FDA, API SUGGEST AMENDMENTS TO PCB-IN-PAPER REGULATION

The Food and Drug Administration and the American Paper Institute have come closer to settling the controversy regarding polychlorinated biphenyls in food-packaging paper and paperboard, with both parties suggesting amendments to the current FDA regulation which sets a 10 p.p.m. tolerance (See FOOD CHEMICAL NEWS, Oct. 13, Page 21).

Both parties apparently are anxious to settle the controversy without going ahead to a public hearing. All parties to the hearing would have to agree with a settlement between API and FDA.

FDA proposed revising the regulation to exempt from the 10 p.p.m. tolerance packaging material "separated from the food contained therein by a barrier belonging to a class of barrier materials found to be functional ..." The §122.10 regulation now exempts packaging material separated from the food by a barrier which is "impervious to migration of PCBs."

API Proposes Exemption For Aluminum Foil, Glassine, Plastic Coating Barriers

API proposed making the 10 p.p.m. tolerance apply to "paper food packaging material intended for use or used as packaging in excess of 24 hours unless the food is separated from the packaging by aluminum foil, plain or waxed glassine, or plastic coating, or by another barrier belonging to a class of barrier materials found to be functional ..."

The Institute proposed defining a barrier material as "functional ... if a representative barrier of the class limits migration of PCBs from the paperboard to food to a level not exceeding 25% of the migration which occurs under the same conditions without the use of a barrier."

FDA, on the other hand, proposed that a barrier be deemed "functional ... if a representative barrier of the class limits migration of PCBs from the paperboard to food to a level not exceeding the migration which occurs from paperboard containing 10 p.p.m. PCB under the same test conditions without the use of a barrier."

There were also differences in the test protocols suggested by the agency and by the industry group.

FDA proposed that tests be run for 90 days at a temperature of 80° F. plus-or-minus 2° F. with a barrier on a PCB content of paper material of 50 p.p.m. plus-or-minus 5 p.p.m. and without a barrier on PCB content of 10 p.p.m. plus-or-minus 1.5 p.p.m. API agreed to the time and temperature specifications, but said the tests should be run on material with a PCB content of 40 p.p.m. plus-or-minus 5 p.p.m., with or without barriers.

The agency said the tests should be run with corn flake crumbs, cupcake mix, rice, and shortbread cookie crumbs. API said the tests should involve ground corn flakes, packaged cake mix, and rice. The package weight ratio, FDA said, should be the ratio "most favorable to PCB migration that is commercially available."

API said the test should be conducted with an inverted culture dish with aluminum foil or other material impermeable to PCBs. FDA included this test, but as an alternative said all test material could be completely enclosed in a glass or a mason jar.

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FDA Warns That PCB Tolerances Could be Lowered

FDA said that all of the PCB tolerances "are under review ... in light of recently reported scientific data," noting that the Environmental Defense Fund and the Natural Resources Defense Council have petitioned the agency to gradually lower all PCB tolerances to zero.

"... While there are no current plans to lower the tolerance for PCBs in paper food packaging material, the possibility that this may occur in the future cannot be ruled out," the agency said, adding: "With this in mind, API may want to consider conducting some tests utilizing paperboard with less than 10 p.p.m. to establish levels of migration without a barrier."

The letters were written by Dr. Howard Roberts, Acting Director of FDA's Bureau of Foods, and by Stephen M. Truitt and Thomas W. Brunner, of the Washington law firm of Wald, Harkrader & Ross. Copies of the letters were sent to all parties in the public hearing. Roberts wrote, in part:

> "I do not believe that the position of the Bureau and API are very far apart in this matter. I do believe that a settlement of the proceeding remains a viable alternative to moving forward with the hearing. However, agreement upon a test protocol acceptable to the Bureau is necessary before the Bureau can recommend to the Commissioner that an amendment to the existing PCB in paper food-packaging material tolerance regulations be proposed. Furthermore, it is only after the parties agree upon a test protocol and the necessary amendments to the regulations are final that we reach the stage where consideration of the results of particular tests to determine the functionality of barriers is appropriate."

The FDA letter said that its proposals "are eminently reasonable," adding, "We do not feel that any testing requirements that are less rigorous than what we are now proposing can be justified."

Roberts said his Bureau is "desirous of bringing this proceeding to a close," adding: "If API is willing to conduct studies along the lines we have indicated, we are willing to discuss technical details with API representatives at any time. If, on the other hand, API cannot agree with the Bureau on the test requirements, we will insist that the hearing be resumed at an early date."

The API attorneys also said, "We do not believe the parties to be far apart regarding the design of a prospective barrier qualification program." They added that "API is prepared to agree to almost all the terms of ... (FDA's) Oct. 6 proposal ..."

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