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CHEMICALS AND PLASTICS

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TO: R. W. Lasher
FROM: UCC - Chemicals and Plastics
SUBJECT: New York, NY (33)

Date May 24, 1978

Originating Dept: R & D

Answering letter date

Subject PI Seminar on Indirect Additives

W. F. Gorham - BB
R. A. Gregory - BB
J. G. Kucsma - NY/33
G. S. Peacock - BB
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Attached is an excerpt from Food Chemical News for May 22 which summarizes the discussions on acrylonitrile and PVC bottles, which were presented at this seminar. My letter to you dated May 17 contained my own summary.

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ACRYLONITRILE POLICY MAY BE SUBJECT TO CHANGE, RONK HINTS

The position stated by the Food and Drug Administration in the acrylonitrile hearing was designed "to win on contest," and will not necessarily always be FDA's policy towards indirect additives, Richard J. Ronk, Director of the Division of Food and Color Additives, said during a recent meeting of The Packaging Institute in Washington (See FOOD CHEMICAL NEWS, May 15, Pages 49 and 53).

In its decision on acrylonitrile, FDA held that a carcinogenic packaging material ingredient could be assumed to migrate to food and, therefore, must be banned under the Delaney clause (See FOOD CHEMICAL NEWS, April 17, Page 14). Ronk said the agency's findings following the public hearing interpreted the statute "fairly directly."

Although he said there might be changes in the policy, Ronk emphasized that FDA will regulate to protect the public from "real risks."

The FDA-er said that three FDA General Counsels have held that public hearings are adversary proceedings in which the agency tries to make its case. Washington attorney Jerome H. Heckman, who is general counsel for the Society of the Plastics Industry, disagreed, saying that FDA's responsibility should be to bring out all facts bearing on an issue.

Court Decision on Acrylonitrile May Take Close to a Year

Heckman predicted that it may be close to a year before there is a court decision on the industry appeal from FDA's acrylonitrile decision, under which use of acrylonitrile for bottles was banned.

Rutgers University's Dr. Seymour G. Gilbert said the FDA acrylonitrile decision defined "assumptions" about migration, saying that science will show whether these "assumptions are valid or merely figments of somebody's imagination." He questioned that there is a linear relationship either between concentration of a substance and its migration potential, or between the dose and the toxic effect. The "burden of proof" is on the FDA assumptions, Gilbert said.

He commented that it is "not correct" to dissolve a polymer and measure a monomer because of changes in the morphology of the polymer. Gilbert said he has shown that migration can be studied "in a practical way" using foods rather than food-simulating solvents. Within 4 months, he said, he will unveil a "more powerful predictive equation" for migration under varying time and temperature conditions.

Rodney L. Derbyshire, of Radiation Dynamics, said his firm is working with Monsanto in applying the Lomo Process irradiation step for reducing monomers in acrylonitrile. He said the electron beam process also has been used for styrene monomer. For Monsanto's Cycle-Safe acrylonitrile bottles, Derbyshire said the process has resulted in "worthwhile reductions" of monomer from 9 p.p.m. to 1 p.p.m. The speaker cautioned that the process is not applicable to all polymers.

Expressing the view that the radiation treatment is a "process" rather than a "food additive," Derbyshire noted that FDA in the past has regulated radiation as an

additive. He said that radiation treatment of packaging has been cleared under Food Additive Orders.

Heckman said that "migration had never in fact been shown to take place in circumstances of conceivable use" of acrylonitrile, but that FDA has concluded that "the instruments are not yet refined enough to detect it." He called this a "Catch-22" situation.

Monsanto's J. Virgil Waggoner said, "Migration studies capable of detecting acrylonitrile at 10 p.p.b. (five times lower than the new maximum being proposed by FDA for all other acrylonitrile food packaging uses) have repeatedly failed to detect acrylonitrile in the contents of the bottles, under intended conditions of use." He added, "Despite this FDA admission, the bottle has been banned."

Calling the Cycle-Safe bottle a "creative" new program, he said that if programs "of this kind are to be arbitrarily terminated, the threat of extreme and unforeseeable government restrictions will inevitably slow the rate of innovation which historically has fueled our nation's enviable economic growth and social progress."

Noting that the "time consumption and costs" of the appeal to the U. S. Court of Appeals in the District of Columbia will be "considerable," Waggoner said, ". . . For the future of plastic packaging in general, we cannot let the decision and particularly the expansive basis for it go unchallenged."

Ethyl's Dr. Gordon A. Hughmark described the work on polyvinyl chloride being done by his firm in close contact with FDA (See FOOD CHEMICAL NEWS, May 1, Page 2). He said:

"The obvious question is -- can we produce 1-2 p.p.b. PVC bottle compound commercially for food-grade use? The answer is that we are confident that we can. Even if migration should be linear with a solvent at this low level, the maximum vinyl chloride monomer (VCM) concentration in the bottle contents would be less than 30 p.p.t. Certainly we are to the point where a legal problem exists -- not a moral problem or a health issue."

The current Ethyl experimental program was described by Hughmark, as follows:

"(1) Repeat of the aqueous stripping of PVC resin with replicate analysis. (2) Six week storage at 120° F of 50% aqueous ethanol and vegetable oil in 1.4 p.p.b. bottles followed by analysis of the bottles. Linear migration would reduce the VCM concentration to about one-third of the initial level. (3) Aqueous steam stripping of PVC resin with different initial VCM concentrations at 50°, 70°, and 100° C to develop diffusivity data as a function of temperature and concentration."

Initial data from this last project, he said, "indicates linear migration above 25 p.p.b., but below that level "the diffusivity decreases with decreasing concentration and should level off at a low concentration as demonstrated by our prior work."

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Saying that Ethyl is keeping FDA informed of the data as they become available, Hughmark said, "Discussion with, and evaluation by, FDA of these data will lead to the establishment of whatever further experimental programs may be required." He said the company anticipates "that an extensive program shall be required to define the linearity and non-linearity regimes with respect to the variables of VCM concentration, bottle contents, and bottle compound composition."

The Ethyl scientist said the objective of the research "is to demonstrate conditions in which there is no VCM after storage that would represent maximum VCM in the bottle contents," but that "we have not had or can ever expect to have an analytical method that will be sensitive to one molecule of VCM in bottle contents."

Working within the limits of analytical methodology, Hughmark said the first effort was to develop a prediction model for measuring VCM in food-simulating solvents held in bottles containing 1 p.p.m. VCM. He said storage tests showed no detectable VCM, and that early in 1975 Ethyl reduced the VCM specification to less than 1 p.p.m. in food-grade PVC bottle compound.

Hughmark said accelerated storage tests with more sensitive analytical methods "have confirmed the validity of Ethyl's prediction model as representing maximum VCM," adding that "room temperature storage" resulted in "lower extraction levels than predicted."

Work completed in 1977 with more sensitive methods "indicated that 0.04 p.p.m. - 40 p.p.b. - initial VCM represented the non-migration level," Hughmark said. Then the specification for food-grade bottles was reduced to a maximum of 0.05 p.p.m. "apparent VCM," he said, adding that the bottle compound actually contains about 20 p.p.b. VCM.

A third phase of the program was instituted, Hughmark said, after FDA scientists developed analytical methods for VCM in PVC compounds sensitive to 0.001 p.p.m. - 1 p.p.b. The FDA decision on acrylonitrile, he said, "presumed that the presence of a substance -- such as VCM in PVC -- means that VCM will be present in contents from PVC containers."

In line with these new developments, he said Ethyl is providing "data that VCM migration is non-linear at low concentrations." He said:

"We have recently obtained experimental results which indicate non-linearity and non-migration level for VCM in PVC. One experiment was to carry out steam stripping of an aqueous slurry of PVC resin at 100° C for 1-1/2 hours. Samples obtained at 15 minute intervals showed decrease of VCM from the initial level of 100 p.p.b. to 1-2 p.p.b. and that VCM remained constant at this level. Similarly intensive mixing of PVC resin plus stabilizer at about 120° C with air sparging also showed leveling off at the 1-2 p.p.b. level. Analysis of bottles made from this resin analyzed about 1.4 p.p.b. Bottles were sent to the FDA and the approximately 1 p.p.b. level was confirmed. An experimental program is in progress following discussion and review by FDA scientists."

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In his discussion of indirect additives, Gilbert said that some substances may be beneficial at some levels but harmful at others, commenting that the direct additive butylated hydroxytoluene may be one of these (See FOOD CHEMICAL NEWS, April 10, Page 2).

Waggoner noted that Monsanto has launched a Chemical Facts of Life public education program, lauding duPont for recently starting its own public information program.

Ronk defended FDA's reliance on animal models as the only available system for demonstrating safety, but Heckman said it is a "perversion" of animal studies to use the Maximum Tolerated Dose. The lawyer noted that FDA in the past has required animal testing at 100 times the anticipated dosage.



NCWM DEVELOPING PROVISIONS FOR MULTI-UNIT PACKAGES, ICE GLAZED SEAFOOD

The Liaison Committee of the National Conference on Weights and Measures has appointed a subcommittee to develop a discussion draft for multi-unit, variety and combination packages.

The draft is aimed at reconciling federal regulatory provisions of the Food and Drug Administration, the Federal Trade Commission, and the U.S. Department of Agriculture, and the Conference's regulations, as recommended by the Committee on Laws and Regulations in its Final Report to the 62nd National Conference on Weights and Measures.

The discussion draft, being developed by committee members Charles Greene and Merrill Thompson, probably will be submitted simultaneously for comment to the Laws and Regulations Committee and the three federal agencies. The Liaison Committee hopes to finalize the draft at the 63rd NCWM, to be held July 9-14, in Washington, D.C.

The Laws and Regulations Committee would then process the draft during 1979 as a proposal to amend the Model State Packaging and Labeling Regulations. On its adoption by NCWM, the Liaison Committee will petition FDA, FTC, and USDA to adopt suitably modified regulations applicable to multi-unit, variety and combination packages to achieve uniformity with the model regulations, according to its Tentative Report for the 63rd Conference.

The committee has been requested by the National Marine Fisheries Service to consider the measurement of ice glaze on seafoods and the determination of compliance with the labeled quantity, the tentative report noted.

NMFS is to submit recommended procedures for uniform standard methods of test for glazed seafood products to the committee, and it has been recommended that the Service also petition FDA to consider changes in its regulations for standards of fill, quality and identity for products of this type.