, 72 Stat. 1785-1789 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.73-13549 Filed 7-5-73;8:45 am]

MONS 061964

No. [illegible]—Pt. II——2

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 6-88, 5600 Fishers Lane, Rockville, MD 20852.

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

Dated: June 21, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

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

MONS 061965

graph (a)(2) of this section and such other pertinent information as may be available, that:

(1) 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 factual 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.73-13739 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 (dichlorodiphenyltrichlorothane) 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 other provisions for preventive and corrective 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 biomagnification, 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 of recurrence of such incidents from all of point source discharges authorized under section 402 of the Act because the present monitoring and effectiveness of abatement activities under other provisions of the Act are not adequate with the nature and extent of the problems identified by the above criteria, and
5. Adequate data are available to establish an effluent standard meeting the requirements of the Act.

MONS 061966

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.

[FR Doc.73-13870 Filed 7-5-73;10:15 am]

MONS 061967