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FROM: C. E. Blades

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cc: E. Donley

Although the attached news bulletin received from SPI Counsel J. Heckman does not interface with TSCA, the report has interest and value to PVC and Polymer Chemicals business centers within the company.

Of particular importance is the FDA stance related to formaldehyde. If the forecast is correct, then we can expect that FDA sanctions permitting the use of formaldehyde in emulsions will not be withdrawn. Further, the Food Chemical News entry concerning OSHA's position suggests that caution is being exercised in promulgating workplace standards pending outcome of epidemiological studies - some of which are now in progress by a number of investigators including the CIIT and the Formaldehyde Institute.

C. E. Blades

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Attachment

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May 30, 1980

TO: Food, Drug and Cosmetic Packaging
Materials Committee

Letter Highlights

1. The White House is asking FDA/USDA for an in-depth analysis of the economic effect of the proposed regulations requiring the removal of PCB from food packaging materials establishments.

2. FDA does not plan any immediate action regarding formaldehyde but will seek additional information.

3. FDA has advised an inquirer that PVC containers may be marketed in the U.S.; the prior sanction remains presently recognized by the Agency.

Ladies and Gentlemen:

This letter is intended to bring you up to date regarding several Food and Drug Administration (FDA) actions relating to matters we know are of direct interest to many of you. To supplement this communication, we are enclosing copies of pages 2, 6 and 7 of the May 26 issue of Food Chemical News with the permission of the publisher since these pages contain articles on the subjects discussed below.

Polychlorinated Biphenyls

For many years now, one federal regulatory agency after another has been concerned with, and has taken action regarding, polychlorinated biphenyl (PCB) products. Recently, we sent all of you copies of FDA's and the United States Department of Agriculture's (USDA) proposal to ban the use of equipment containing PCBs in food and animal feed plants, including plants where food packaging materials are manufactured.

We are currently preparing comments objecting to the inclusion of facilities manufacturing plastic packaging materials in the ban because such materials have never posed a PCB contamination problem and because implementation of the proposal would be extremely expensive. We were, thus, most pleased to learn that the White House has asked for further economic analysis of the proposal. We are sure that an honest and accurate assessment of the cost of implementing it would reveal that the costs would be staggering with no public health benefit since the costs would be incurred to solve a non-problem.

Formaldehyde

Early this spring, the Chemical Industry Institute of Toxicology (CIIT) reported to FDA a preliminary result observed during an ongoing inhalation study on the toxicology of formaldehyde. In particular, CIIT reported that tumors had been induced in the nasal passages of rats (but not mice) exposed at the higher test doses. Wisely, in our view, FDA has decided that no immediate action on its part is required to protect the public health since exposure to formaldehyde via the oral route in cleared food additives is at a very low level.

The agency will recommend that the National Toxicology Program examine the effects of oral administration of formaldehyde in chronic studies. In addition, the agency is considering the need for other studies to supplement the rather comprehensive investigation being conducted by CIIT. Unless these "other studies" show completely unexpected hazards, it seems unlikely that FDA will take any formal regulatory action against formaldehyde in the foreseeable future.

PVC

For some time now, we have been reporting that FDA has been moving toward removing the cloud that it placed over polyvinyl chloride (PVC) in 1973 and again in 1975 when the agency proposed to revoke the portion of the prior sanction that related to the use of rigid and semi-rigid PVC products for food and alcoholic beverage packaging applications. Recently, we have been informing you about the so-called "Constituents Policy" that would set criteria for permitting traces of carcinogenic contaminants to be present in a food additive without the need to invoke the Delaney Clause. After this policy is in place, current FDA planning is to clear all PVC packaging that complies with the requirements of the Policy, i.e., that will not yield a vinyl chloride migration level greater than that established as "negligible" by application of the Policy.

We have consistently and persistently advised that, in the meantime, PVC remains prior sanctioned for all food packaging applications (except liquor bottles because of separate action by the Bureau of Alcohol, Tobacco and Firearms) although we recommended that attention be directed to keeping the residual monomer (RVCM) level as low as feasible. This same opinion has apparently been expressed in a more formal FDA setting by Taylor M. Quinn, Acting Deputy Director of the Bureau of Foods, during a conference held with representatives of a British company, Sterling Mineral Water Company of London. More specifically, "Quinn informed them that PVC, covered by prior sanctions or existing regulations, may be marketed in the US."

Many of you have expressed both interest and concern that FDA might specify a maximum level of residual monomer in PVC packaging materials that might be too low for feasible commercial production. A possible hint as to FDA's thinking in this view also apparently surfaced during the meeting since Food Chemical News reports FDA advised "that it is possible to obtain base polymer with residual VCM levels of less than 10 ppb." This should not be read as a prediction of what FDA will actually set forth in any future PVC clearance. Nevertheless, if the agency should propose to require unreasonably low RVCM levels, you can be certain we will oppose them with all possible vigor.

* * *

If any of you have any questions or need further details regarding any of the covered subjects, please do not hesitate to contact us.

Cordially yours,

Jerome H. Heckman

Enclosures

PCB regulations proposed by USDA, FDA and EPA have come under scrutiny by the White House, which has asked for a more in-depth economic analysis and for possible alternatives to the current plan to ban all PCB-containing electrical equipment in food and feed plants (See FOOD CHEMICAL NEWS, May 12, Page 3).

COFFEE bean reconditioning plan will be submitted to FDA by General Foods within a week to ten days, company representatives told Bureau of Foods officials at a May 23 meeting (See FOOD CHEMICAL NEWS, May 19, Page 23). At the meeting, the company officials informally discussed two possible approaches to reconditioning coffee beans which were contaminated with antimony trioxide in a warehouse incident.

NATIONAL ACADEMY OF SCIENCES President Dr. Philip Handler is resigning from the post. He will become a Director of Squibb.

ANIMAL HEALTH INSTITUTE petitioned FDA on May 22 to handle animal dosage form products containing nutrient ingredients under the policy followed for non-dosage form products used in feed and water. Currently, the Bureau of Veterinary Medicine policy requires proof of therapeutic benefit in order to permit inclusion of the nutrients in dosage form products, while only a label review is required in the case of non-dosage form products.

CANADIANS fear that commonly used food additives represent a health hazard, accorc to a recently released survey of 25,000 persons, which disclosed: (1) 70% feel additive: not improve the quality of food; (2) 60% say they would pay more for additive-free foods and (3) 91% indicate they need to know more about the use of additives.,

SACCHARIN may act as a tumor promoter by inhibiting metabolic cooperation betwee cells, according to researchers at Michigan State University. In a series of experimer reported in the May 8 issue of the British journal, Nature, the results indicated that saccharin has properties similar to those of other known promoters.

METRIC labeling may be used with customary quantity of contents labeling with one the other in parentheses, FDA-ers have said, clarifying a recent ruling by agency attor against metric only labeling (See FOOD CHEMICAL NEWS, May 5, Page 31).

BATF has announced it will adopt a simplified approval procedure for distinctive liquor bottles -- permitting bottlers and importers to certify the total capacity of a represente sample bottle before closure along with their request for label approval, and to submit photographs of the front and back of the bottle, rather than an actual specimen bottle an authentic model. The alternate approval procedure, noted in industry circular numb 80-4, will be published in the April-June quarterly issue of the ATF Bulletin. The ager reserved the right to specifically request a sample bottle or model.

FDA-ER MARY POLK BALL became the first FDA-er to receive the Secretary of H Education and Welfare's (now Health and Human Services) Award for Exceptional Achie ment, the highest award made personally by the Secretary. An FDA-er since 1965, Bal in the Office of Consumer Affairs and was honored for her efforts in health education f minority groups.

MEAT AND POULTRY Inspection Advisory Committee of USDA will meet on July 2 and 30 in Washington, D.C. No agenda has yet been set.

It was predicted recently by USDA's Thomas Grumbles, of the Food Safety and Quality Service, that if BATF does not resolve the labeling issue, there will be some effort by Congress to move the labeling authority out of Treasury (See FOOD CHEMICAL NEWS, April 28, Page 2). At the same meeting, FDA's Dr. Sanford A. Miller, Director of the Bureau of Foods, said his agency does not want to take over alcoholic beverage regulatory authority.

It is believed that FDA Commissioner Jere E. Goyan is not as anxious as some of his predecessors to get involved in the alcoholic beverage labeling issue. On the other hand, it is understood that some Treasury Department officials would be happy to be rid of the long-pending problem.

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NO REGULATORY ACTION AGAINST THE USE OF FORMALDEHYDE IS PLANNED BY FDA

The Food and Drug Administration (FDA) has concluded that no regulatory action against the use of formaldehyde in the products it regulates is necessary at this time to protect the public's health, as expected (See FOOD CHEMICAL NEWS, March 31, Page 2).

The Chemical Industry Institute of Toxicology (CIIT) has reported to FDA the preliminar results of a study that suggest the inhalation of formaldehyde has induced tumors in the nasal passages of rats. However, most of the formaldehyde exposure resulting from FDA-regulated products is at low levels from ingestion, according to an FDA spokesman.

In the on-going CIIT study, a significant incidence of cancer of the nasal passage of rats was observed during the first 18 months of inhalation when 15 p.p.m. of formaldehyde was in the air, a level that would be "intolerable" for humans, according to FDA. No tumors were observed at a dose of 2 p.p.m., which the spokesman said would be "uncomfortable" for humans and cause their eyes to water. Only one rat out of 240 exposed to 6 p.p.m. developed a tumor in the nasal area.

Uses of formaldehyde regulated by FDA do not lead to direct exposure to nasal tissue or inhalation exposure to humans comparable to the conditions of the CIIT study, the agency said.

No systemic tumors (those which occur in parts of the body remote from the site of application) have been reported to date in the animals exposed to formaldehyde in this or in previously conducted studies, FDA's spokesman said.

Furthermore, he continued, the mouse, unlike the rat, failed to develop carcinomas of nasal tissue in inhalation tests, suggesting that rats and mice do not react biochemically in the same manner to formaldehyde. The agency said it must be determine whether human susceptibility to this exposure more closely resembles that of the rat or the mouse.

The Consumer Product Safety Commission, the National Cancer Institute, and the Occupational Safety and Health Administration will conduct epidemiological studies among people who have had long-term and possibly high-level exposure to formaldehyd

FDA has also requested the National Toxicology Program to give high priority to examining the effects of oral administration of formaldehyde to both rats and mice in chronic studies. In addition, FDA is considering the need for other studies to determine conclusively whether a public health problem exists and the extent of the problem, if there is one, the spokesman said.

Formaldehyde solution (formalin) is used in numerous FDA-regulated veterinary and human drugs, biologicals and cosmetics, as an inactivating agent, antibacterial agent, preservative or sterilant. Formaldehyde is also cleared as a direct food additive and has a number of indirect additive approvals for packaging and other uses.

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FDA REQUESTS INFORMATION FROM BRITISH FIRM ON MAKEUP OF PVC BOTTLES

The Food and Drug Administration has asked an English company preparing to market mineral water in the United States to supply the agency with details of the makeup of the polyvinyl chloride bottles in which the product will be packaged (See FOOD CHEMICAL NEWS, April 14, Page 2).

The request for information was made during a May 1 meeting with representatives of the Stirling Mineral Water Co., London, which had presented for examination samples of the carbonated product packed in glass and the non-carbonated product in PVC.

FDA's Taylor M. Quinn, Acting Deputy Director of the Bureau of Foods, suggested changes in the specimen labels required to meet FDA requirements, according to a memorandum of the conference prepared by FDA's Dr. Vir D. Anand.

FDA discouraged the company from placing the Seal of the Royal Institute of Public Health on the containers, advising that the agency frowns on this practice since it implies that the product is approved by the U. S. government.

Anand said FDA also advised Stirling to make arrangements for an FDA inspection of its facilities through the British government after the firm's officials indicated that they would like the agency to determine whether the company is meeting Good Manufacturing Practice requirements.

The firm was also told that the product would have to conform to bacterial standards for bottled water, although these standards do not apply to mineral water, the memo said.

After requesting the data on the PVC bottles, Anand said, FDA informed the Stirling representatives of the agency's concern about the carcinogenicity of vinyl chloride monomer (VCM) in PVC, both by ingestion (0.3 mg/kg) and inhalation (10 p.p.m.), advising that it is possible to obtain base polymer with residual VCM levels of less than 10 p.p.b.

"Quinn informed them that PVC, covered by prior sanctions or existing regulations, may be marketed in the U.S.," the memo continued, pointing out that the agency is actively reviewing the status of the PVC sanction in view of the carcinogenicity of VCM (See FOOD CHEMICAL NEWS, Oct. 15, Page 3). Quinn suggested that the situation could change in the future, the memo said. ●