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SETTLEMENT OF PCB ISSUE WITHOUT A HEARING WEIGHED

The American Paper Institute and the Food and Drug Administration are weighing a possible settlement of the issues involving polychlorinated biphenyls in food-packaging paper and paperboard without proceeding to a public hearing (See FOOD CHEMICAL NEWS, Oct. 6, Page 16).

Terms of a possible settlement were stated by attorney Stephen M. Truitt, of the Washington law firm of Wald, Harkrader & Ross, in a Sept. 18 letter to Dr. Howard R. Roberts, Acting Director of FDA's Bureau of Foods. Saying that its letter was designed to "facilitate a possible settlement," the attorney said that API is prepared to oppose FDA's 10 p.p.m. tolerance in a hearing "if necessary." However, he added:

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NCA URGES FDA TO PUBLICLY EXPLAIN USE OF TERM "FILTH"

The National Canners Association has urged the Food and Drug Administration to include in its public statements an explanation of use of the term "filth."

FDA Assistant Commissioner for Public Affairs John T. Walden, at an Oct. 2 meeting with NCA's Roger Coleman and Richard Dougherty, "agreed to consider" use of the proposed language, according to a memo of the meeting written by the FDA-er. The NCA representatives proposed that FDA use the following explanation:

> "The term 'filth' as used in this release is a technical term taken from the law. It is not intended to conform to the general public understanding of the word. It refers to certain natural substances which may be included in canned foods despite every precaution possible under modern technology. In foods packaged according to standards established by the Food and Drug Administration these fragments present no health hazard and are present in such small quantity that they usually cannot be seen and have no effect on color, flavor, or any other important quality characteristic of the food in question. It has been found almost impossible to eliminate them entirely whether the food is packed in a commercial factory or in the home. Normally, they are in no way offensive and need cause no concern to the consumer."

The NCA representatives met with Walden to "discuss possible alternatives to use of the term 'filth' in referring to unavoidable, natural contaminants in foods." Walden, in the memo, said he "agreed that the term was unfortunate, but suggested it was unlikely the FDA or anyone else could direct the press away from the term when reporting on what were, in fact, 'unavoidable natural contaminants.'"

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> "...API is prepared to withdraw its objections to the proposed tolerance in the interest of promptly concluding this proceeding if the tolerance regulation is modified so as (1) to exclude from the scope of the tolerance food board intended for use with a functional barrier

under either of two realistic definitions of functionality set forth below, and (2) to exclude from the scope of the tolerance food board intended to be used with food consumed within 24 hours of its initial contact with the board."

FDA initially indicated that a barrier would have to be "impermeable" in order to exempt paperboard from the 10 p.p.m. tolerance for PCBs. The agency has now conceded that an exemption is possible if paperboard with a "functional" barrier results in no more migration to foods of PCBs than would paperboard meeting the 10 p.p.m. tolerance without a barrier.

The API proposal, and FDA's response, made it clear that the major point of dispute now involves the methodology of testing the functionality of barriers in preventing migration of PCBs to food. If this dispute can be settled, the entire matter probably will be resolved without a public hearing.

Truitt conceded FDA's concern that PCB levels might rise in paperboard and not be covered by the tolerance with the revised barrier exemption. However, he said that the API-proposed modification would still require testing of "a substantial proportion of the recycled paperboard," since "PCBs persist in the paper-making machinery, and production lots subject to the tolerance would necessarily be interspersed with those excluded from the tolerance. . ." Test results, the attorney wrote, would provide "an accurate indication of generally prevailing PCB levels in all food board, including exempt production."

Roberts, in an Oct. 6 reply to Truitt, said FDA "is unable to accept the API proposal as submitted," but suggested modifications which he said "could form the basis for terminating the PCB proceeding insofar as the Bureau is concerned."

He noted that any settlement would require concurrence by FDA Commissioner Schmidt and by the other parties in the hearing, such as Diamond International and Newark Boxboard. Roberts suggested that Truitt inform the other parties in the hearing about the API letter and the FDA response.

Discussing the difference of opinion about test methodology for barriers, Roberts wrote, "I do not believe that API and the Bureau are substantially at odds concerning the test conditions to be employed."

Indicating that chances for a settlement are good, Roberts wrote to Truitt: "The Bureau agrees that classes of barriers which meet the . . . standard for effectiveness, under agreed upon test conditions for all test foods, would be identified as functional."

In stating that "food board used with functional barriers that significantly reduce potential migration of PCBs should be excluded from the scope of the tolerance," Truitt commented, "We understand the Bureau to agree."

He said API accepts FDA's "approach. . . that barriers be considered effective if they do not allow any higher level of PCB to migrate to food than migrates to food from paper packaging containing 10 p.p.m. in direct contact with food." Truitt explained:

"Classes of barriers which under. . . test conditions permit no more migration than was found with 10 p.p.m. board without a barrier would be identified as functional, and board used with these classes of barriers would be exempt from the tolerance."

In its "narrative statement" of its case for the public hearing, which was filed with FDA's Hearing Clerk, API said the FDA proposal would exempt from the tolerance requirements "impermeable" barriers,which were asserted to be metal cans, bottles, and polyvinylidene chloride plastic films.

API said, "Two sets of circumstances require recognition of barriers which, though not totally impermeable to PCB migration, are nevertheless effective in preventing all but trivial PCB migration." The Institute said it would show at the hearing that a number of packaging barriers in common use protect food against PCB migration, adding:

> "FDA's rigid insistence upon absolute impermeability in a barrier is totally inconsistent with the stated goal of reducing average dietary intake of PCBs and needlessly inflicts added costs on the recycling section of the paper industry and ultimately on the waste management system and the consumer, without compensating benefit."

In discussing testing of barriers, Truitt urged use of "realistic conditions," saying, "In dealing with a substance which even in the Bureau's view poses at most a limited chronic rather than acute toxicity hazard, it is inappropriate to require the use of 'worst case' conditions in testing barriers."

Roberts rejected this contention, saying:

> "The use of 'worst case' conditions in testing is designed to provide an adequate margin of safety to account for unknown or unquantifiable factors. With respect to PCBs, the testing conditions under discussion, particularly use of a closed system, although referred to as 'worst case' conditions, do in fact more closely approximate actual market conditions than the conditions API has proposed.
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> "The laboratory closed system (e.g., packaged food inside a mason jar) is similar to the conditions found in the marketplace, where, for example, boxes of cereal will be tightly packed in shipping cartons for relatively long periods of time. The shipping carton environment is a closed system that facilitates migration of PCBs from the paper packaging into the food. Given the marketplace conditions, failure to use a closed system such as the mason jar, would cast serious doubt on the validity of the barrier testing. It is a risk that the Bureau is unwilling to countenance."

Truitt said that if "FDA prefers closed cell tests where an extreme PCB driving force is used," API is proposing as an alternative methodology a test "which compares migration in the barrier and non-barrier settings using the same force migration cell structure

employed in the study of barrier effects prepared by the Institute of Paper Chemistry for the St. Regis Paper Company."

The API letter said this test uses a temperature of 73°F. with 50% relative humidity, rather than an elevated temperature setting. Under this approach, Truitt wrote, "a class of barriers should be recognized as functional (and board used with the barrier as exempt) . . . if the barriers reduce migration by 75%."

The Institute proposed barrier tests on glassine, plastic coated papers, plastic films, and aluminum foil on paper.

For testing with products - - not in a closed system - - API proposed tests with packaged corn flakes, packaged cake mix, and rice. The paperboard would be tested at two levels: (1) 10 p.p.m., plus-or-minus 1.5 p.p.m., PCBs; and (2) 40 p.p.m., plus-or-minus 5 p.p.m., PCBs.

The API-preferred test conditions would include a weight of board and weight of food at the lowest ratio corresponding to standard commercial practice. The packages would be "in their normal state, i.e., not over-wrapped." The tests would be made at 70° plus-or-minus 2° F., with exposure for 60 days. Extraction would be by the Armour-Burke extraction method.

Two packages each of corn flakes, packaged cake mix, and rice would be tested in paperboard with 10 p.p.m. PCB with no barrier. Two samples of each product would be tested for each of 8 barriers with board containing 40 p.p.m. PCBs. This would make a total of 54 packages in the test.

Roberts said FDA has "no objections in principle" to the proposed testing method, but said it "might be useful to test four rather than three foods." He wrote that the Bureau of Foods "would like to discuss the possibility of substituting certain other products for the products currently listed."

FDA Makes "Counterproposal" on Barrier Testing

Making a "counterproposal," Roberts said that, "If adequate data are promptly supplied . . . demonstrating that the levels of PCBs currently found in non-food grade recycled domestic paperboard is comparable to the PCB levels found in food-grade, recycled domestic paperboard, the Bureau will approve testing of commercially produced paperboard with: (a) PCB content 10 p.p.m. plus-or-minus 1.5 p.p.m.; (b) PCB content 50 p.p.m. plus-or-minus 5 p.p.m."

If the data are not supplied, or if the PCB levels are not comparable, Roberts wrote, "commercially produced paperboard containing 100 p.p.m. plus-or-minus 5 p.p.m. PCBs must be used in place of paperboard containing 50 p.p.m. plus-or-minus 5 p.p.m. PCBs." Also, the FDA-er said his Bureau "desires to explore the possibility of obtaining data on PCB levels in imported paperboard," possibly through "an API-FDA cooperative effort."

Discussing the test conditions when a non-closed system is utilized, Roberts said the package weight to food weight ratio must be the "most favorable to migration so long as

the ratio occurs in the marketplace." He said the tests should be made at 80° F. plus-or-minus 2°, with exposure to last 90 days. He agreed that the Armour-Burke extractive method should be used.

Roberts also said that additional "control" samples containing 10 p.p.m. PCBs, with no barrier, should be used, suggesting 6 packages of each test food.

Truitt wrote that, "In the event new classes of barriers were developed, they would be tested in accordance with these procedures but no additional testing would be required for the barriers in the four enumerated classes."

Roberts agreed that new classes of barriers would have to be tested, but added that "additional testing would be required for the barriers in the four enumerated classes if significant changes in the PCB levels found in paperboard are noted or if the temporary tolerance for PCBs in paper food-packaging material is lowered." In that event, the FDA-er said, "the Bureau would require additional testing for all barriers previously approved, under test conditions appropriate to the changed PCB levels or the lower tolerance."

In weighing FDA's counterproposal, Roberts urged that "API carefully consider this response, keeping in mind the Bureau's primary responsibility to insure that exposure to PCBs be kept at the lowest level possible." Because of this, he continued, test conditions for barrier effectiveness must be "rigorous," adding: "The Bureau believes that the conditions outlined in this response are appropriately rigorous but also genuinely realistic."

Truitt said the test conditions proposed by API represent "concessions on two major points." He explained:

> "First, API no longer insists, as it has in previous discussions with your staff, that the board tested with the barrier contain 25 p.p.m. PCB even though that level is vastly higher than the levels currently found in paperboard. Secondly, API is willing to have the tests conducted with the package weight to food weight ratio most favorable to migration so long as that ratio actually occurs in the marketplace. API is unwilling, however, to agree as part of this equivalence test that the test be conducted as an artificial closed system, favoring migration still further, as has been suggested by your staff."

Pressing for an exclusion from the tolerance requirement for board intended to be used with food consumed within 24 hours of initial contact with the board, Truitt explained that "this exemption would apply principally to various take-out items."

He noted a study by the Institute of Paper Chemistry which "showed that even after two days (48 hours), migration to . . . foods from board with high PCB levels was very low." Tests with cake packaged in board containing 76 p.p.m. PCBs showed migration of .025 p.p.m. after 48 hours, and tests with cake packaged in board containing 129 p.p.m. PCBs slowed .012 p.p.m. after 48 hours, Truitt wrote. Tests with buttered popcorn in board containing 76 p.p.m. PCBs after 48 hours showed 1.0 p.p.m. migration, he added.

Roberts replied that his Bureau "does not rule out the possibility that an exemption from the tolerance for paperboard to be used within 24 hours of initial contact with the food may be appropriate." However, he recounted "several problems," explaining that the Bureau "will need data on the migration based on a larger sample, including a fuller explanation of the migration occurring from paper-packaging containing 129 p.p.m. PCBs. . ."

The FDA-er also said the data to which API referred "suggests that the level of migration from the paper-packaging to the food may be unacceptably high."

In order to exempt paperboard used within 24 hours, Roberts said, "it will be necessary to establish that: (1) Such paperboard will, in fact, be used within the 24-hour period; and (2) Assuring that the paperboard to be so used will not require monitoring by the FDA." He said the Bureau of Foods "is open to any suggestion from API as to how this might be accomplished."

Extraction Method Hit by API, Alternative Proposed

Proposing use of a direct hexane method to determine extraction, Truitt said, "We have very recently established that the alkaline testing procedure currently used in determining PCB levels both in food and in paperboard, the Armour-Burke method, is invalid for measuring PCBs in paperboard because much of the PCB so measured is unavailable for migration to food." He explained:

> "The PCB formerly used in carbonless copy paper was present in micro-capsules (3-10 microns in diameter) having a complex colloid capsule wall composed of gelatin and gum arabic cross linked to an infusible, insoluble state with an aldehyde. To give adequate shelf-life for carbonless paper, the capsule walls used with this paper had to be essentially impermeable to migration of PCB. The manufacturing specifications for that paper required that, after extraction with hexane, the capsules retain over 90% of the PCB.
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> "When dry, the capsule walls are readily ruptured by typing or writing pressures. When wet, as in a hydrapulper, they absorb water and become rubbery and will withstand considerable mechanical action. Thus, when carbonless copy papers are recycled by defibering by mechanical action in water, many of the microcapsules remain unruptured and are present in the recycled paperboard with capsule walls intact. That portion of the PCB within intact capsules cannot migrate to food as the wall acts as an impermeable barrier but, nevertheless, is measured by the current test procedure.
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> "The capsule walls will be destroyed by a potassium hydroxide digestion, such as is used in the Armour-Burke procedure, but PCB inside these capsules will not be extracted with hexane. Accordingly, the alkaline extraction procedure is inappropriate in determining compliance with the proposed tolerance since it does not measure PCBs available to migrate to food and should be replaced by the hexane extraction method."

In its "narrative" statement of the case it intends to present at the public hearing -- if there is one -- API said, "FDA has not recognized the effectiveness of the microcapsule barrier to PCB migration in any manner whatsoever."

Roberts wrote to Truitt that, ". . . The Bureau would need to review and discuss with technical representatives of API data supporting API's contention that the direct hexane extraction method is appropriately used to determine the level of PCB available for migration before evaluating this aspect of API's proposal."

Truitt assured FDA that API "is prepared, on behalf of its members who are now participating in the Boxboard Research & Development Association CQA Program, to undertake the continuation of that program for non-exempted board for a period of time even though such continuation is, from a quality control standpoint, superfluous in light of the low levels detected." He also said API would "consider a limited sampling program for non-regulated board for the purpose of identifying any abrupt rise in PCB levels in exempted production."

Roberts replied that "it is absolutely essential that the Boxboard Research and Development Association CQA program be continued for non-exempted paperboard," as well as "a sampling program for non-regulated board. . ."

Any "settlement" of the issue, Roberts said, "is contingent upon assurances that the Bureau will continue to receive, from the paperboard industry, data on PCB levels in paperboard, since the Bureau's willingness to agree to the proposal is founded, in part, on the CQA data and other data on the levels of PCBs currently found in paperboard."

In the narrative statement of its case, API said "the principal effect of promulgating a tolerance. . . would be to relieve FDA of the necessity of proving in a court seizure action that seized paper food packaging material exceeding the tolerance posed an actual threat to public health." Saying that the Bureau of Foods bears the "burden of proof," API continued:

> "Unless its narrative statement inaccurately or incompletely reflects its intended evidentiary case, however, the Bureau of Foods has already indicated. . . that it will not even attempt to meet its burden to satisfy the statutory requirement governing the issuance of tolerance. The mere incantation of the phrase 'protection of the public health' is not an adequate substitute for scientific proof, and certainly not a response to the evidence, much of it from FDA, showing no conceivable danger to human health related to PCBs in paper food packaging material."

Questioning whether current levels pose a threat which requires issuance of a tolerance, API said FDA must show "what the dietary intake of PCBs actually is," and must "establish that this level of intake is higher than the safe dietary level. . ." If it can show this, the statement said, FDA must then "prove that paper packaging materials make a significant contribution to the total dietary intake of PCBs."

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"Only then could tolerances rationally be set and the total 'pie' (overall dietary intake) be divided between food categories by setting tolerances for each so as to reduce dietary intake below the safe level," API said.

However, the group said the Bureau's statement did not "indicate even a rudimentary appreciation of the nature of the proof it must put forth or slightest intent to bear its burden." API added, "If its narrative statement is a fair summary of the Bureau's case, that presentation will wholly fail to establish the need for a tolerance and will not support a departure from the conventional approach of proving injury to the public health in seizure actions."

API said it will show, "principally from FDA's own studies," that there "is no potential long-term human toxicity hazard from dietary intake of PCBs at the levels that are currently being ingested." The statement said that from October, 1972, through January, 1975, total intake declined to approximately 118 p.p.t., and that "quantifiable PCBs according to FDA's total diet studies have literally vanished."

Saying that current "trace" readings are "far below the analytical reliability of the testing method employed," API said application of the 100-to-1 safety ratio to the 10 p.p.m. no-effect level would give a figure of 100,000 p.p.t., compared with the current dietary intake of 18 p.p.t.

Mantel Listed Among API's Witnesses

In correspondence, API and FDA have differed over whether the Mantel-Bryan statistical method is applicable to the PCB controversy. API listed among its witnesses for the hearing Nathan Mantel, formerly with the National Cancer Institute and now with George Washington University.

API said Mantel-Bryan may be used on the hypothesis by FDA that at least one PCB, "which is not the PCB present in paper food-packaging material," is a potential carcinogen. The group said it will "show that under the Mantel-Bryan procedure, in its most rigorous form as well as in the diluted FDA modification, dietary intake of PCBs is still far less than the safe dose."

Conceding that "some PCBs are unavoidably included in paper food packaging material even under the most careful manufacturing and testing conditions," API said FDA has not taken "adequate account" of this fact and that "the inevitable effect of the tolerance will be to impose new costs on the recycling segment of the paper industry."

API said the tolerance will "arbitrarily stigmatize" recycled paperboard and "cause substantial shifts of customers to virgin board." The statement also said the FDA action would "expose food board manufacturers to excessive financial liability for seizure-related customer losses resulting from inadvertent production of over-tolerance material which cannot be detected with model testing procedures."

The statement said that FDA should have "regulated PCBs through conventional food tolerances which obviously deal with the root of legitimate concern." Proper food tolerances, API said, "would adequately protect the public from any threat of chronic

toxicity while the current unprecedented effort to extend regulatory controls of PCBs to packaging brings with it major adverse consequences to the national recycling effort."

Saying that the "amount of PCBs entering the human diet from paper food-packaging material is negligible, indeed unquantifiable, and toxicologically an insignificant contribution to the total dietary intake," API alleged that FDA's Bureau of Foods "has not even alleged to date that paper food-packaging is a substantial source of PCBs." Total diet studies indicate that in the food category of grains and cereals "there has been a total elimination of dietary PCB intake," API said, adding: ". . . PCB levels in food board have declined virtually to the vanishing point."

The Newark Boxboard Company also submitted a narrative statement of the case it plans to present at a hearing. The firm said it has made no effort to monitor or upgrade its waste paper, but that recent tests at three of its six recycled paper mills indicate PCB levels well within 10 p.p.m.

"It is this company's position that this reduction is not due to efforts by paper mills to control their waste paper furnish, but rather the disappearance of the original source of PCB contamination, and that accordingly the FDA's tolerance is not necessary to control the level of PCBs in paperboard food packaging material," the firm stated.

Newark said the FDA proposal "would damage the operation of . . . paperboard mills, jeopardize their continued viability, and jeopardize the nation's recognized recycling objective by reducing the already diminished markets for their products."

Newark said its Secretary and Counsel, Donald Ochacher, will appear as a witness at the hearing. The firm's President, Edward K. Mullen, was listed as one of API's witnesses.

In addition to Mantel and Mullen, the API witnesses are: API's J. Rodney Edwards and Einar Wulfsberg; Rutgers University's Dr. Seymour G. Gilbert; Industrial Bio-Test Laboratories' Dr. M. L. Keplinger; Diamond International's Robert W. Long; The Mead Corporation's Dr. E. G. Brookbank, Jr.; Container Corporation of America's Dr. Paul E. Trout; Sonoco Products Company's Donald R. Russell; Boxboard Research and Development Association's A. Thomas Luey; and Arthur D. Little's Peter L. Oliver.

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