The judge noted that a decision resulting from such an administrative proceeding could be appealed in court.

Intervening in the Hoffman-La Roche case on FDA's side was Internal Medications, for which FDA had approved an NDA covering a generic version of a drug pioneered by one of the plaintiffs under the "paper NDA" policy.

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## PCB WIDESPREAD POISONING INCIDENT IN TAIWAN REPORTED

A Japanese professor of medicine has reported to the National Institute of Environmental Health Sciences that "a mass poisoning by ingesting a commercial rice oil contaminated with polychlorinated biphenyls occurred. . . in Taiwan."

Dr. Masanori Kuratsune, of Kyushu University, on Dec. 11 wrote to NIEHS' Dr. Raymond E. Shapiro that "the poisoning started in March this year involving more than two thousand people."

Kuratsune said he was told that two samples of rice oil "consumed by the victims" contained 65 p.p.m. and 108 p.p.m. of PCBs, and that PCBs in nine blood samples ranged from 54 p.p.b. to 136 p.p.b.

"Epidemiological studies so far conducted there seem to be inadequate and the process of contamination of the oil is not clear yet," the MD wrote, adding that, "Dark colored babies were already noted to have been born."

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## NMFS REITERATES ITS CALL FOR A 3.5 P.P.M. PCB TOLERANCE IN FISH

The National Marine Fisheries Service has reiterated its belief that a reduction of the polychlorinated biphenyl tolerance in fish to 3.5 p.p.m., rather than the 2.0 p.p.m. set by the Food and Drug Administration, would result in a more realistic balance between the protection of public health and loss of food (See FOOD CHEMICAL NEWS, Aug. 27, Page 23; and Dec. 10, Page 7).

NMFS had proposed that the 3.5 p.p.m. tolerance be an initial reduction for a period of two years, to be followed by a reduction to 2.0 p.p.m. if warranted.

Expanding on its earlier comments at FDA's request, NMFS Assistant Administrator for Fisheries Terry Leitzell discussed further risk analyses performed in cooperation with FDA at the 4.5, 4.0, 3.5, 3.0 and 2.5 p.p.m. levels, concluding that the difference in risk between the 2.0 and 3.5 p.p.m. tolerances "appears to be small -- 0.2 - 0.52."

The group also looked at the intake of PCBs from fish for eaters of the species of interest assuming eight different tolerance levels, and pointed out that "small differences in intake are noted between a 2.0 and 3.5 p.p.m. tolerance level." NMFS said, "A tolerance of 3.5 p.p.m. allows an additional inteke of only 1.0 ug/day or 0.01 ug/kg/day."

NMFS noted that the 3.5 p.p.m., rather than the 2.0 p.p.m., tolerance provides a decrease of 81% in the impact on the affected fisheries, with an even greater reduction of 94% observed for the Great Lakes commercial fishery.

The group also submitted a table showing the mean PCB levels in four of the species of interest assuming different tolerances. "As noted before, the mean level for all the species listed is below 2.0 p.p.m. even with no-regulation in place," NMFS stressed, adding that "this is reflected in the low level of intake of PCBs observed for the majority of fish consumers."

Leitzell said NMFS continues to believe more definitive information on the toxicity of PCBs as they occur in fish is needed and offered to cooperatively support additional research in that area.

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## LUBRICANT CLEARANCE IS NOT "AFFIRMATION" OF PVC SAFETY: FDA

The Food and Drug Administration on Jan. 4 cleared use of pentaerythritol adipate-stearate as a lubricant in the fabrication of polyvinyl chloride, but said, "This regulation should not be viewed as an affirmation of the safety of PVC used in food-contact articles."

Noting that its proposal to "prohibit such uses" of PVC is still "under active consideration" (See FOOD CHEMICAL NEWS, Oct. 15, Page 3), FDA said it "has concluded, however, that the ongoing investigation of PVC -- including complex legal and scientific issues regarding indirect additives in general -- should not continue to prevent safe and useful technical improvements in its manufacture."

The new §178.3690 for pentaerythritol adipate-stearate resulted from a Petition filed by Henkel (See FOOD CHEMICAL NEWS, March 26, Page 2). It cleared use of the lubricant in the fabrication of rigid and semi-rigid polyvinyl chloride and/or vinyl chloride-propylene copolymers complying with §177.1980, contacting foods -- other than those with an alcohol content greater than 8% -- which are room temperature filled and stored, refrigerated stored, or frozen stored, with no thermal treatment in the container.

§178.3690 specified a melting point (dropping) of 49°-52° C as determined by ASTM Method D566; an acid value not to exceed 15 as determined by ASTM D1386; a saponification number of 270-280 as determined by ASTM Method D1387; an iodine number not to exceed 2 as determined by the Association of Official Analytical Chemists method; and a total amount of ester (calculated as free pentaerythritol) not more than 0.4% by weight of the polyvinyl chloride end/or the vinyl chloride-propylene copolymers.

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## FDA DROPS GUM GUAIAC GRAS LISTING, RETAINS FLAVOR CLEARANCE

The Food and Drug Administration on Jan. 4 finalized its proposal to delete the "generally recognized as safe" listing for gum guaiac, but at the same time withdrew its proposal to rescind clearance for gum guaiac under a Food Additive Order.