



ETHYL CORP. CRAD

INTRA-COMPANY CORRESPONDENCE

ATTENTION OF: (see distribution list)

Date: December 15, 1966

From: H. R. Dittmar

SUBJECT: SPECIAL MEETING REPORT

WEF	SEC
FC	KLL
CWM	MD
AJH	EDH
JRZ	CGM
RLH	NGA
JDJ	DEJ
APG	RLM
HS	BMO
WBG	RLJ
BEH	AOW
SWH	CLK
GAS	CRB
V FmB	AFL
FILES	RBA

ROCKAWAY, N.J.

The Society of the Plastics Industry - Food Packaging Materials Committee
Washington, D. C. - December 14, 1966

Guest Panel: Mr. L. Ramsey, Asso. Director, F.D.A.
Dr. J. McLaughlin, F.D.A. -Div. of Toxicological Evaluation

Mr. Ramsey and Dr. McLaughlin represented the F.D.A. to answer 16 specific questions prepared by the Food Packaging Committee of the SPI. These questions (attachment No. 1) were submitted to the FDA prior to the meeting. The Packaging Industry was represented by a broad cross-section. For example; Monsanto, W.R. Grace, Dow, Owens-Illinois, Phillips, Hedwin, Goodrich, Gulf, Diamond, Shell, Union Carbide, Hercules and many others.

Summary:

1. I don't believe the packaging industry stands a chance of having any tin compound approved for food use. I asked a very specific question, "Will ten parts per billion tin extraction from PVC be considered as zero?" Mr. Ramsey's answer was a definite no, for organic tin.

The legal counsel for SPI, Mr. J. Heckman, was more optimistic. He believes a tin compound will be approved for food within weeks.

2. Question after question indicated that the FDA was going to get tougher. For example; a particular additive may currently be approved as a food additive and still not be acceptable as an additive in a packaging material. A particular additive may be approved for a resin, such as polystyrene or polyethylene and still be rejected for use in PVC. The reasoning being that the total intake of this additive should not exceed specific levels. Approval in the new resin may cause the level to be exceeded. Apparently it will take the combined effort of the

EC 3115

SPECIAL MEETING REPORT

12/15/66

industry, acting through a group like the SPI, to make significant progress with the FDA.

With reference to attachment No. 1, this is how the questions were answered:

1- a No Migration

The Scientific Advisory Committee to the FDA has reported that zero extraction or zero migration is normally not attainable. An exception could exist if a barrier metal like aluminum foil is between the packaging material and the food product. Thus, for all practical purposes, every food application must be complete with analytical procedures and extraction data.

1- b No answer other than that in 1 - a.

2. Functional Barriers

Most packaging materials are not considered functional barriers. For example, three mils of polyethylene is not a functional barrier for printing inks. The industry must prove by theoretical or actual tests that a particular product is a functional barrier.

3. Minor Indirect Additives

No blanket approvals will be given for minor additives. Each material must be judged on its own data. Some materials may be considered not extractable. But the fact that industry runs extraction tests on these materials indicates to FDA that some extractability was expected. This is a unique piece of reasoning, but will continue within the FDA until changed by considerable organized pressure. Another peculiarity is that additive "X" may be approved to be added directly to salt but not approved for the package that is used for the salt. The reason; salt is used in very limited quantities and during a lifetime only "Y" quantity of "X" component will be consumed. However, if additive "X" is used in a packaging material that has many uses, the total intake of the additive may exceed estimated safe levels. Therefore, each component must be considered (according to the FDA) as a part of the whole packaging and food additive industry. Mr. Ramsey suggested that if we object strongly to these regulations, that we must work as a group to change the law. Apparently, the FDA intends to enforce the law to the letter until it is changed. They believe that they must assure the consumer that his food is safe to eat.

SPECIAL MEETING REPORT

12/15/66

4. F. D. A. Contacts

Mr. Ramsey recommends that industry avoid contacts with the FDA during review of a petition. Contacts are welcomed at other times but should be through the head of the branch handling the application. He discouraged direct contact with individual scientists within the FDA.

5. Food Additives in Packaging Materials

This was answered in part 4. Not automatically approved.

6. Extraction Tests for Indirect Additives

- a. The FDA will insist upon extraction data. This cost must be handled by industry. Extraction tests could indicate the necessity (over 50 PPM) of running two year feeding tests on at least two species.

7. Solvent Ratio for Extraction Tests

Industry can use whatever solvent ratio is appropriate. Ten milliliters of solvent to one square inch of surface is satisfactory.

8. Compliance with Existing Regulations

All regulations must be adhered to. Data that indicates that one component slightly exceeds the regulation can be submitted for an opinion.

9. Basic Polymers

Basic polymers are the finished resins. They include trace quantities of catalysts but do not include other materials added after recovery of the resin.

10. Collateral Regulations

Collateral regulations do not exist. Each material must be evaluated in its intended use. If in doubt, ask for an opinion from the FDA.

11. Functional Type Regulations

The FDA invites broader regulations. Joint petitions by the SPI or other groups are encouraged. (Vypak, M&T, and Advance, should

SPECIAL MEETING REPORT

12/15/66

approach the FDA for an opinion on the use of tin stabilizers for non-food applications such as mouthwashes and drugs).

12. Modification of Regulations

The FDA will consider revisions of the regulations when petitioned by industry, the SPI, etc. Money is limited and the FDA will not initiate the changes.

13. Additional Petition Data

Preliminary hearings and reviews will not eliminate the necessity for additional data. However, they will reduce the possibility of additional work.

14. Bona Fide Additive Function

Section 409 of the Food Drug Regulations states that every additive must have a function. The responsibility is with industry to prove that each component is required. In addition each component is to be used at the minimum level required to perform the intended function.

15. F.D. & C. Certified Colors

F.D. & C. certified colors are approved for use in packaging materials provided they don't color the packaged food.

16. Inorganic Pigments

In general, inorganic pigments with extraction less than 10 ppb, comply with the food additive law. There are some exceptions. For example; inorganic mercury, cadmium and antimony, are not acceptable under these conditions. If in doubt, ask for a formal opinion.

Conclusion:

This was a long meeting but extremely informative. A few questions were answered in an evasive way. However, in general, Mr. Ramsey and Dr. McLaughlin indicated that the law will be enforced with firmness.

HRD/dec
att.

cc: RWK(3)
RFS
FDA file
FMB

H. R. Dittman