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PCB HEARING TO BE CONDUCTED UNDER NEW FDA PROCEDURAL REGULATIONS

Food and Drug Administration attorneys last week agreed that the formal §701(e) public hearing on the 10 p.p.m. tolerance for polychlorinated biphenyls in food-packaging paper and paperboard will be conducted under the terms of FDA's new administrative procedures.

They pointed out at the July 21 pre-hearing conference that the new regulations did not become effective until today (July 28), but conceded that the new rules would apply so long as they did not result in unreasonable delay. Administrative Law Judge Horace H. Robbins noted that the new regulations were not in effect at the time, but repeatedly said that the "thrust" of the new rules should be followed.

The following of the new procedures was urged by Stephen M. Truitt, of the Washington law firm of Wald, Harkrader & Ross, who represented the American Paper Institute.

FDA to Submit All Relevant Data from Its Files

FDA attorney Stuart Pape, after extended discussion, said that in one week -- by July 28 -- FDA would submit the records from agency files required by the new procedural regulations, as well as massive documentation requested by API under the Freedom of Information Act. The agency also will submit by July 28 a narrative statement of its case and lists of witnesses and exhibits.

Thirty days after July 28, Pape said, submissions of a narrative presentation, witness list, and exhibits would be due from API. Two weeks after that, written direct testimony would be submitted. FDA lawyer Allan Bennett added that two weeks after submission of the written direct testimony, motions for cross-examination will be due.

At that point, Robbins is expected to schedule a second pre-hearing conference, as is required by the new procedural regulations, to work out plans for cross-examination.

At the start of the pre-hearing conference, Pape said that the Bureau of Foods in one week would submit its narrative statements and its lists of witnesses and exhibits, and that in two weeks written direct testimony from both parties would be expected.

Truitt, however, said the new administrative procedural regulations provide for a "staggered presentation" of material, and that the FDA Bureau of Foods has the burden of proof.

The API attorney said he had requested under FOI material that would be required under the new regulations, but that he had not received the material. Bennett said API would have the documents "in a very short time."

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§2.153 of the administrative procedures, Truitt said, provides that FDA must submit all "relevant portions" of administrative proceedings. Bennett then opposed starting the whole PCB proceeding over under the new regulations because of the delay. Robbins suggested giving API a period of time after the FOI documents are available in which to prepare its submissions. Bennett replied he had no objections, but said the new regulations require direct testimony to be submitted concurrently, not in sequence.

Truitt said he would not accept "any less" than the information required under the new regulation. Denying any "undue delay," he said the FOI exemptions differ from the provisions of the administrative regulations.

When Robbins said the FOI material would be furnished to API by July 28, Truitt said he would need at least four weeks to review this material and prepare the narrative statement. If the new administrative procedures are not to apply, he asked Robbins to certify the question so that API could take an interlocutory appeal to the Commissioner.

Truitt noted that the new regulations allow 60 days for response to material submitted by the agency, saying this much time may not be necessary. He said FOI excludes some internal memos on policy matters, while the procedural regulations require submission of all factual data, both favorable and unfavorable. Under the new regulations he added, FDA would be "bound" by the submission.

Bennett replied that all "factual scientific" information will be supplied to API under its FOI request, commenting that internal policy issues in internal memos are not contemplated by the administrative regulations. He said he is willing to "comply with the spirit" of the new regulations, adding that his "major concern is the time frame."

Robbins agreed that the regulations do not require submission of internal policy memos, but do require relevant factual information.

Bennett suggested that API be given a shorter period for its submission than 60 days, with a provision that more time could be granted if API needs it in light of the FOI-requested materials. Robbins expressed the view that major positions have already been made known in the course of the lengthy controversy.

Bennett agreed to submit the data from FDA files in the form specified by the new procedural regulations, and Robbins gave API four weeks after the FDA submittal to submit its materials.

API Moves to Include Consideration of Recycling Program

Truitt said the environmental impact of the FDA tolerance should be considered at the hearing, saying that FDA's position on this is "plainly wrong" in the light of a June 24, 1975, U. S. Supreme Court decision. The API attorney said FDA should reconsider its position on considering whether there are effective alternative actions which would not adversely affect the recycling industry.

Bennett responded that the hearing is designed to obtain factual information, not for "legal arguments." He said FDA has decided that it may act only under the Food,

Drug and Cosmetic Act, not under the National Environmental Policy Act. Bennett also noted that under the administrative procedural regulations, the Administrative Trial Judge cannot add any issues in the hearing.

Robbins said that most of the API arguments can be considered under the hearing issues as framed. He added that he is not in a position to determine FDA policy on NEPA.

Truitt said NEPA established government-wide policy to promote recycling. If Robbins refuses to grant his motion, he said, API will ask Commissioner Schmidt to reconsider his position on the basis of the Supreme Court decision.

Bennett said §406, which deals with poisonous and deleterious substances, includes consideration of economic impact and unavoidability, but not of recycling. Robbins expressed the view that the issue goes to the "economic feasibility of the tolerance."

Objecting to the framing of one of the issues in the hearing, Truitt said it sounds as though each single molecule of PCB in paper must be avoided. He said there should be consideration of the extent of PCB in paper and paperboard, as well as of other dietary sources of PCBs. The attorney said it should be possible to conclude that there is some migration, but that it makes an "unimportant contribution."

The Administrative Law Judge replied that the issues as framed provide for presenting evidence on levels of PCBs. Bennett said FDA has received no evidence on levels of ingestion, and that if there is such data FDA will consider it. Truitt responded that API has submitted data on this topic, and that the principal source of the data has been FDA's market basket surveys.

Bennett said he has no objection to presentation of data, but only as it bears on the question of whether 10 p.p.m. is the proper tolerance level, not on whether or not there should be a tolerance. Truitt disagreed, saying the hearing issues provide for consideration of whether any tolerance is needed.

The API lawyer said FDA assumes that if there is a poisonous and deleterious substance, the tolerance must be as low as possible. API, on the other hand, holds that if there is no hazard to the public health, there is no need for any tolerance. Truitt hit the assumption that there must be a tolerance.

Bennett replied that the law provides that a poisonous and deleterious substance in food, if it is unavoidable, can be permitted only under a tolerance. Robbins interjected that it is "not profitable at this time to argue the law."

It appears that FDA and API will be the only parties to the hearing. New York State, which filed documents in support of FDA, and a number of boxboard manufacturers, which filed documents in support of API, are not expected to take an active part in the hearing.

New Proposal Suggested by Industry; New Migration Test Reported

Meanwhile, a memo of a meeting held a month earlier indicated there was a last-minute effort to avert the public hearing. At a meeting held on June 13, representatives of the

paper industry "proposed that the Bureau of Foods consider the possibility of FDA modifying its pending regulation along the following lines -- the 10 p.p.m. tolerance for PCBs in paper food packaging material would only apply to such packaging intended for a use that will result in direct contact with the food therein, i.e., where no barrier whatsoever is employed."

According to the memo prepared by FDA's John R. Wessel of the Office of the Associate Commissioner for Compliance:

> "The basis for this proposal is that the industry feels that since the current data indicate most recycled paper is well below 10 p.p.m., there is no longer a need for the 'barrier exemption' but, as long as this exemption is part of the regulation, it gives the false impression to the users of recycled paper that PCBs continue to occur at sufficiently high levels that, therefore, require a barrier. The industry contends that as long as the levels are low, there is no need to even mention the possibility of requiring a barrier. Eliminating the 'barrier exemption' from the regulation will also serve to eliminate the testing of packaging material intended to be used with a barrier.
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> "We informed the paper industry representatives that we would give consideration to their proposal and requested that they submit this proposal, including the language for a revised regulation to the Bureau of Foods as soon as possible."

Paul Trout of the Container Corporation of America described recently-completed migration studies. In a shelf-life study conducted by his firm, and completed in April, he said corn flakes were held in paper board cartons, without barriers, containing 8 p.p.m. and 60 p.p.m. PCB. The food was stored at 72° F. at a relative humidity of 50%. Trout reported:

> "Through 4 months there was no detectable PCB transfer. After 7 months the level was determined to be .04 p.p.m. with the 60 p.p.m. PCB paper; after 9 months .10 p.p.m. was detected. At the end of 15 months the levels were determined to be .2-.3 p.p.m. The results of this study, which will be made available to FDA, led the paper industry to conclude that even where no barrier was present, the rate of PCB transfer is significantly less than originally thought."

At the meeting, the late Selma Levine, of Ward, Harkrader & Ross, stated API's position that "the Food, Drug and Cosmetic Act does not authorize FDA to establish a tolerance for PCBs in paper packaging," and that "current scientific data does not justify" the tolerance. According to the memo, she stated that API was prepared to go ahead with the hearing, but that "in order to avoid a hearing, there are perhaps some areas on which the paper industry and the Bureau of Foods could agree."

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