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Food and Drug Administration

Polychlorinated Biphenyls (PCB's); Reduction of Tolerances

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 109

[Docket No. 77N-0080]

Polychlorinated Biphenyls (PCB's); Reduction of Tolerances

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

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

DATES: Effective August 28, 1979; objections on or before July 30, 1979.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-85, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Howard N. Pippin, Bureau of Foods (HFF-312), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204,202-24$3092.

SUPPLEMENTARY INFORMATION: In the Federal Register of April *1,1977* [42 FR 17487), FDA proposed to reduce the temporary tolerances for unavoidable residues of PCB's in several classes of food. The agency received over 100 comments on the proposal from interested individuals, consumer groups, businesses, trade associations, State government agencies, and others. The agency has considered these comments and is now issuing a final order reducing the PCB tolerances as originally proposed. Following a brief discussion of the background, this document will respond to the comments the agency received and explain the agency's reasons for adopting the reduced tolerance levels.

I. Background

PCB's are a class of toxic industrial chemicals that have become persistent and ubiquitous environmental contaminants as a result of past widespread, uncontrolled industrial use, As explained in the preamble to FDA's proposal initiating this rulemaking proceeding (see 42 FR 17489), one result of PCB contamination of the environment has been contamination of certain foods. In the Federal Register of July 6,1973 (38 FR 18098), FDA issued regulations to deal with the problem of PCB contamination of food. Among those regulations was one establishing temporary tolerances for unavoidable PCB residues in various categories of food. Those original tolerances are now codified in $109.30 (21 CFR 109,30). The order FDA is issuing in this document reduces certain of those tolerances.

FDA's authority to issue tolerances for unavoidable food contaminants is derived from sections 402(a)(2)(A) and 406 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(A) and 346). Section 402(a)(2)(A) deems food adulterated, and thus prohibited from interstate commerce, if it contains "any added poisonous or added deleterious substance" that is unsafe within the meaning of section 408, Section 408 deems any added poisonous or deleterious substance to be unsafe unless its presence in the food is required in the production thereof or cannot be avoided by good manufacturing practice. Section 408 also authorizes the agency to promulgate regulations limiting the quantity of such a required or unavoidable substance that can be present legally in food. Such limits, called tolerances, are to be set by FDA at the level found necessary to protect the public health, taking into account the extent to which the . substance is required or unavoidable and the other ways the consumer may be affected by the same or other poisonous or deleterious substances, Once a regulation establishing a tolerance has been promulgated for a particular poisonous or deleterious substance, food containing that substance in an amount exceeding the tolerance is deemed adulterated under section 402(a) (2)(A].

One of the primary purposes of section 406 of the act is to enable FDA to deal effectively with environmental contaminants such as PCB's, These substances often enter food as a result of events beyond the reasonable control of the food manufacturer or processor and, once in the food, usually cannot be removed by good manufacturing practice. For example, in the case of PCB's, some species of fish have become contaminated to varying degrees as a result of the dumping of PCB-containing industrial waste into the nation's waters (see the Federal Register of March 18, 1972 (37 FR 5705)]. Once the contamination occurs, there is little that can be done to remove the PCB's from the water or from the fish; their presence is, in that sense, unavoidable. Because the initial contamination of fish with PCB's cannot be avoided (nor the PCB's processed out), the only way to avoid PCB's in fish is to remove fish from commerce if it contains PCB's above a given tolerance level. The degree of avoidance accomplished by this method is, of course, a function of the level at which the tolerance is set, In this way, it is theoretically possible to avoid PCB's in fish absolutely by removing from commerce all fish that contain any amount of PCB's.

Section 406 of the act authorizes FDA to make a practical judgment in dealing with such environmental contaminants: Based on an assessment of the degree to which the contaminant poses a threat to consumers, the agency can decide to tolerate the contaminant's presence in food up to a level the agency considers appropriate to protect the public health, taking into account, among other factors, the extent to which the presence of the contaminant is unavoidable, In making this judgment, the agency's paramount concern is protection of the public health: The tolerance cannot be set above the level. the agency finds necessary to protect the public health adequately. But in determining what tolerance level provides an adequate degree of public health protection, FDA is required by section 406 to consider the extent of unavoidability—in the case of PCB contamination of fish, the amount of PCB-contaminated fish that must be disposed of to reduce human exposure to PCB's to a tolerable level, As a practical matter, of course, a tolerance, if it is to be enforceable, cannot be set below the level at which the contaminant can be reliably measured for enforcement purposes by available analytical methods.

The toxicological data available on PCB's make it clear that, in an ideal situation, it would be preferable not to have PCB's in food at any level. As discussed more fully below, the data do not permit the identification of any level of PCB exposure that can be said to provide an absolute assurance of safety, It is equally clear, however, that the reduction of PCB exposure from food sources to zero, or to a level approaching zero, would require elimination of large amounts of food, especially fish. Hence, in deciding the appropriate levels for PCB tolerances under section 408, FDA has had to make some extraordinarily difficult judgments. It has had to decide, in effect, where the proper balance lies between providing an adequate degree of public health

protection and avoiding excessive losses of food to American consumers.

The comments received on the proposal reveal that by far the most controversial aspect of this rulemaking proceeding is the balancing judgment FDA made in proposing to reduce the PCB tolerance in fish from 5 to 2 ppm. Some comments argued that the proposed reduction would cause an excessive loss of food and significant adverse economic impact without providing any significant increase in public health protection. Other comments argued the converse, i.e., that the proposed reduction to 2 ppm would not adequately protect the public health and that the tolerance should be reduced to 1 ppm (the lowest level at which PCB residues in fish can be reliably measured fop enforcement purposes), despite the additional losses of food that a reduction to 1 ppm would cause. In each case, the comments bolstered their arguments by contending that FDA has either overestimated or underestimated the toxicity of PCB's and the impact of the proposed reduction of the tolerance in terms of food loss and adverse economic consequences.

The comments criticizing the proposed reduction of the fish tolerance highlight the difficulty of the judgment FDA must sometimes make in establishing tolerances. Not only must FDA make a qualitative judgment about the proper balance between adequate public health protection and excessive loss of food, it also must often make that judgment on the basis of data that are incomplete, or even in dispute, and that can easily lead reasonable people to differing conclusions. As the comments illustrate, it is nearly always possible to conduct additional studies and investigations to refine further the knowledge of a substance's toxicological profile, the incidence and-degree of human exposure to it, and the impact a given tolerance reduction will have on the food supply. As an agency whose first responsibility is to protect the public health, however, FDA must act on the basis of the information available to it, even when the information is incomplete. Neither the agency nor the public can afford to wait until every uncertainty is resolved. See *Ethyl Corp. v. Environmental Protection Agency, 541* F. 2d 1, 24-29 (D.C, Cir,) (en *banc*), *cert. denied, 426* U.S. 941 (1976).

In the case of PCB's, even though there are obvious shortcomings in the available data, which are discussed below, FDA considers the data to provide a more than adequate basis for the exercise of its judgment in reducing the PCB tolerances. There would be no advantage in delaying this action because it will take years to resolve certain of the shortcomings in the data on PCB's, if they can be resolved at all. For example, no chronic toxicity studies have been performed on the specific, chemically distinct composition of PCB's found in fish residues. Even if such studies were begun immediately, it would be 3 to 4 years before results could be available. That plainly is too long to wait to take action necessary for the protection of the public health.

Because of the emphasis the comments placed on the proposed reduction of the fish tolerance, this document reviews the basis on which the reduction was proposed and explains why, after considering the comments, the agency has decided to promulgate the reduction as proposed. After discussing the fish tolerance and the major points raised about it in the comments, this document responds to the remaining comments received on other aspects of the proposal.

11. The Tolerance for Fish and Shellfish

In the preamble to the April 1, *1977* proposal, the agency discussed new toxicity data that had become available after the original PCB tolerances were promulgated in 1973 [42 FR 17488-9). In contrast to the data underlying the original tolerances, which consisted primarily of data from retrospective studies of humans in Japan who were exposed to high doses of PCB's and showed acute toxic effects from the exposure (42`FR 17487–8), the new toxicity data consist primarily of animal studies showing an association between PCB exposure and serious subchronic and chronic toxicities, including adverse reproductive effects, tumor production, and, possibly, carcinogenicity, as well as effects on numerous biochemical systems [42 FR 17488-9). Although the data do not fully resolve such important questions as the carcinogenicity of PCB's, they lead to the conclusion that neither "no effect" nor "allowable daily intake" levels for PCB's can be established with any confidence and that, from a toxicological point of view, human exposure to PCB's should be reduced.

The preamble to the proposal also discussed data FDA had gathered on human exposure to PCB's, especially from dietary sources *(42 FR 17489-90),* These data show that the current incidence of PCB contamination of food has declined significantly in comparison to that on which the original PCB tolerances were based (see 37 FR 5705), Indeed, the new data show that fish are the only food group in which detectable levels of PCB contamination are now routinely found.

Based on the declining incidence of PCB contamination, which means that PCB's are avoidable in food to a greater degree now than they were earlier, as well as the new toxicity data suggesting chronic toxic effects, FDA decided the PCB tolerances should be reduced.

In the preamble to the proposal, the agency analyzed the new toxicity and exposure data as they bore specifically on the tolerance for PCB's in fish *(42 FR 17492-3). The* agency concluded that reduction of the tolerance from 5 to 2 ppm was necessary to protect the public health adequately, even though that reduction would result in the estimated loss of a minor percentage of marine fish (approximately *0.2* percent) and up to 25 percent of freshwater fish shipped interstate (the loss of marine and freshwater fish having a combined landed value of approximately $8 million per year). The agency concluded that the increment of public health protection afforded at least theoretically by a further reduction of the tolerance to 1 ppm did not justify such a reduction in light of the substantially greater loss of food that would result (a combined landed value, marine and freshwater. of approximately *$18* million per year).

As noted, a large majority of the comments on the proposal dealt with some aspect of the agency's proposal to reduce the fish tolerance to 2 ppm. Some of the comments agreed that the proposal struck a proper balance between the need to protect the public health and the need to avoid excessive loss of food. Other comments argued that the tolerance should be reduced to 1 ppm in light of the new toxicity data on PCB's, despite any additional loss of food that might result.

Most of the comments on the fish tolerance, however, were submitted by members of the fishing industry, by trade associations, and by agencies of State governments involved in commercial fishing matters, who argued that reduction of the tolerance to 2 ppm is not justified. Some of these comments contended that the health hazard presented by occasional consumption of fish containing 5 ppm PCB's is not significant and that any reduction in risk to consumers accomplished by reducing the tolerance to 2 ppm would be minor. These comments also argued that any such risk reduction would be outweighed by the resulting adverse economic consequences, which some argued would be far in excess of those cited by the agency in its proposal. In support of the latter argument, some of these comments estimated the impact a

2 ppm tolerance would have not only on the commercial fish catch, but also on employment and income in the fishing and related industries and on recreational fishing. Arguing that the States would curtail recreational fishing in certain areas if the tolerance were reduced to 2 ppm, the comments projected large losses of sales among those supplying boats, licenses, tackle, and bait to sport fishers.

Due to the large volume of comments challenging the proposed reduction of the fish tolerance, the agency has carefully reassessed the justification for lowering the tolerance from 5 to 2 ppm. It has reviewed the toxicological data and has attempted to estimate in quantitative terms the degree to which lowering the tolerance would reduce risk to consumers. In addition, it has re-examined the question of how much additional loss of fish would occur as a result of the proposed reduction. Based on its reassessment, the agency concludes that reduction of the tolerance for PCB's in fish to *2* ppm strikes the proper balance between the need to protect the public health and the need to avoid unnecessary loss of food. Hence, the reduced tolerance is being promulgated as proposed.

A. Risk Reduction

As noted earlier in this preamble, the proposal to reduce the fish tolerance was based in part on new toxicity data showing a relation between PCB exposure and an increased incidence of various subchronic and chronic toxic effects, including adverse reproductive effects, tumor production, and, possibly, carcinogenicity (42 FR 17487-9). The proposal itself noted certain factors that complicate the evaluation of PCB toxicity (e.g., varying degrees of toxicity among the several forms of PCB's, the presence of toxic impurities such as chlorinated dibenzofurans in commercial preparations of PCB's, the differences in chemical composition between commercial PCB's and PCB residues in fish, and varying susceptibilities of different animal species to the toxic effects of PCB's); these complicating factors were also pointed out in some of the comments received on the proposal,

Notwithstanding these factors, however, there is little genuine dispute over the fact that exposure to PCB's must be considered to pose a risk of serious, chronic toxic effects in humans. The toxicological judgment that flows from this fact—i.e., that a reduction in human exposure to PCB's will reduce this risk-was an important part of the agency's rationale for proposing to reduce the fish tolerance. Nothing in the comments and nothing discovered during FDA's reassessment of the toxicity data alters the validity of that fundamental judgment. The agency therefore concludes that it is important as a matter of public health protection to minimize human exposure to PCB's.

The real question raised by the comments is whether the degree of risk reduction accomplished by lowering the fish tolerance to 2 ppm is sufficient to justify the increased loss of food that the lower tolerance will cause. This is an extremely difficult question because it is not now possible for toxicologists to quantify precisely, on the basis of toxicity data derived from animal studies, the risks posed to humans. Using classical toxicological methods, the most that can be done reliably is to make qualitative judgments about risks: A statistically significant increased incidence of adverse effects in animals is good evidence of a risk to humans, and, generally, the greater the incidence of effects in animals, the greater the risk to humans (Ref. 43). Having identified the risk of a chronic toxic effect from exposure to a substance, classical toxicological principles lead to the conclusion that reduction in exposure will reduce the risk (Ref. 44). Again, there is no evidence that these principles do not apply to PCB's.

Scientists have recently developed methods, incorporating mathematical extrapolation models, for making quantitative estimates of risks to humans based on toxicity data from animal studies. These risk assessment methods do not purport to quantify precisely the expected human risk, but rather attempt to estimate in quantitative terms an upper limit on the risk to humans that can be expected from a given level of exposure to a toxic substance, assuming humans are no more susceptible to the effects of the substance than are the most susceptible members of the animal species for which toxicity data are available. These risk assessments can be useful as a means of comparing risks at various exposure levels and illustrating the toxicological judgment that a reduction in exposure will reduce risk. Because of all the problems inherent in extrapolating from animal data to the expected human experience, however, the numbers produced by a risk assessment must be interpreted cautiously: They are estimates of upper limits on risk and, though potentially useful for comparative purposes, cannot be said to quantify actual human risk precisely. These assessments attempt to avoid underestimatin, human risk, but even that cannot be guaranteed. The Work Group on Risk Assessment of the Interagency Regulatory Liaison Group (IRLG) has recently prepared a report that discussers many of the principles involved in risk assessment.

As part of its review of the toxicological justification for reducing the fish tolerance, the agency has performed a risk assessment aimed at comparing the estimated risks associated with PCB exposure at the various levels of exposure that would result from different tolerance levels The written report on this risk assessment has been made a part of the record of this proceeding as Reference *45.*

As explained in that report, the risk assessment involved the use of the most recent available data on the incidence of PCB contamination of fish to calculate the level of exposure to PCB's that could be expected to result from tolerance levels of *5,2,* and 1 ppm (Table 4, Ref. 45). These calculations were based on the assumption that under a given tolerance level, no fish containing PCB's in an amount above that level would be consumed, It is true, of course, that an FDA tolerance level directly affects only fish shipped in interstate commerce, but States often adopt FDA's tolerance levels for application to intrastate and recreational fishing. Thus, even if the exposure calculations used in the risk assessment (Table 4, Ref. 45) do somewhat overstate the absolute amounts of exposure reduction, they nevertheless demonstrate that a reduction of the PCB tolerance for fish would result in a significant reduction of PCB exposure [e.g., for heavy consumers of the affected species, reduction of the fish tolerance from 5 to 2 ppm reduces exposure from an estimated 20.1 micrograms (µg) per day to an estimated 14.9 µg per day). Such significant reductions in PCB exposure from fish are especially important in terms of risk reduction because fish are the only food group in which detectable levels of PCB's are still regularly found.

Based on the calculations of exposure at various tolerance levels and toxicity data from animal studies, the agency used a linear extrapolation method to estimate the upper limits on certain risks posed by exposure to PCB's, This analysis resulted in estimates of significant potential risk to humans who consume PCB-contaminated fish on a continuing basis, especially fish contaminated at or above the 5 ppm level (Tables 6 and 7, Ref. 45). For example, using the total malignancy data from the National Cancer Institute (NCI] Bioassay (Ref. 19), it is estimated

that the upper limit on the lifetime risk of cancer for heavy consumers of fish most affected by the tolerances is 9.8 incidence of cancer per 100,000 of the population, assuming the tolerance is 5 ppm; 7.2 per 100,000, assuming the tolerance is 2 ppm; and 4.4 per 100,000, assuming the tolerance is 1 ppm (Table 6, Ref. 45). Stated another way, it is estimated that the upper limit on the number of new cancers per year among heavy consumers of fish most affected by the tolerances is 46,8, assuming a tolerance of 5 ppm; 34.3, assuming a tolerance of 2 ppm; and 21, assuming a tolerance of 1 ppm (Table 7, Ref. 45).

As explained in the report (Ref. 45), the utility of this risk assessment for evaluating actual risk to humans from exposure to PCB's is extremely limited. This is due both to difficulties inherent in making such extrapolations from animals to humans and, perhaps more importantly in this instance, to gaps and uncertainties in the data available for this particular risk assessment. For example, the toxicity studies on which the risk assessment is based used commercial preparations of PCB's, which are chemically different from the PCB residues found in fish and which contain small amounts of highly toxic impurities (e.g., dibenzofurans) not known to be present in fish residues, Also, in making the exposure estimates required for the risk assessment, it was necessary to use existing data on the numerical distribution of PCB levels in fish and rely on the assumption that the effect of a given tolerance level is to remove from commerce all fish containing PCB's exceeding the tolerances. It is possible that neither the assumption nor the data precisely reflect what actually occurs.

For these reasons and others discussed in the report (Ref. 45), the risk assessment does not provide a basis for precise quantification of the amount of risk reduction accomplished by reducing the fish tolerance, Despite the limitations inherent in the risk assessment, however, the agency regards it as illustrative of the basic validity of the toxicological rationale for reducing the tolerance for PCB's in fish: Reduction of the tolerance will result in a significant reduction in risk among those who consume PCB-contaminated fish. FDA considers this risk reduction to be of significant public health value, even though it cannot be precisely quantified.

B. Loss Of Food

In the preamble to the proposal, the agency estimated that the loss of food from commercial channels resulting from a 2 ppm tolerance for PCB's in fish would be approximately $8 million in landed value, compared to approximately $1 million for the 5 ppm tolerance and $18 million for a 1 ppm tolerance, The estimated $8 million loss resulting from a 2 ppm tolerance encompassed a negligible percentage of the marine-fish catch (about 0.2 percent) and about 25 percent of the freshwater catch (42 FR 17492),

The agency arrived at these figures by assuming that all fish containing PCB's above the tolerance would be removed from both interstate and intrastate commerce ("Economic Impact Assessment for Proposed Reduction of Temporary Tolerances for Polychlorinated Biphenyls in Food," Ref. 39). There are several difficulties inherent in this assumption. On the one hand, it may tend to overstate the loss because (a) some states may not apply FDA's reduced tolerance to intrastate fish, (b) some violative fish will be part of nonviolative lots, and (c) some violative lots may enter commerce undetected. On the other hand, it may tend to understate the loss because once the violative percentage of a given species reaches a certain level, commercial fishers may stop fishing that species altogether. Some of the comments cited these difficulties in support of arguments that FDA had either overestimated or underestimated the amount of fish that would be lost as a result of a 2 ppm tolerance. Despite its acknowledged limitations, adoption of the assumption is a necessary and reasonable method for dealing with the uncertainties inherent in predicting the impact of a tolerance reduction. None of the comments suggested an alternative method for estimating the amount of fish that would be removed from commerce as a result of the proposed tolerance reduction.

Because of the comments it received questioning the justification for the proposed reduction in the fish tolerance, the agency has re-examined its projections of the food loss expected to result from such a reduction. The projections made in the preamble to the proposal were based on data obtained in 1974 on the levels of PCB's in commercial fish, primarily from the Great Lakes (Ref. 39), In making those original projections, the agency was forced to rely on the assumption that PCB levels in freshwater fish nationwide were as high as those found in the Great Lakes. FDA now has more recent and more representative data on PCB levels in commercial fish, which it obtained through a nationwide sampling program conducted in 1978 and 1979, Based on these more recent data, the value of the fish projected to be lost at tolerance levels of 5 ppm and 2 ppm is substantially less than was projected in the proposal. The loss projected under a 1 ppm tolerance would remain about the same (Table B, "Regulatory Analysis for Final Regulation for Reduction of Temporary Tolerances for Polychlorinated Biphenyls in Food," Ref. 46). Specifically, the amount of commercial fish now projected to be lost as a result of a 2 ppm tolerance is about $5.7 million (expressed in 1974 dollars) compared to the previously estimated $8 million; the current estimated loss of fish under a 5 ppm tolerance is about $0.6 million (compared to the previously estimated $1.1 million). Under a 1 ppm tolerance, however, the projected fish loss, using the new sampling data on PCB levels, is about $16 million (compared to the previously estimated $18 million). The percentage of the freshwater fish catch now estimated to be lost under a 2 ppm tolerance is 14 percent (compared to the 25 percent that had been estimated from the 1974 data); under a 1 ppm tolerance, the currently estimated loss of freshwater fish is 35 percent (compared to the previously estimated 43 percent) (Ref. 46),

As noted earlier in this preamble, many of the comments argued that the impact of the proposed tolerance reduction must be measured not only by the amount of the resulting fish loss but also by other economic impacts, such as potential unemployment and loss of income in the fishing industry and postulated disruption of the recreational fishing industry (e.g., reductions in boat, tackle, and bait sales]. The comments provided figures ranging into the hundreds of millions of dollars on the total economic value of these industries and, without offering any further analysis, contended that the impact on them would be "severe" or "major." The predicted impact on recreational fishing was premised on the possibility that State governments would severely curtail recreational fishing if the tolerance were reduced to 2 ppm.

In establishing a tolerance for PCB's in fish, FDA must take into account the amount of fish a given tolerance would remove from commerce. Section 406 of the act, however, neither requires nor authorizes FDA to weigh secondary economic impacts when it considers the level at which a tolerance should be set. Consideration of such impacts would be inconsistent with the paramount concern of section 406, which is protection of the public health, and would complicate the decisionmaking process under section 406 in a way

Congress did not intend. Obviously, consideration of the amount of food loss caused by a tolerance helps to ensure that the direct economic consequences of the tolerance (in this case, decreased sales and employment in the commercial fishing industry) will not be disproportionate to the increased degree of public health protection accomplished by the tolerance; but the agency considers secondary economic consequences, such as potential impact on the recreational fishing industry, totally beyond the scope of section 406.

None of this should suggest that the agency is unaware of, or unconcerned about, the economic consequences of its actions. It is keenly aware that actions it takes to protect the public health can have adverse economic consequences, both direct and indirect, and that these consequences can sometimes be felt with particular severity in certain narrow segments of the economy. For example, some of the comments on the proposal argue that the impact of a 2 ppm PCB tolerance for fish will be especially severe for small-scale, freshwater fishers who specialize in certain species that happen to be heavily contaminated. The agency acknowledged this possibility in the preamble to the proposal (42 FR 17492).

in the present case, however, the agency has reason to believe that the claims of adverse economic impact are exaggerated. Based on the 1078/1979 data on PCB levels in freshwater fish, a 2 ppm tolerance will remove from commerce about $5.7 million worth of commercial fish. Although it is possible that fishing for certain heavily contaminated freshwater species may cease entirely in locations where PCB contamination is concentrated, at least some affected fishers-both commercial and sport-can be expected to adjust to the reduced tolerance by increasing their catch of other species or transferring their activities to other, less contaminated locations within their current area of operation.

In evaluating claims of economic impact, it is theoretically and pragmatically sound to take into account the motives and opportunities for adaptive behavior by affected individuals and fins. If the public demand for commercially caught fish remains stable or increases, and if the attractions of sport fishing remain strong, it can be expected that some fishing activity will shift to species that are not contaminated above the tolerance. Over time, the shifts will become easier as the levels of PCB contamination decline because more and more species will have average PCB levels well below 2 ppm. Over the long term, the adjustments will help to minimize the net economic impact of the tolerance reduction on both individual fishers and the overall commercial freshwater fishing industry.

None of the comments attempted to quantify in dollar terms the impact of the tolerance reduction on the recreational fishing industry, but several postulated a "severe" or "major" impact premised on voluntary decisions by individuals not to fish and mandatory curtailments of recreational fishing by State authorities. FDA is in no better position than were those submitting the comments to make precise predictions about the future behavior of individuals and State agencies. However, the agency considers the premises underlying the projections of "major" or "severe" impact to be somewhat speculative and of questionable validity. As noted to the extent that the behavior of individual recreational fishers is affected by the tolerance reduction at all, they, as much as commercial fishers, can be expected to adjust to the tolerance by shifting their activities to the less contaminated species and locations. Also, even if State agencies decide that some curtailment of recreational fishing is necessary in light of the reduced tolerance, it is reasonable to expect that their actions will be tailored by species and location. In the past, the most common response of State agencies to FDA's PCB tolerance for fish has not been the mandatory curtailment of recreational fishing. Instead, they have issued warnings concerning particular species and locations and made suggestions regarding both limitations on consumption of particular species and methods of preparing and cooking fish that minimize the amount of PCB's actually consumed from contaminated fish. Thus, there is little reason to believe that a 2 ppm tolerance will lead to widespread, mandatory curtailment of recreational fishing and the resulting drastic economic impact the comments postulate.

C. Conclusion

Based on the data now before it, the agency concludes that a reduction of the fish tolerance from 5 to 2 ppm will result in a meaningful decrease in the risk experienced by consumers from exposure to PCB's. Some reduction of the tolerance is clearly in order because the toxic effects associated with exposure to PCB's are serious and irreversible; and, due to declining levels of PCB contamination the current 5 ppm tolerance permits contamination that can fairly be termed "avoidable'' -even among the-more highly contaminated commercial species most likely to be affected by a reduced tolerance, only a minor percentage (about 1.5 percent) contain PCB's at levels as high as 5 ppm (Table A, Ref. *46). The* agency's judgment is that the balance between public health protection and loss of food is properly struck by a 2 ppm tolerance. As noted, as 2 ppm tolerance effects a meaningful decrease in risk to consumers while still excluding from commerce only a relatively small amount of food (about $5.7 million landed value in 1974 dollars).

Several comments argued that an adequate degree of public health protection can be provided only by lowering the fish tolerance to 1 ppm, the lowest level at which PCB's can be reliably measured in fish for enforcement purposes. Indeed, as one would expect, the risk assessment performed by the agency, and discussed above, indicates that the estimated risks that might be experienced by consumers of contaminated fish would be reduced even further by a reduction of the tolerance to 1 ppm (Tables 6 and *7,* Ref. 45). Based on the evidence now before it, however, the agency does not consider a reduction to 1 ppm necessary or appropriate in light of the policy of section 408 of the act.

The risk assessment the agency made incorporated several conservative assumptions that were designed to avoid understatement of the human risk. Thus, it is expected that the actual risk experienced by consumers of the 12 more heavily contaminated species covered by the risk assessment is less than that estimated. Moreover, the average consumer, who eats fish from a variety of freshwater and marine sources, will actually experience a far lower level of PCB exposure and a correspondingly lower degree of risk than those whose fish consumption is concentrated among the more heavily contaminated (predominantly freshwater) species. For these reasons, notwithstanding the quantified risk estimates produced by the risk assessment, the agency reaffirms the conclusion it expressed in the preamble to the proposal: The 2 ppm tolerance provides an adequate degree of protection for all but those who consume above-average amounts of freshwater fish taken from contaminated waters *(42 FR 17493).*

In the agency's judgment, the additional increment of public health protection that might be provided by reducing the tolerance to 1 ppm does not justify the additional loss of food that

would resuIt. First, as discussed above, the agency estimates that under a tolerance of 1 ppm, approximately $16 million worth of the commercial fish catch would be violative and thus, presumably, removed from commerce. This is nearly triple the $5.7 million worth estimated to be violative under a 2 ppm tolerance. It is far more likely under a 1 ppm tolerance than under a ppm tolerance that the more heavily contaminated species of freshwater fish would be violative in percentages high enough to put an end to their commercial exploitation and, possibly, force some segments of the freshwater fishing industry to cease operations completely. Thus, the actual loss of food resulting from the 1 ppm tolerance could greatly exceed even the $16 million landed value (1974 dollars) estimated above.

Second, for the average consumer, current exposure to PCB's in fish is at a tolerably low level, when considered in light of the criteria of section 406 of the act, without a 1 ppm tolerance, The average consumer eats a modest amount of fish from a variety of sources, both freshwater and marine, most of which yield fish with PCB levels below 1 ppm. Because their exposure is thus low to begin with, they are adequately protected by a 2 ppm tolerance, which ensures that they will not be exposed to the unusually high levels of PCB's found in some species of fish. The slight additional protection these average consumers might gain from a 1 ppm tolerance does not justify the significantly greater impact such a tolerance would have on the availability of food. On the other hand, atypical heavy consumers (e.g., the Great Lakes sport fisher who catches and consumes large quantities of the contaminated species) would likely not be adequately protected by even a 1 ppm tolerance because of the amount of fish they eat and because those fish are seldom affected by FDA tolerances (either because they are sport fish or are from intrastate commercial channels and, in either case, are outside FDA's jurisdiction). Protection of these consumers depends on actions by State authorities.

Finally, though the new toxicity data on PCB's clearly support the need to reduce exposure to this contaminant, the uncertainties in the data (discussed above) cast some doubt on the degree to which consumers are at risk from extremely low levels of PCB exposure, and therefore weigh against lowering the tolerance to 1 ppm. If, for example, more definitive and incriminating data on the reproductive risks posed by PCB's are forthcoming, the agency might consider establishing a 1 ppm tolerance despite the effect that would have on the availability of food.

For these reasons, the agency concludes that at this time a 1 ppm tolerance would not strike the proper balance between protection of the public health and the need to avoid excessive loss of food.

Though FDA considers 2 ppm to be the appropriate tolerance level for PCB's in fish under the criteria imposed by section 406 of the act, the agency is concerned about the health of certain groups that may not be adequately protected by a 2 ppm, or even a 1 ppm, tolerance. As noted, sport fishers and others who consume abnormally large amounts of the more highly contaminated species may be at risk from PCB's regardless of any tolerance FDA establishes. (The agency's risk assessment, using data from a study of Lake Michigan sport fish eaters, estimated that the upper limit on the lifetime risk of cancer for heavy eaters of sport fish from Lake Michigan is about 12 to 14 times greater than the corresponding risk for heavy eaters of those commercial fish most affected by a PCB tolerance, even assuming the tolerance remained at 5 ppm (Table 6, Ref. 45).] Those individuals, whose high exposures to PCB's tend to result from localized conditions and fishing practices beyond the control of FDA, should take steps to reduce their exposure to PCB's. FDA urges State and local health officials to evaluate the situation in their own localities and determine what steps, if any, they can take to address these special situations. In the past, some State and local agencies have made FDA's tolerance level for PCB' s applicable to fish in intrastate commerce and have issued advisories to sport fishers warning that consumption of certain species of fish should be minimized and suggesting other ways in which PCB exposure could be reduced. These agencies should review their past actions in light of the current state of knowledge about PCB's and make the changes or take the additional steps that may now be appropriate, FDA will cooperate with these agencies, as it has in the past, by providing technical advice and assistance. FDA is sending letters to the governors of States most affected by PCB's in fish, discussing the agency's concerns about aspects of the PCB problem that may require an up-to-date review in their States.

The agency is advising that State health departments be particularly concerned about women of childbearing age, especially pregnant and lactating women, who may have consumed, or are consuming, higher than normal amounts of PCB-contaminated fish. Data that were discussed in the preamble to the proposal *(42 FR 17468-9)* suggest an association between PCB exposure and reproductive disjunction in rats and monkeys. They also show acute toxic effects in the nursing offspring of maternal monkeys that had been exposed to toxic levels of PCB's. Data gathered by FDA since it issued the proposal in 1977, and discussed in the report on FDA's risk assessment on PCB's (Ref. *45),* establish more clearly the link between PCB exposure and adverse reproductive effects in the rhesus monkey. They also confirm the earlier data showing acute toxic effects in the nursing offspring of PCB-exposed maternal monkeys. As explained in the risk assessment report (Ref. 45), it is not possible at this time to determine with confidence the significance of these data in terms of human risk. There have been no reports of human reproductive abnormalities or overt toxic effects in nursing human infants that can be attributed to PCB's. That fact is of only limited significance, however, because epidemiological studies adequate to detect such adverse effects in humans have not been conducted.

An additional reason for concern in this area is that PCB's ingested by human mothers are found, and to some extent are concentrated, in human breast milk (see the discussions in the preamble to the proposal and in the risk assessment report (Ref. 45)). In a recent nationwide survey, consisting of 1,038 samples of human breast milk collected in 44 States, the mean concentration of PCB's was estimated to be in the range of 1.00 to 1.10 ppm (on a fat basis) (Ref. 45). Though the data are scanty, it is reasonable to assume that among women who consume above-average amounts of PCB-contaminated fish, or who are exposed to PCB's from other sources, the levels of PCB's in breast milk are significantly higher, As noted it is not now possible to determine the significance of these facts in terms of increased risk to the nursing infant.

In sum, although the agency concludes that a 2 ppm tolerance for PCB's adequately protects most consumers, women of childbearing age, especially pregnant and lactating women, are among those who should be careful to avoid abnormally high exposure to PCB's in fish, They can avoid such exposure by minimizing consumption of both commercial and noncommercial fish from waters known to be contaminated with PCB's and avoiding

entirely those species of sport fish known to contain high levels of PCB's (e.g., coho and chinook salmon from the Great Lakes, and freshwater trout, striped bass, and catfish from some locations). State and local governments have the important role of advising consumers about conditions in particular localities.

The agency is aware that its decision to set the fish tolerance for PCB's at 2 ppm, rather than leaving it at 5 ppm or reducing it further to 1 ppm, is inherently judgmental in character. Section 406 of the act provides no formula for balancing public health protection against loss of food, and, hence, there is no way for the agency's decisions under section 406 to be arrived at mechanically or quantitatively or to appear clear-cut in every case. In this case, for example, forceful arguments have been made in the comments in support of both a 5 ppm and a 1 ppm tolerance, but those arguments all reflect the subjective" judgments of those who made them. In the end, the agency has been mandated by the Congress to make its own informed judgment about what is necessary to protect the public health. It has done that herein setting the fish tolerance at 2 ppm.

The statute provides an opportunity for a public hearing on the agency's order lowering the PCB tolerance for fish. Such a hearing would provide persons adversely affected by the order an opportunity to present any additional evidence they may have bearing on the matters that influenced the agency's judgment. As always, the agency is prepared to reevaluate its position in light of evidence adduced at a hearing.

D. Other Comments on the Fish and Shellfish Tolerance

In addition to the points addressed above, the comments raised several other points relating to the tolerance for fish and shellfish:

1. One comment recommended that FDA review its entire mechanism for handling recurrent problems of environmental contaminants in fish. The comment stated that the PCB tolerance should remain at 5 ppm for marine fish because the levels in those fish are low enough that a reduction to 2 ppm would have no increased protective effect, but would result in economic problems that are unnecessary for species with only occasional high PCB levels. The comment stated further that tolerances should be set for freshwater fish based on their individual place in the market—their tonnage, distribution patterns, and consumption patterns. When such factors combine to present a risk, it was argued, the tolerance should be applied selectively to both the species and the body of water.

The individualized approach to establishing and enforcing tolerances for environmental contaminants suggested by this comment is not feasible because the necessary species-by-species, location-by-location data on PCB occurrence do not exist. Furthermore, many lots of fish, as currently packaged and shipped, do not bear the water-of-origin information required for the recommended regulatory approach. These limitations make it necessary for the agency to establish tolerances for fish on a generic basis. The result is a uniform regulatory approach for all species, which provides clear and fair rules for all segments of the fishing industry and is necessary to ensure that uncertainties and limitations in data will not result in increasing human exposure to PCB's. To the extent that certain species only occasionally have PCB levels above 2 ppm, the economic impact of the reduced tolerance will be slight.

2. One comment stated that any FDA regulatory action regarding PCB's in fish should apply to sport fish as well as commercial fish.

FDA's regulatory authority extends only to foods shipped in interstate commerce and clearly does not extend to fish caught and consumed by individual sport fishers. FDA cooperates with the State agencies who have authority over sport fishing by sharing data and views regarding toxicological, analytical, and compliance matters, but FDA has no direct control over the regulatory approaches adopted by the States. As noted, however, the agency urges State and local health officials to look closely at the PCB problem in their areas and take whatever steps they find necessary to address those aspects of the PCB problem, such as the exposure of sport fishers, that are beyond FDA's authority.

3. One comment requested reconsideration of the proposal to reduce the fish tolerance on the ground that overall ingestion of PCB's is reportedly declining. Because levels in other foods have already decreased considerably, it was argued, there is less need to lower the fish tolerance,

The agency is aware that PCB levels in foods other than fish have declined and that overall PCB intake is lower than it was in 1973, when the original temporary tolerances were established. However, as discussed in the preamble to the proposal and in section II of this preamble, toxicological considerations now make it desirable to reduce dietary exposure to PCB's even further. Reduction of the tolerance for PCB's in fish will bean especially effective step toward accomplishing that goal, because fish are the one remaining significant source of dietary exposure to PCB's.

4. One comment contended that fish products are being subjected to an entirely different regulatory standard than are poultry products, with no reasonable basis for the different treatment. The comment stated that the emphasis in establishing 2 ppm as the tolerance for fish appears to have been safety to the consumer despite a considerable economic impact. Yet, it argued, the higher level of 3 ppm for poultry is based on economic considerations relating to feed contamination, apparently without public health considerations. The comment went on to state that the average per capita consumption of fish is 19 grams (g) per day compared to 63 g per day for poultry products. According to the comment, this means that under the proposed tolerances, and assuming maximum permissible levels in all foods, the average person will receive five times as much PCB's from poultry as from fish.

The agency does not agree with the comment's contention that the considerations involved in establishing the tolerances for poultry and fish result in different or conflicting regulatory approaches for these products, First, the 3 ppm tolerance for poultry is based on PCB residues in the fat of the bird, not in all the edible tissue as it is for fish, Poultry generally averages about 10 percent fat; hence, the 3 ppm tolerance is comparable to a level of about 0.3 ppm for the entire edible portion. Thus, even taking into account the higher average level of chicken consumption and assuming all foods contain maximum permissible amounts of PCB's, poultry will actually be regulated at a level that will result in a substantially lower intake of PCB's from poultry than from fish. Second, data show that detectable PCB residues occur so infrequently in poultry that exposure to PCB's from that source is already at an insignificant level. Hence, further reduction of that tolerance would not significantly reduce dietary exposure to PCB's and would not enhance protection of the public health, Fish data, on the other hand, show frequent occurrence of PCB residues at significant levels, so that reduction of the tolerance will result in increased protection for consumers of fish.

As explained in the preamble to the proposal (42 FR 17491-2), the agency selected 3 ppm (fat basis) as the

tolerance for PCB's in poultry to allow for the regular use of poultry feed contaminated up to, but not exceeding, the 0.2 ppm tolerance for PCB's in poultry feed. (0.2 ppm is the lowest feasible tolerance for PCB's in poultry feed because of limitations on analytical cap ability.) The 3 ppm level took into account the biomagnification of PCB's in poultry that results from regular feeding with poultry feed contaminated up to, but not **above,** 0.2 **ppm.** The agency reasoned that it would be inconsistent to set tolerances on two products at levels such that the use of one product that complies with the applicable tolerance causes the second product to be illegal and, thus, that it would be inappropriate to do so in the absence of other overriding considerations [e.g., safety). For the reasons stated in the preceding paragraph, the 3 ppm tolerance for poultry adequately protects the **public** health and is thus consistent as a matter of public health protection with FDA's other tolerances for PCB's.

5. One comment stated that any decision to lower the fish tolerance made in reliance on the regulation of point source discharges and manufacture of PCB's should not fail to consider the fact that PCB levels in contaminated waters are not expected to decline for many years.

The agency is aware that, despite Environmental Protection Agency (EPA) antipollution activities and the resulting gradual decline in PCB levels in at least some contaminated waters, there will continue to be a significant occurrence of PCB's in fish for at least the next several years because of the stability and persistence of the PCB's now contaminating the environment. That fact was taken into account in deciding to reduce the tolerances.

6. One comment stated that, because pollution of water with PCB's is expected to continue, PCB levels in fish will continue to rise, and susceptible fish should be harvested now before the increased contamination makes them all inedible.

Although the levels of PCB's in waters currently contaminated may not decrease substantially in the near future, the agency does not expect those levels to increase, nor does it expect the levels of PCB's in fish to increase. Better control of PCB levels should result from efforts by the EPA and industry to control discharge of additional PCB's into the environment. Hence, even if it were possible to harvest whole species of fish now, that step would not have the effect of preventing increased future exposure to PCB's. Finally, FDA has no authority to regulate the pace at which particular *species* of fish are exploited commercially.

7. Several comments stated that the decision to reduce the tolerance for fish should be reconsidered and the current 5 ppm level reaffirmed because PCB's are being steadily eliminated from the environment and may be expected to disappear as a significant problem within the next decade.

The agency does not agree that PCB's can be expected to be an insignificant problem within 10 years. Although EPA's continuing activities have resulted in a significant decrease in the amount of PCB's being introduced into the environment especially into water, the stability and persistence of these chemicals and the likelihood that some amount of additional contamination will continue to occur from waste disposal sites ensures that PCB contamination will remain a problem for the foreseeable future. Moreover, that PCB levels are declining (i.e., that PCB's are becoming more avoidable) is a reason to consider lowering the tolerance. not a justification for leaving it unchanged.

8. One comment argued that the decision to reduce the fish tolerance should be reconsidered because by lowering the fish tolerance, thereby preventing consumption of contaminated fish, some might be led to believe that the problem of exposure to PCB's had been solved. This misconception could in turn reduce the pressure to attack the real problem—pollution, However, the comment argued, if the environmental contamination itself is viewed as the "real" PCB problem of importance, changing the fish tolerance is almost irrelevant, given the small quantity of PCB's affected.

PCB contamination of the environment is itself an important part of the PCB problem because, as discussed in the preamble to the proposal *(42 FR 17469-90),* some human exposure to PCB's comes from the air and water, though the amount is probably minimal. EPA is addressing that part of the problem. However, FDA disagrees with the view that exposure to PCB's from dietary sources is insignificant in comparison to the amount of exposure from the air and water. The agency has based the proposed tolerance reductions on its conclusion that dietary exposures to PCB's pose significant risks to consumers, which can be reduced by reducing exposure. That there is some exposure to PCB's from other sources is not a good reason for withholding action that can significantly reduce dietary exposure.

9. Two comments **requested FDA** to hold a public hearing before finalizing reduction of the fish tolerance.

The agency does not consider a public hearing on the fish tolerance to be necessary or appropriate at this time. Tolerances are established under section 406 of the act under the formal rulemaking procedures set forth in section 701(e) of the act (21 U.S.C. 371(e)). Under those procedures, any person adversely affected by this order may file objection within 30 days and request an evidentiary hearing on the issues raised by those objections. The opportunity for a hearing ensures that all genuine, material issues relating to the PCB tolerances will be fully aired. Holding a hearing before issuing this order would only duplicate the opportunity for a public hearing already available in formal rulemaking and unnecessarily delay the proceedings.

10. One comment stated that the 5 ppm tolerance for PCB's in fish should be retained but requested that FDA provide guidance to State agencies regarding use or implementation of the 2 ppm tolerance if it is adopted.

As noted, FDA provides data and views to the States on a range of matters related to implementation of tolerances for PCB's in food and will continue to do so.

11. One comment asked whether procedures other than reducing the fish tolerance have been evaluated as alternative means of reducing intake of PCB-contaminated fish.

The agency has considered the use of general public warnings and/or labeling as ways to limit consumption of contaminated fish. Such approaches have been rejected, except as they apply to certain heavy consumers of contaminated sport fish (discussed above]. A public warning **about fish** generally, or even about particular species of fish, would not be effective in protecting the general public from commercial fish because, assuming no changes are made in labeling, consumers have no way to determine the species or waters of origin of most commercially prepared fish products. In addition, general public warnings might unduly discourage consumption of fish, most of which is safe to eat and nutritious. Similarly, the requirement of warning labels on fish products in lieu of a tolerance, even on a species-specific basis, is not a sufficiently precise regulatory approach because not all fish from even the most heavily contaminated species contain levels of PCB's above the 2 ppm tolerance level.

Thus, as with general public warnings, warning statements on labels are likely to discourage consumption of safe fish.

12. Some comments contended that most Americans would probably prefer to be warned of the potential danger from PCB residues and retain the option of eating freshwater fish, rather than be deprived of any choice in the matter by having the fish removed from the market.

The agency acknowledges that some people would probably prefer to be left with the choice of whether to consume fish contaminated with PCB's above the 2 ppm level. As noted, however, the consumer of commercially marketed fish generally lacks the information on water-of-origin, size, and sometimes even species that is needed to control his or her intake of PCB's. Under these circumstances, there is no genuine opportunity to exercise informed choice. Moreover, the agency believes that as a general matter it is obligated under section 406 of the act to exercise its scientific judgment and determine what level of exposure, and thus what tolerance level, will provide an adequate degree of public health protection,

13. One comment referred to the agency's decision not to reduce the temporary tolerances for infant and junior foods and for animal feeds on the ground that the current tolerances are "at the lowest level at which PCB's can be reliably determined for enforcement purposes" and argued that lowering the tolerance for fish would probably create much greater economic hardship than would developing and using more sensitive analytical methods so that other tolerances could be lowered,

The agency acknowledges that the fish losses resulting from a 2 ppm fish tolerance would probably be greater than the costs of developing and using the more sensitive enforcement analyses that would be necessary for a reduction of the other tolerances. The occurrence of PCB residues in infant and junior foods and animal feeds is now so infrequent, however, that those foods do not contribute significantly to dietary exposure to PCB's. Thus, spending the resources to develop more sensitive methodology and thereafter reducing the tolerances for these foods would not significantly increase the protection of consumers, and it still would be necessary to reduce the fish tolerance, Because PCB's do occur consistently at significant levels in some fish, the reduction of the fish tolerance can provide increased protection for consumers.

14. Some comments included requests for compensation for commercial fishers and processors whose livelihoods are destroyed by reduction of the fish tolerance. One comment asked, in effect, that the effective date of the tolerance reduction be delayed for 10 years so fishers would have time to adjust economically.

For reasons discussed earlier in this document, the agency considers it unlikely that the reduction of the fish tolerance to 2 ppm will have the dire consequences on which these comments are premised. Moreover, FDA has neither the authority nor the resources to provide compensation for economic losses that might be suffered as a result of regulatory actions it takes. The proposed 10-year postponement of the effective date would be inconsistent with the agency's conclusion that a reduction of the tolerance is necessary to protect the public health.

15. A number of comments were concerned that if the 2 ppm tolerance for fish is adopted, FDA will close certain waters to fishing or prohibit fishing of certain affected species in certain waters. They requested that more studies be carried out before determining whether such steps should be taken.

The concern underlying these comments is misdirected, FDA does not have authority either to close waters to fishing or to prohibit harvesting or possession of fish. Any actions to close waters to fishing would have to be instituted by State agencies.

16. One comment suggested that if the 2 ppm tolerance is adopted, the counties affected should be allowed to conduct more comprehensive testing of residue levels in the fish before any ban or impoundment of fish in interstate commerce is imposed.

In enforcing the fish tolerance, FDA will sample and analyze individual lots of fish in interstate commerce and take regulatory action against lots, or the shippers of lots, that exceed the tolerance, There is nothing to prohibit any interested party, including local and State authorities, from conducting comprehensive testing of fish before shipment in interstate commerce and from withholding from commerce fish that exceed the tolerance.

17, One comment suggested that the proposed 2 ppm tolerance for PCB's in fish is inadequate for protection of public health, The comment stated that the tolerance levels must be based on the "no-effect" level observed in-the most sensitive animal species for which toxicological data are available, and it suggested that the rhesus monkey is more sensitive to PCB's than the dog or rat.

This comment is based on an apparent misunderstanding of the toxicological rationale underlying the 2 ppm fish tolerance. In evaluating the safety of substances in food, FDA ordinarily attempts to determine the "no-effect" level for the substance, i.e., the highest level of exposure at which no adverse effect is observed in appropriate animal studies, It then uses appropriate safety factors to extrapolate the results of the animal studies to the human situation and determine safe levels of human exposure. In this case, however, the reduction of the fish tolerance is not based on any "no-affect" level, It is based instead on a body of data that associate PCB exposure with several serious chronic effects but that do not permit the establishment of "no-effect" levels for those effects, Thus, the comment's argument that one species is more sensitive to PCB's than another and that the tolerance should be based on the "no-effect" level observed in the most sensitive animal species is not relevant to the toxicological rationale the agency relies on for reducing the PCB tolerance to 2 ppm.

18. One comment disagreed with the proposal to establish a 2 ppm tolerance for fish instead of a 1 ppm tolerance. One ppm is the lowest level of PCB residues in fish for which there is analytical methodology suitable for enforcement purposes. The comment stated that toxicological information, especially that suggesting the carcinogenicity if PCB's coupled with the presence of PCB residues in human milk, requires the lowest possible tolerance.

With respect to the carcinogenic potential of PCB's, NCI has concluded that PCB's (specifically, Aroclor 1254, the commercial PCB most similar chemically to the PCB residues in fish) are not carcinogenic in Fischer 344 rats under the conditions of the bioassay (Ref. 47). After thoroughly reviewing NCI's report, the Data Evaluation/Risk Assessment Subgroup of the Clearinghouse on Environmental Carcinogens accepted the report's conclusion that PCB's were not demonstrated to be carcinogenic in that study, but suggested that PCB's might act as a tumor promoter. For the reasons discussed in the preamble to the proposal (42 FR 17489), FDA considers the question of the carcinogenicity of the PCB's unresolved. For the purposes of its risk assessment on PCB's (Ref. 44), however, the agency treated the various PCB's as though they were carcinogenic,

and it considers the carcinogenicity of PCB's to be a matter worthy of further serious inquiry.

The agency has long been concerned with the exposure of nursing infants to PCB's in human breast milk. This, too, is an area in which more must be learned before definitive statements can be made about the incremental risks posed by this particular avenue of exposure. For reasons discussed earlier in this document, however, the agency considers a 2 ppm tolerance adequate to protect all but those who consume above-average amounts of the more heavily contaminated species.

111. Response to Comments on Other Aspects of PCB's

Following are the agency's responses to the comments that did not specifically address the reduction of the fish tolerance:

1. Some comments recommended that the government regulate PCB's only in the environment rather than in food products. Another comment suggested that the limits on PCB's in foods not be reduced until PCB levels have been reduced in the environment, where the foods are produced.

EPA has the authority to control environmental pollution and has already taken important steps to prevent further pollution by PCB's. Some environmental contamination with PCB's already exists, however, and will undoubtedly persist for some years. FDA would be failing in its duty to protect the public health if it withheld the actions necessary to minimize human exposure to PCB's from dietary sources until the long-term problem of environmental contamination has been solved.

2. One comment asserted that the primary toxicological basis upon which FDA established the temporary tolerances for PCB's in *1973 (38 FR 18096)* consisted of two long-terms feeding studies in rats and dogs that were performed by the same testing laboratory and that demonstrated a "no-effect" level for PCB's at 10 ppm. This comment also suggested that these same two studies serve as the primary basis for the current proposal to reduce those original temporary tolerances: The comment stated that discrepancies and inconsistencies have recently been found in these two feeding studies, as well as in other unrelated studies from the same testing laboratory, which would indicate that toxic effects might actually have been produced in both rats and dogs, at dietary levels as low as *1* ppm. The comment requests that FDA extend its audit of the testing laboratory in question to include a review of the data obtained in the two toxicity tests of PCB's in rats and dogs. The comment suggested that FDA reconsider the proposed temporary tolerances on the basis of a reevaluation of the data from the two long-term studies and, if judged necessary, propose new tolerances or reopen the matter for public comment.

Though the data from the two long-term toxicity studies of PCB's in rats and dogs referred to in the comment were considered, the human toxicological data formed the primary basis for developing the original temporary tolerances for PCB's. This fact was stated in the July 6, 1973 document establishing the tolerances and in the preamble to the April 1,1977 proposal to reduce some of the tolerances.

The agency is aware that doubt has been cast on the validity of the two long-term toxicity tests of PCB's in rats and dogs referred to in the comment, as well as on the validity of numerous unrelated toxicity tests performed by the laboratory facility in question (Ref. 48). Therefore, the results from these two tests are no longer considered worthy of reliance and, as explained earlier in this document, these studies played no part in the agency's decision to lower the PCB tolerances.

3. One comment asserted that the agency's statement in the preamble to the proposal that it was unaware of any consumers who had suffered deleterious effects caused by PCB ingestion (42 FR 17491) is misleading, in that the statement actually reflects a lack of knowledge rather than awareness of the results of properly designed epidemiological studies.

In making this statement the agency relied on, the results of an epidemiological study carried out with sport fishers in Michigan that failed to establish a correlation in humans between the ingestion of PCB's and the occurrence of deleterious effects (Ref. 40). The study is discussed in the preamble to the proposal (42 FR 17492-3). The only purpose of the statement was to cite an instance in which relatively high exposure to PCB's in fish had not resulted in overt, *acute* toxic effects, such as occurred in the Yusho incident in Japan *(42 FR 17488). The* Michigan example was intended to illustrate the observation the agency made in the preamble to the proposal that the *amount* of PCB's in environmental samples required to cause Yusho-type effects is not known. This study has no direct bearing on the agency's conclusion that the chronic effects of PCB's require a reduction of the tolerances,

4. One comment opposed reduction of the temporary tolerance for PCB's in eggs on the ground that there are no substantial data that suggest that the current temporary tolerance is not sufficient to protect consumers of eggs. The comment contends that lacking such evidence, there is not justification for reducing the tolerance.

The agency acknowledges that the data indicate that eggs do not contribute measurably to dietary PCB exposure and that reduction of the egg tolerance will not significantly affect PCB intakes. However, tolerances established under section 406 of the act are intended to permit only those residues that are unavoidable. Because the available data indicate that residues above the analytical limits in eggs are avoidable and because no evidence was presented to the contrary, it is appropriate to reduce the temporary tolerance for PCB's in eggs as proposed.

5. One comment requested that the temporary tolerances for PCB's in animal feed be reduced, but it did not present a rationale to justify reduction.

The presence of PCB's in animal feed is of concern because PCB's transfer and accumulate in human food products derived from animals that consume contaminated feed. The tolerance for finished animal feed is currently set at 0.2 ppm—the lowest level at which available analytical methodology can measure PCB's in animal feed for enforcement purposes. It would serve *no* useful purpose to reduce the tolerance below this level in the absence of analytical methodology for enforcing a reduced tolerance. Moreover, in light of the rare occurrence of PCB's in animal feeds, the agency considers the *0.2* ppm level to provide an adequate degree of public health protection, For these reasons, the agency declines to reduce the tolerance for PCB's in finished animal feed.

IV. "Temporary" Status of the Tolerances

As currently codified in § 109.30, the tolerances for PCB's are designated as "temporary," The term "temporary" was used to reflect the fact that the tolerances are subject to revision as new data become available. In the preamble to the proposal for reducing the tolerances, the agency stated that it would retain the "temporary" designation because of the possibility that further downward revisions of the tolerances might be necessary (42 FR 17493). The agency has now reconsidered this use of the term "temporary" and has decided to abandon it. The term has never had any

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legal significance as applied to tolerances established under section 406 of the act, and its use is not provided for in FDA's procedural regulations governing tolerance setting in Part 109 (21 CFR Part 109). When circumstances are changing so rapidly that a particular tolerance level is likely to be rendered inappropriate in the near future, the agency establishes an action level rather than a tolerance (see § 109.6(c) (21 CFR 109.6(c))). In the case of PCB's, however, the agency has concluded that formal tolerances are appropriate. The term "temporary" is being abandoned to avoid the suggestion that the legal status of the PCB tolerances is something other than that of a formal section 406 tolerance.

Any FDA tolerance, just like any other regulation, is "temporary" in the sense that it is subject to reevaluation and, if necessary, revision as new data become available. The agency will continue to monitor the PCB problem and, if appropriate in light of changing circumstances or new data, will propose revisions in the PCB tolerances.

V. Analytical Methodology

Section 109.30(b) has been revised to refer to FDA's updated compilation of analytical methodology for PCB's "Analytical Methodology for Polychlorinated Biphenyls, June 1979." There have been improvements in the analytical methodology for measuring PCB residues since 1973, and most of the revised procedures have now been published in scientific journals. A copy of each procedure or a reference to the appropriate journal is provided in the updated compilation. As stated in § 109.30(b), the compilation is available from the Hearing Clerk, Food and Drug Administration, Room *4-65, 5600* Fishers Lane, Rockville, MD *20857.*

VI. References

The preamble to the proposal cited 42 references the agency relied on in developing the proposal and stated that those reference documents had been placed on file with the Hearing Clerk, FDA *(42* FR 17493-4). The following additional references, which are cited in the foregoing preamble, have also been placed on file with the Hearing Clerk, FDA, Rm. *4-85, 5800* Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

43. DuBois, K. P. and E. M. K. Ceiling, "Textbook of Toxicology," Oxford University Press, 1959, pp. 24-28.

44. Ariens, E. J., A. M. Simonis, and J. Offermeier, '*Introduction to General Toxicology," Academic Press, 1976, pp. 124-31.

45. An Assessment of Risk Associated with the Human Consumption of Some Species of Fish Contaminated with Polychlorinated Biphenyls (PCB's), 1979, FDA document.

46. Regulatory Analysis for Final Regulation for Reduction of Temporary Tolerances for Polychlorinated Biphenyls in Food, 1979, FDA document,

47. National Cancer Institute Carcinogenesis Technical Report Series No. 38, 1978.

48. Letter from Donald Kennedy, Commissioner of Food and Drugs, to various clients of Industrial Bio-Test Laboratories, Inc., June 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sees. 306, 402(a), 406, 701(a), 701(e), 52 Stat. 1045-1046 as amended, 1049 as amended, 1055, 70 Stat. 919 as amended (21 U.S.C. 336, 342(a), 346, 371(a), 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5,1), Part 109 is amended in $109,30 by revising the section heading and paragraphs (a)(l), (2), (3), (4), and (7] and (b) to read as follows:

$109.30 **Tolerances** for **polychlorinated biphenyls** (PCS'S).

(a) • • •

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

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

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

(4) 0.3 part per million in eggs.

• * * * *

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

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(b) For determining compliance with the tolerances established in this section, a compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, June 1979" is available from the Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 1–65, 5600 Fishers Lane, Rockville, MD 20857,

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Any person who will be adversely affected by the foregoing regulation may at any time on or before July 30, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD *20857,* written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation, Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective *date.* This regulation will become effective for foods initially introduced into interstate commerce after August *28, 1979* except as to any provisions 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,

[Sees. 306, 402(a), *408,* 701(a), 701(e), 52 Stall 1045-1046 as amended, 1049 as amended, 1055, 70 Stat. 919 (21 U.S.C. 336, 342(a), 346, 371(a], 371(e)])

Dated: June 26, 1979.

Donald Kennedy,

Commissioner of Food and Drugs.

[FR Dec. 79–20266 Filed 6–28–79; 8:45 am]

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