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FDA DOUBTFUL THAT PACKAGE "BARRIERS" CAN REDUCE PCB MIGRATION

The Food and Drug Administration indicated heavy skepticism that "barriers" in food packaging will work to reduce migration of PCBs to food as the agency released last week an "environmental impact statement" on the polychlorinated biphenyls (See FOOD CHEMICAL NEWS, May 8, Page 12).

The statement was released along with a report on the industrial compound by the Interdepartmental Task Force on PCBs. Release of the documents had been sought by the packaging industry in their objections to the practicality of the proposed .5 p.p.m. tolerance for food packaging.

There is at present, FDA said, "no available information clearly indicating that such a barrier would be a feasible or practical solution to this problem." The agency continued:

> "Neither is there research on the types of materials that would prevent PCB migration. As shown in FDA's food-packaging survey, inner wrappers of various composition that were used as barriers for different types of packaged foods either contained PCBs or failed to completely prevent migration."

The agency also referred to problems of converting existing food packaging machinery. Thus, FDA said, "the proposed temporary tolerance for food packaging materials appears to be a more reasonable and realistic alternative to this specific problem."

The agency was accused by Consolidated Packaging Corporation of "ignoring" the use of barriers. Consolidated also said, "There is only 'circumstantial evidence' that PCBs migrate from packaging materials to food stuffs, and there is nothing quantitative in the data regarding this presumption."

The 181-page Task Force report on PCBs said FDA's proposed PCB policy prohibiting use of PCBs in and around food processing plants and establishing "limitations on the use of salvaged paper containing industrial chemicals for food packaging . . . should prevent occurrences such as the Wilmington incident and the problem of PCB in food packaging materials."

However, the Task Force said, problems will remain "as evidenced by the Coho Salmon contamination, the mysterious Minnesota turkeys, and the discovery of high levels of PCBs in cardboard food containers."

Existing regulatory authority is "generally inadequate to prevent more PCBs from entering the environment," the Task Force said, noting:

> "The government has no power to restrict imports of PCBs by foreign manufacturers, and if it disagreed with Monsanto's judgment on allowable uses it could not impose more stringent limitations on Monsanto or on any other potential manufacturer.

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> "This regulatory gap would be filled by the Administration's proposed Toxic Substances Control Act . . . Action by the Congress to approve the Act is the most important step which can be taken to deal with PCBs and similar problems."

Noting that the exact cause had not been found for the most recent PCB incident in Maine, in which more than a million chickens were destroyed, the Task Force said:

> " . . . Insofar as detection of problems relies on inspection of food products shipped to market, it is impossible to inspect even a small fraction of the foods being shipped. Factory inspection can detect some problems, but even this approach is severely limited by available resources. The prime reliance must be on controlling the use of the offending substance."

The report disclosed that the Environmental Protection Agency and Justice Department are planning to apply the well-publicized "Refuse Act of 1899" to limit discharges into rivers or lakes. The report noted: "To keep levels in fish as low as possible, and in any case below FDA's interim action level of 5 p.p.m., concentrations in rivers or lakes from all sources should not exceed 0.01 parts per billion."

In addition to action by FDA and EPA, it was noted, the Department of Agriculture "has acted under the Wholesome Poultry Act and other statutes to prevent accidentally contaminated foods from reaching the market."

The report reprinted data on U. S. sales of PCBs for various purposes by Monsanto Chemical. This data had been sought by researchers.

Essentially a review of past and pending research and other actions on PCBs, the Task Force report recommended continued use of PCB for transformers and capacitors "because of the significantly increased risk of fire and explosion and the disruption of electrical service which would result from a ban on PCB use."

Current levels of PCBs in man do not appear to present an imminent hazard, the report concluded. Environmental effects on other animals, the Task Force said, "indicates that the PCBs must be viewed as potential problems at present environmental levels."

Echoing the Task Force notations as to the lack of specific information on PCB effects, Consolidated Packaging said in its filing on the PDA temporary tolerances proposal:

> "Members of the industry are particularly irritated by the fact that the (proposal) has as its background such a paucity of convincing scientific data. Toxicity levels

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> of PCBs in humans have not been established - - certainly there is no evidence that harm to the metabolism results from the presence of any particular level of PCBs in food stuffs except for the very dramatic incident wherein the intake was probably in the hundreds of parts per million of a different type of PCB . . . "

The proposal, Consolidated said, would "cause the operations of already marginal recycling mills to become completely uneconomic." The company continued:

> "The very low level of PCB content permitted by the (proposal), together with the inadequacy of available testing procedures, makes it impossible for the containerboard and boxboard producer to guarantee his product to food processing customers, and it is highly unlikely that any underwriter will insure the mill with regard to this risk."

The company said its own continuous testing program indicates that the proposal is "not only premature" but is "presumptive of many factors which are yet to be proved and involves considerable extrapolation . . . "

Fears that the proposal would "retard or possibly cancel" the development of paper recycling were expressed by the firm, which said the proposal should be set aside pending "clarification of pertinent data and the examination of alternate approaches . . . "

The Inmont Company said, however, that the PCB proposals "are probably wise from an ecological standpoint," while noting agreement with FDA's statement that PCBs do not present an immediate hazard to the public health and "immediate elimination of all food packages containing them is thus not warranted."

The company asked two changes: (1) "The standards should be recast in the light of currently available analytical techniques, and some standard deviation should be allowed, and (2) An additional 60 days of time for compliance with whatever regulation is finally adopted should be allowed over and above the presently proposed 30-day compliance period."

The firm, which manufactures coatings for use on packaging materials, suggested that if it is determined that a particular test method can extract and accurately identify PCBs in amounts of 5 p.p.m. plus or minus 2 p.p.m., the "standard be so worded."

Well before the publication of the proposed rules, Inmont was working on a replacement for PCBs in heat exchange units, the firm said, but has run into unforeseen problems, including lower flashpoints for replacement materials (340° as against 775°) and the necessity of draining heat exchanger coils, washing them out with replacement fluid for 30 to 60 days and redraining before replacement with permanent materials.

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FDA to Allow 60 Additional Days for Comment

The legal firm of Wald, Harkrader & Ross, representing the American Paper Institute, wrote to FDA that consttuctive comments on the proposal are "plainly impossible" until FDA releases the data on which its proposal was based. On May 2 the firm requested the information under the Health, Education and Welfare Department's Freedom of Information rules.

It was learned last week that FDA will allow 60 additional days for study of the now-released data and comment on the PCB proposal.

In a list of 13 items requested of FDA, API included:

" . . . All 'investigations' which have revealed PCB migration to food resulting from the use of PCB containing food packaging materials," and "the national survey conducted by FDA 'which revealed (PCB levels in food packaging and in the foods contained therein).'" The latter request included data and worksheets from each of the 17 districts whose reports constituted the survey.

The Packaging Institute-USA asked a four-month extension of time for filing comments, stating:

"The testing procedure now available and most widely used . . . is specifically for analyzing paper packaging materials . . . (and) will not provide an assured extraction of all PCBs from many non-paper packaging materials.

"Current industry studies are under way to establish the effectiveness of a wide range of packaging materials as a barrier to PCBs."

An intensive industry effort to eliminate PCBs will continue, the Institute said, "during any delay granted in the implementation of the proposed regulation . . . "

The law firm of Keller and Heckman, working on the submission of comments for the Society of the Plastics Industry, noted in draft comments that the plastics packaging industry would be thrown into a "dilemma of having to prove compliance without a scientifically sound means of doing so."

FDA was requested to "exclude coverage of plastics or, at the very least," delay implementation until the industry has completed current studies.

Noting that current information indicates that FDA's data is on paper products only, the draft said recycled use of waste paper is not applicable to plastics packaging materials and: " . . . the only way PCBs might be present in a plastics material would be as a result of some type of accidental or general environmental surface contamination." The draft said, also, that there is no reason to believe PCBs in food have resulted from migration from plastics packaging materials.

FDA to Publish General Policy on Impact Statement

The availability of FDA's environmental impact statement on PCBs was noted in the May 11 Federal Register. FDA's general policy on environmental impact statements - - issues on which it will file and other matters - - is expected to be published this week.

In the impact statement on PCBs, the agency said the banning of all PCBs from food-packaging materials regardless of the level of PCB contamination would be "an unreasonable solution to the problem and would serve no useful purpose," with an adverse impact on recycling programs. Much of the statement was a reiteration of the preamble to FDA's proposed temporary tolerances.

SENATE SUBCOMMITTEE REPORTS "SURE THING" PESTICIDES LEGISLATION

As new pesticides legislation began to look like a "sure thing" this year, the Senate subcommittee on Agricultural Research and General Legislation reported a revised HR 10729 to its parent Agriculture Committee May 11.

When the two remaining Senators in the executive subcommittee mark-up session split on three controversial provisions, the bill was referred on up to the full Committee for resolution of - -

- - Third party rights in the initiation of judicial review (See FOOD CHEMICAL NEWS, May 1, Page 43).

- - Indemnities for persons holding stocks of cancelled or suspended pesticides.

- - Rights of citizens to institute civil suits against the Administrator of the Environmental Protection Agency for action or inaction.

The subcommittee adopted a proposal by the National Agricultural Chemicals Association to take away from EPA the discretion as to what constitutes trade secrets or other valuable commercial information to be prohibited from public disclosure.

The subcommittee vote would give manufacturers an apparently incontrovertible right to mark the portions of their registration or tolerance petitions as to confidential data.

The vote preceded by two days the publication of Freedom of Information Rules by EPA, which would retain discretion within the agency as to what constitutes information required to be kept secret.

In an earlier version of the regulations, EPA had made no provisions for "advisory" opinions (See FOOD CHEMICAL NEWS, April 17, Page 22). The rules finalized May 13 provide that the EPA General Counsel "may issue written determinations as to whether specified information contained in EPA records does or does not

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