Craddock, Jim Wilson

PCB 2 P.P.M. FISH TOLERANCE BECOMES EFFECTIVE IN 90 DAYS

The Food and Drug Administration on May 22 lifted the stay from the 2 p.p.m. tolerance for polychlorinated biphenyls in fish, as expected (See FOOD CHEMICAL NEWS, May 21, Page 2), announcing that the tolerance will go from 5 p.p.m. to 2 p.p.m. in 90 days.

FDA Acting Commissioner Dr. Mark Novitch concluded "that a tolerance of 2 p.p.m. for PCBs in fish and shellfish adequately protects the public health, while not causing excessive loss of food to American consumers."

In exceptions to the initial decision to lower the tolerance, the National Marine Fisheries Service urged a tolerance of 3.5 p.p.m., and the National Fisheries Institute and General Electric urged retention of the 5 p.p.m. tolerance. Rejecting these recommendations, Novitch said:

> ". . . I believe it is important to keep in mind that a decision to set the tolerance at 2 p.p.m., rather than at some other higher or lower level, is inherently judgmental in character. . . . §406 of the Act does not provide a formula for weighing public health concerns against loss of food. In the final analysis, as Commissioner of the agency charged by Congress with protecting the public health in this area, I must make an informed judgment in the light of the statutory criteria. My judgment is that 2 p.p.m. is the appropriate tolerance."

FDA in 1977 proposed lowering the tolerance from 5 p.p.m. to 2 p.p.m. (See FOOD CHEMICAL NEWS, April 4, 1977, Page 6). The 2 p.p.m. tolerance was set in 1979 (See FOOD CHEMICAL NEWS, July 2, 1979, Page 12), but it was stayed because of a hearing request from NFI. Parties to the hearing were NFI and FDA's Bureau of Foods (now the Center for Food Safety and Applied Nutrition), with participation from NMFS. The Environmental Defense Fund had filed a notice of participation in the 1981 hearing, but withdrew from participation.

Administrative Law Judge Daniel J. Davidson issued his initial decision recommending the 2 p.p.m. tolerance in 1982 (See FOOD CHEMICAL NEWS, Feb. 15, 1982, Page 37). Exceptions were filed by the Bureau and NFI, and briefs were also filed by these parties plus NMFS, EDF, the Chemical Manufacturers Association, General Electric, and the State of Michigan.

The issue of the hearing was the amount of food that would be lost under the lower tolerance. Differing from both FDA's initial estimate of the food loss and Judge Davidson's estimate, Novitch concluded:

> ". . . The annual dockside human food loss is $13.5 million, rather than the $9.6 million estimate stated in the preamble to the final rule. I have further concluded that the Risk Assessment supporting the final rule continues to be valid in light of newly submitted scientific information. The only question that remains is whether a balancing of the unchanged public health considerations and the increased human food loss yields a tolerance greater than 2 p.p.m. I conclude that the answer is no. I conclude that, even with an estimated human food loss of $13.5 million rather than $9.6 million, 2 p.p.m. is nevertheless the proper balance between public health protection and loss of food.
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> "I believe that we should keep in mind the fact that total annual domestic landings of fish are almost $1.6 billion. Thus, the total human food loss is less than 1% of all domestic landings."

An FDA-er last week noted that Novitch "determined that the cost should indeed be figured at dockside," reasoning "that fishermen, not canners and retailers, will bear the brunt of the loss in unsellable fish -- primarily some whitefish, chubs, catfish and striped bass in the Great Lakes."

Davidson had approximated the loss at $86.7 million, determining the loss at 2 p.p.m. by subtracting the loss at 5 p.p.m. from the loss at 2 p.p.m. and applying a multiplier of six to derive retail value from dockside value.

The Administrative Law Judge said no human food loss from imports could be determined, and NFI filed objections on that point, saying there is a loss of $31.4 million. Concluding "that no food loss can be attributed to imports," Novitch said imported lobster samples were found to contain no significant levels of PCBs, and that there was no testimony on PCB levels in other imported fish or shellfish.

Although the Acting Commissioner conceded "that FDA's samples may have included imports," he said that "any finding concerning a specific human food loss due to imported fish would be speculative."

Davidson did not estimate loss because of companies which might become "unviable," and NFI filed an exception to this point, claiming a $51.6 million loss. Supporting the Administrative Law Judge's conclusion, Novitch said "NFI has not substantiated its claimed loss due to unviable fisheries."

A position paper submitted by NFI assumed that a fishery would become unviable if the percentage of the catch exceeding a 2 p.p.m. tolerance went above 25%. Novitch said the 25% trigger would apparently only apply to Great Lakes fisheries, and that the position paper included calculations on striped bass and lobster, which are not found in the Great Lakes. Estimating the catfish loss would be below the 25% trigger level and eliminating the two marine species, Novitch said "a loss for unviable fisheries can be calculated only with respect to trout." He continued, "Even if I were to include any loss due to unviable fisheries, it would only be $179,000."

Davidson found that reducing the tolerance to 2 p.p.m. would result in an annual loss of alewives with a dockside value of $834,900, but the Bureau filed an exception saying no loss should be attributed to alewives. Rejecting the Bureau's position, Novitch supported Davidson's estimate.

In its proposal, FDA had stated that the processed value of fish is about 7 times its dockside value, but the Bureau during the hearing urged consideration of only the dockside value. NFI stated that FDA was bound by the multiplier of 7. Davidson based his initial order on retail value, using a multiplier of 6. The Bureau filed exceptions stating that the multiplier should be 1 or 3.

Novitch concluded "that it is appropriate to measure human food loss in dockside value, rather than value after processing or retail value." He noted that the decision to lower the tolerance was based on the assumption that the resulting human food loss would have a landed value of $9.6 million.

The Administrative Law Judge found that there would be a $6 million annual cost due to the "elasticity effect," reasoning that lowering the tolerance would increase the value of the fish remaining on the market by no more than that amount. The Bureau filed an exception, but NFI supported Davidson's position. Novitch threw out the "elasticity effect."

Declining to make any findings about human food loss at tolerances between 2 p.p.m. and 5 p.p.m., Novitch concluded that the loss at 2 p.p.m. is $13.5 million. Noting that

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NFI called for a broader inquiry on economic costs, while EDF argued that economic considerations could not play a significant part in the rulemaking, Novitch said:

> ". . . The agency's paramount consideration in establishing a tolerance is protection of the public health. FDA is authorized by §406 of the Act to consider the unavoidability of substances such as PCBs. It is in connection with the unavoidability of PCBs that human food loss, and thus the limited issue of the value of the food loss, are relevant."

Although the food loss issue was the basis of the public hearing, Novitch also considered the scientific issue of PCB toxicity, basing his conclusions on "a review of all submissions on the health effects of PCBs in connection with the rulemaking. . .," prepared by Dr. Phillip A. Johns, a toxicologist in FDA's Office of Science Coordination.

The report concluded: "The relevant data submitted in response to a request for additional data on health effects of PCBs support the findings and conclusions of the risk assessment that a reduction of the tolerance for PCBs in fish and shellfish from 5 p.p.m. to 2 p.p.m. would reduce the risk of liver cancer."

Johns explained that FDA's risk assessment, using National Cancer Institute data, estimated that the upper limit on the lifetime risk of cancer for heavy consumers of fish most affected by the tolerances would be reduced from 9.8 incidences of cancer per 100,000 of the population at a tolerance of 5 p.p.m. to 7.2 per 100,000 at 2 p.p.m. The estimates for average consumers of such fish were 3.7 per 100,000 at 5 p.p.m. and 2.7 per 100,000 at 2 p.p.m.

The toxicologist wrote that, "Generally, newly submitted data relating to the safety of PCBs to humans support the conclusion of the risk assessment," adding that "no data were submitted that significantly refute the findings of the risk assessment." Reviewing studies, Johns found:

"(1) No data were submitted that refute the conclusions of the assessment of risk of carcinogenesis from PCBs.

"(2) Additional data were submitted that support the conclusions of the risk assessment. These include studies that show: (a) liver is a target organ in rodents, non-human primates and humans; (b) adverse liver function was observed in non-human primates and humans; increased liver weights were observed in rodents and primates; (c) liver nodular hyperplasia, hepatoma and cholangiohepatoma were observed in rats; (and) (d) PCB-moieties were found apparently covalently bound to macromolecules in rat hepatocytes.

"(3) No data were submitted that refute or alter the conclusions and speculations of potential reproductive risks considered in the risk assessment.

"(4) A no adverse effect dosage level for the observed reproductive and toxic effects in Rhesus monkeys has not been determined. These effects raise concerns about PCB toxicity in addition to carcinogenesis.

"(5) In terms of reproductive effects, the subhuman primate appears to be more sensitive than the rodent; more data are required to determine the sensitivity of the primate to carcinogenic activity of PCBs.

"(6) The exposure to PCBs in fish and shellfish is in addition to the other human exposures already existing from milk, manufactured dairy products, eggs, poultry, and other sources."

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Novitch said there was "good cause for including in the rulemaking record all newly submitted reports and studies that are not presently part of the record." He rejected a suggestion from NMFS that the Bureau's submissions not be included in the rulemaking record.

Saying that he agrees with the Johns review and adopts the report as part of his final decision, the Acting Commissioner disagreed with briefs from NFI and General Electric which took the position that potential health risks from PCBs are overstated.

Noting that NFI argued that FDA's concerns are unfounded because PCBs are only a cancer promoter and not an initiator, Novitch said, "Presently there is no consensus in the scientific community regarding the mechanisms of initiation and promotion." However, he added, ". . . Regardless of whether PCBs are promoters or initiators, I believe the data indicate that PCBs present a significant potential risk to our population." Discussing a study of human consumption of Lake Michigan fish contaminated with PCBs, cited by NFI and General Electric, Novitch said:

> "Although no adverse health effects or groups of symptoms that were clearly related to PCB exposure could be identified in the exposed group, the investigators reported a highly significant correlation between the quantity of Lake Michigan fish consumed and the concentration of PCBs in the blood of study participants. It is significant that abstinence from Lake Michigan fish consumption for a period of 90 days did not significantly change PCB blood levels. Moreover, the study's authors cautioned that the absence of any adverse health effects similar to those effects observed in workers exposed to PCBs does not exclude the possibility that long term effects will occur.
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> "NFI states that occupational exposure to PCBs at levels very much higher than would be experienced by those ingesting contaminated fish 'leads to some health problems but not cancer or chronic health problems.' FDA has identified a potential risk of PCB-induced hepatocellular carcinoma and adenoma by use of data from rodent carcinogenicity bioassays. This risk is supported by data in non-human primates and man indicating that the liver is a target of PCBs. There are also reports that an increased incidence of cancer has been observed in workers exposed to PCBs. Although the incidence is low and a cause-and-effect relationship has not been established, these data -- coupled with the fact that cancer has a long latent period -- support the conclusion that chronic exposure to PCBs through the diet poses a potential risk."

Noting that General Electric questioned extrapolation of animal data to man, Novitch said, "There is general consensus among scientists that properly conducted animal studies are useful in the assessment of human health risks." He added that "a review of the available carcinogenesis data in 1978 compared the responses of man, monkey, and rat to PCBs and concluded that hepatic hypertrophy was one of the responses common to all species."

Conceding that "remaining unanswered questions about the human responses to PCBs probably will be resolved only by valid human data," Novitch said that "submitted data not available at the time of the risk assessment underscore the agency's concerns about PCBs and support the hypothesis that the human liver is a target of PCBs and may be adversely affected by exposure to PCBs."

GE pointed out that PCB-induced morphological changes in the gastric mucosa of monkeys are not reported in rodents or other species, and that there are no clinical findings

suggesting increased occurrences of stomach cancer in man. Novitch commented that "GE's suggestion misses the point, as the human liver, not the stomach, is the principal source of concern."

Conceding that "the question of whether PCBs are carcinogenic still has not been fully resolved," the Acting Commissioner said "results of studies completed since the risk assessment support its conclusion that the liver is a target organ for PCBs in the rodent and that hepatocellular carcinoma or adenoma can result from PCB ingestion."

Novitch said that "there is agreement among scientists that induction of hepatocellular carcinomas early in the course of a bioassay is indicative of carcinogenicity under bioassay conditions," adding that "the occurrence of hepatocellular tumors in more than one species and/or more than one sex gives added weight to a finding of carcinogenicity."

General Electric questioned any "serious risk of teratogenesis to human beings," a question which was raised in the risk assessment based on a study with Rhesus monkeys. Novitch said:

> "These concerns continue because a subsequent report of behavioral tests with the infant Rhesus monkeys who survived that study indicated increased errors in five of nine learning tasks at ages 8 and 24 months, even though they were no longer nursing. During that period, tissue concentrations of PCBs in those infant monkeys decreased linearly with time. This suggests that PCBs may cause irreversible neurobehavioral abnormalities. Additional support for this concern is provided by the results of a study in minks in which PCBs at 2 p.p.m. in the diet caused complete reproductive failure."

Based on a study of PCBs in human milk in Michigan, General Electric contended there were no serious effects on reproduction or infant mortality. However, Novitch said that, "That study does not support GE's contention, because it did not purport to collect data concerning adverse health consequences to any of the donors." He added that the study did demonstrate "that PCBs have been found in human milk at levels. . . almost the same as those levels found in the milk of Rhesus monkeys whose infants displayed significant signs of toxicity."

GE contended that the observed increase in enzyme activity is of no consequence to health over an individual's lifetime, but Novitch responded that, "The fact that an increase in enzyme activity in the human liver was observed supports the conclusion that the liver is a target organ of PCBs in human beings and more generally underscores FDA's concerns about the safety of PCBs to human health."

Novitch rejected an objection by NFI that the hearing was overly narrow, saying that the hearing involved "precisely the issue" raised by the Institute.

NMFS asked that FDA perform a new risk analysis taking lobster into account, and Novitch said calculations by a Bureau scientist indicated that the overall risk estimates would increase by 1.5% at most.

NFI filed a motion to strike FDA's recalculation of the risk assessment on the grounds that it would not have a chance to rebut the Bureau's calculations. Novitch denied the motion, noting that "the Bureau stated that it would not oppose the submission of any rebuttal information by NFI," which did not submit any rebuttal. The Acting Commissioner also said the recalculation "had nothing to do with the hearing issue. . ."

NMFS asked a new risk assessment to take into account tolerance levels between 2 p.p.m. and 5 p.p.m., offering to work with FDA. Novitch said FDA "must act on the basis of

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existing information, even if incomplete." Acknowledging NMFS' offer of assistance, he said the agency "will consider it in connection with FDA's on-going monitoring of PCBs, and, if necessary, future revisions of the tolerance."

A tolerance of 3.5 p.p.m. was suggested by NMFS. Rejecting this approach, Novitch said:

> "The risk calculations for tolerances between 5 p.p.m. and 2 p.p.m. do not show any sudden decrease in the number of expected cancers below the 3.5 p.p.m. level. Rather, the expected cancer rate drops quickly between 2 p.p.m. and 1 p.p.m. These calculations show that the expected cancer rate is basically an arithmetic progression at levels between 5 p.p.m. and 2 p.p.m. and are consistent with my final decision that 2 p.p.m. is the appropriate tolerance.
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> "Moreover, NMFS' argument is based on a comparison of Judge Davidson's total human food loss findings at 2 p.p.m. and 3.5 p.p.m. As I have already stated, Judge Davidson's human food loss figures for intermediate tolerances are seriously incomplete, such that no meaningful comparisons between 2 p.p.m. and higher tolerances are possible."

NFI said that FDA failed to comply with the Regulatory Flexibility Act and Executive Order 12291. However, Novitch said the Executive Order states that "it does not apply to administrative actions governed by 5 U.S. Code 556 and 557, which apply to rule-makings pursuant to §701(e). . ." He added that the Regulatory Flexibility Act does not "apply to rulemaking initiated before its effective date, Jan. 1, 1981."

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SODIUM BICARBONATE FIRM ASKS SODIUM LABELING STAY, RECONSIDERATION, HEARING

Church & Dwight Co. has petitioned the Food and Drug Administration for reconsideration of the agency's final rule on sodium content labeling of food, a stay of action on the rule's effective date, and for a public hearing, requesting that these actions be considered to pertain to those portions of the rule including provisions for sodium bicarbonate (See FOOD CHECMICAL NEWS, April 23, Page 3).

The firm asked reconsideration of the final rule and modification to exclude sodium bicarbonate in the provisions which: "(1) Establish definitions for the terms 'sodium free,' 'very low sodium,' 'low sodium' and 'reduced sodium'; (2) Provide for the proper use of these terms in the labeling of foods; (3) Provide for the appropriate use of such terms as 'without added salt,' 'unsalted' and 'no salt added'; (4) Specify that sodium content of foods be included in nutrition labeling information whenever nutrition labeling appears on food."

The stay of action was requested on the application of the regulations to sodium bicarbonate until such time as a decision is made on the petition for reconsideration.

In the objections and request for hearing, the firm specifically limited these also to the application of the final rule to sodium bicarbonate, stating that it has no objection to any other portion of the regulation.

Church & Dwight contended that it would be "directly and substantially harmed by inclusion of sodium bicarbonate under §105.69," noting that it is the firm's principal product and is a common ingredient in food products. "If the amount of sodium contributed by sodium bicarbonate is included in sodium calculations required by the regulation,

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