

FDA SETS 0.5 P.P.M. ACTION LEVEL FOR DDT IN COCOA BEANS

The Food and Drug Administration has decided to set an action level of 0.5 p.p.m. for DDT in cocoa beans.

The guideline was established by the agency after FDA ran into several consignments of beans in Philadelphia shipped from Ecuador that had DDT residues. One of the shipments was detained, and presumably will be shipped elsewhere, now that FDA has set the 0.5 p.p.m. action level.

There is no tolerance for DDT in cocoa beans and an action level had not been necessary until FDA detected the beans with DDT residues. The level was set at the sensitivity of the method. The DDT was believed to have been used for public health purposes for disease control.

The Environmental Protection Agency, which has taken over tolerance-setting responsibilities from FDA, is expected to establish a temporary tolerance or guideline for DDT in cocoa beans as it has for other pesticides which have been detected in foods for which no official tolerance has been set (See FOOD CHEMICAL NEWS, April 30, Page 2; and June 11, Page 2).

HEARING ASKED ON PCB PAPERBOARD TOLERANCE

The American Paper Institute has objected to the Food and Drug Administration's final order on polychlorinated biphenyls which, among other tolerances, establishes a 10 p.p.m. tolerance for PCB's in paperboard used for food packaging (See FOOD CHEMICAL NEWS, July 9, Page 11). API has requested a public hearing.

API's objections were supported in objections filed by the Boxboard Research & Development Association, the Paperboard Packaging Council, Diamond International and the Washington, D.C., law firm of Peabody, Rivlin, Gore, Cladouhos & Lambert, acting for Newark Boxboard, Middletown Paperboard, Crown Paper Board, Newman and Company, Stone Container Corp., Lawrence Paperboard, Simkins Industries and Tennessee Paper Mills (Recycled Paperboard Companies).

The three major points raised by the Institute in its filing were:

- "I. The Commissioner erred as a matter of law in determining that §406 authorizes tolerance for paper food packaging material.
- "II. There is no 'potential long-term hazard' posed by current dietary intake of PCB's, and thus imposition of a tolerance on paper food packaging materials is unnecessary to minimize long range exposure thereto.
- "III. The PCB order will significantly and unnecessarily harm the nation's recycling effort."

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An evidentiary hearing was sought by API on the last two points, and the Institute filed several affidavits supporting its position on these points.

In support of its assertion that there is no "potential long-term hazard" from current levels of dietary intake of PCB's, API pointed to the toxicological guidelines determined by a committee of the National Academy of Sciences-National Research Council in 1969 and to an earlier report of an NAS-NRC Pesticides Residues Committee in 1965, which it characterized as indicating that there is "a scientific consensus" that there is "no need to limit the presence of a chemical in the food supply when current dietary levels are well below the 'safe' level as calculated by an accepted safety factor."

"Judged by the NAS-NRC Guidelines, current dietary intake of PCB's is so far below the acceptable safe level that there is neither a possibility of a long-term hazard nor need for regulation," API stated.

Included in the API filing was an affidavit from Dr. Moreno Keplinger, manager of the toxicological division of Industrial Bio-Test Laboratories, who stated:

"In my professional judgment, dietary intake of PCB's is so far below the acceptable or safe level that regulation is totally unnecessary to protect the consuming public from any threat of potential chronic toxicity."

Affidavits filed by API from Robert W. Long, Vice President and General Manager of Diamond International's Paperboard Division; Federal Paperboard's Senior Vice President L. Baxter Chamberlain; James C. Morris, Senior Vice President of Hoerner Waldorf's Mill Division; Edward K. Mullen, President of Newark Boxboard, and Dr. Paul E. Trout, Director of Environmental Control for the Container Corporation of America, supported the Institute's contention that the FDA regulation would "harm the nation's recycling effort" by its economic impact on waste paper recycling mills. In addition, API has commissioned an A. D. Little study on the potential economic impact of the 10 p.p.m. tolerance on the recycled paper industry.

API, Others, Hit Requirement that Barriers Be "Impermeable"

API held to be invalid FDA's conclusion in a Supplemental Environmental Impact Statement that exemption of paper packaging used with "impermeable" barriers from the tolerance requirement would "minimize" or "negate" the impact of the Order on recycling.

The Institute noted that the only impermeable materials are glass bottles and metal cans, which are "overwhelmingly" packaged in corrugated containers made from virgin fiber, because of the greater strength of such fiber.

The Institute urged that the barrier exemption be extended to materials which prevent or significantly reduce PCB migration, noting that a Hazleton Laboratory study had found that polyvinylidene coated paper significantly lowered the

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rate of migration, while a later study by the Institute of Paper Chemistry indicated that waxed glassines, particularly amber or chocolate glassines, also were highly effective in reducing the amount of PCB migration.

In his affidavit, Trout noted that FDA's statement "does not specify whether its assumption of a lessened impact on the recycling industry will automatically result from recognizing glass and cans as impermeable or from a scientific investigation of barriers presently in widespread use which will establish that they are impermeable," and continued:

"In either case, however, its assertion that the barrier exemption... will 'minimize or negate' any effect on the recycling portion of the paper industry is factually erroneous."

Trout pointed out that virgin fiber is used for packaging cans and bottles because of its greater strength per unit, and:

"Virtually every barrier commonly used with recycled packaging material is permeable to detectable PCB migration. Thus further scientific investigation cannot be expected to establish that such materials meet FDA's rigid definition of an effective barrier as one to which 'there is no evidence of migration of PCBs to ... food.'"

Studies conducted by Hazleton Laboratories, Trout noted, found that "the mechanisms of PCB transmission from paper packaging to food is a vapor phase phenomenon," and he observed:

"It follows from the basic laws of chemistry that the overwhelming bulk of barrier materials now in use in the recycling industry, all of which are permeable to one degree or another, can never be shown absolutely to prevent PCB migration. Thus combination paperboard packaging used with such barriers will not be exempt from the 10 p.p.m. tolerance and the barrier exemption as presently defined cannot have the effect of 'minimizing or negating the impact of the rule making on recycled programs.'"

While barriers of foil-film combination may be found to be impermeable, Trout said, their cost would be so high as to lead customers to turn to virgin fiber instead.

The Paperboard Packaging Council called FDA's "approach to the functional barrier concept ... unnecessarily restrictive," urging the agency to "reconsider this most restrictive approach to functional barriers with a view towards expanding the list of barriers which will qualify the packaging material for exemption from the tolerance level."

One of the objections filed by the law firm of Peabody, Rivlin, Gore, Cladouhos & Lambert for the Recycled Paperboard Companies, asserted: "The Commissioner has erred in promulgating a higher PCB tolerance level for paper food-packaging

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materials since any PCB migration that does exist is greatly affected by barriers, the type of food, the ratio of package weight to food weight, and exposure time and conditions."

The law firm said FDA's failure to differentiate food-packaging material according to the type of food it will contain is "a particularly curious omission in view of the fact that the FDA has differentiated foods themselves by establishing temporary tolerances for certain specified foods including milk and dairy products, poultry, eggs, fish, animal feed and infant and junior foods ranging from 5 parts to .2 p.p.m. while failing to set tolerances for all other foods."

The law firm complained that FDA's failure to take the factors of functional barriers, type of food, ratio of food weight to package weight and time and conditions of exposure into full account "will result in a substantial case of over-regulation with the paper recycling industry suffering the consequences."

Other objections filed by the firm for the Recycled Paperboard Companies were:

"The Commissioner has erred in failing to exempt from its order paperboard plants whose annual production of paperboard for food-packaging material represents only a small portion of their total annual production of paperboard and which will be unable, due to their operating characteristics, to control the PCB content of such paperboards;(and)

"The Commissioner has erred in basing his regulation of the PCB content of paper food packaging material on the erroneous conclusion that 'the level of PCB's in packaged food is related to the level of PCB's in its packaging' because the FDA admits that there is no evidence giving any clear causal connection between any given level of PCB's in paper food-packaging material and PCB's in the packaged food."

"The FDA's own explanation for its establishment of a higher tolerance ... states," the argument continued: "Data from the FDA survey of PCB's in foods and food-packaging material showed that the food portion of the samples with 5-10 p.p.m. PCB's in paper food-packaging material contained the same range of PCB level ... as the food portion of the samples with 0-5 p.p.m. in paper food-packaging material."

"This evidence, while not disproving a causal connection, does demonstrate the inconclusive and incomplete information on which the FDA relies," the objection pointed out.

Diamond International's Long, supported the API's objections, and protested that an "undue burden is posed on our industry where we have little or no control or testing procedures to determine levels of PCB's in our supply of raw materials and no control of the possible contamination after paperboard leaves our plant and is converted into packaging by others."

Long said possible sources of contamination were storage areas, inks, adhesives, spray materials, and handling of products converted from paperboard.

The Paperboard Packaging Council expressed concern about the compliance sampling procedures prepared by the Division of Mathematics in FDA's Bureau of Foods. The Council said "the compliance sampling procedures should be broadened to insure that the samples upon which the compliance decision is based are truly representative" of the paperboard packages in question.

In the August 8 Federal Register, FDA corrected the effective date for the final order on PCB's, saying it had intended that the Order become effective in 60 days, rather than 30 as the FR publication had stated. The new effective date is Sept. 4, 1973, rather than Aug. 6, 1973.

BUREAU OF STANDARDS DEVELOPING NET WEIGHT REGULATION

The National Bureau of Standards is developing a precise model regulation on net weight of food products, which may take into account loss of moisture.

The Agriculture Department, in view of the NBS development, on Aug. 8 said it will not finalize its proposed rule on determining the net weight of food products (See FOOD CHEMICAL NEWS, Dec. 20, 1971, Page 47). This proposal would have utilized "average" net weight.

The expectation that the NBS regulation may be a detailed model specifying moisture weight loss for different sorts of food products was stated by Swift's Harvey L. Hensel at an Aug. 8 meeting of the American Bar Association's Food, Drug and Cosmetic Law Committee in Washington, D.C.

Stating that variation in net weight due to loss or gain in moisture is a pressing problem, Hensel said that USDA, the Food and Drug Administration, and the Model Law and Regulations have all permitted variations due to moisture loss. However, the State of California in 1971 decided no longer to recognize this principle and took actions against Rath Packing Co. involving bacon (See FOOD CHEMICAL NEWS, July 17, 1972, Page 33). Hensel said Rath took counter-action in court against two district attorneys.

California Court Decision Voids Federal Regulations

In April of this year, he said, a court decision said, in part, that the federal regulations are too vague, and therefore are void. Other parts of the decision said that the federal regulations, if valid, would preempt the States and localities, and that products would have to be at full weight with variation at the time of retail sale rather than at the time of packing.