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To the Members of the SPI Food, Drug, and Cosmetic
Packaging Materials Committee

Gentlemen:

Following up on Mr. Heckman's communication to the Committee on Friday, August 16, and with the permission of Louis Rothschild, I am enclosing herewith a copy of an article that appeared in today's Food Chemical News bearing on hoped for revisions in FDA's policies concerning indirect food additives.

We shall continue to keep a close watch on the situation and will be advising you as further substantive developments occur.

Cordially yours,

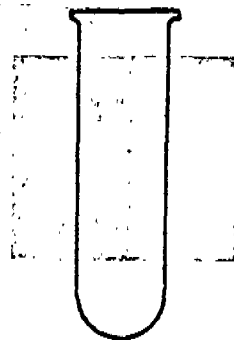
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FDA TOPSIDERS WEIGH EASING OF INDIRECT ADDITIVE REQUIREMENTS

A proposal to lift some of the procedural food additive requirements from hundreds of food additives used in small amounts is now being studied at the top levels of the Food and Drug Administration.

The change being considered by FDA Commissioner Ley would go at least part of the way in the direction suggested by Hercules' Dr. John P. Frawley.

Frawley's proposal, in brief, would exempt indirect additives from testing data requirements if they could migrate in food at no more than 0.1 p. p. m. FDA now does not require safety data if an indirect additive can migrate at no more than 0.01 p. p. m. The FDA compromise under consideration is believed to exempt packaging materials from the data requirements if they can migrate at not more than 0.05 p. p. m.

Both the Frawley and FDA proposals would not eliminate any ban on carcinogens or requirements for heavy metals or agricultural chemicals.

Extraction Tests Might Be Required

Among the differences between the Frawley proposal and FDA's draft proposal is that Frawley would exempt from the Petition requirements indirect additives used at less than 0.2% by weight of a food container, without extraction studies. The FDA proposal is expected to require extraction studies to ascertain whether a component could migrate at more than 0.05 p. p. m.

The Frawley proposal would exempt substances which could migrate no more than 0.1 p. p. m. in the diet of man. FDA's staff paper would probably exempt substances which could migrate at no more than 0.05 p. p. m. into the specific food being packaged.

Another part of the proposal would exempt from the procedural requirements minor ingredients that are intended for repeated use, such as rubber articles intended for repeated use. Also to be exempted are believed to be components of food packaging adhesives. There would also be exemptions for other kinds of indirect additives which would not be expected to become components of food, for example indirect additive colorants.

If Ley Approves Proposal, Industry Will Be Consulted

The indirect additive proposals are by no means firm. FDA's Bureau of Science made the proposals, which cleared the agency's top-side administrators. It is believed that William W. Goodrich, chief counsel for FDA's parent Consumer Protection and Environmental Health Service, has given his OK.

The ultimate decision, of course, is up to Ley. It is believed that he is now being briefed on the background of the situation.

If Ley approves the proposal, FDA will then consult with representatives of the various segments of the food packaging industry. L. L. Ramsey, Assistant Director of the Bureau of Science, in May promised that his agency would consult with industry prior to a decision on indirect additives (See FOOD CHEMICAL NEWS, May 27, Page 15). At a national meeting held by FDA on indirect additives, industry made a strong pitch for an FDA-industry advisory committee to work on the problem (See FOOD CHEMICAL NEWS, February 19, Page 10), but there is no indication that FDA will create such a committee.

There are indications that industry would like FDA to confer with representatives of all segments of the food packaging industry together, rather than in a series of separate meetings.

If the FDA staff proposal is adopted by Ley and survives a number of FDA-industry conferences, the question will arise of what to do with voluminous Subpart F of the food additive regulations. Many of the long lists of ingredients cleared under Food Additive Orders in Subpart F would become obsolete. For example, the entire list of substances under § 121.2520 for adhesives could become meaningless.

Policy Change Would Mean Revision of Subpart F

The current bulk of Subpart F is due in part to FDA requirements. But in part it is due to industry insistence of listing substances which may not be food additives in order to have evidence of FDA approval for marketing purposes. Some firms might not be happy about the deletion of some of the listings.

At this time, no decision has been made about how to revise the existing regulations if the proposal is adopted. But it is clear that Subpart F could become much abridged, either at one time or through gradual revisions.

Under Frawley's proposal, all indirect additives, except heavy metals and pesticides, used at 0.2% or less would be added to § 121.2500(d) of FDA's regulations, which would exempt them from the procedural regulations (See FOOD CHEMICAL NEWS, October 30, Page 3). However, it would not exempt them from the provisions of the Food Additive Law, such as the ban against carcinogens.

August 19, 1968

FOOD CHEMICAL NEWS

The rationale for the Frawley proposal was that, except for pesticides and heavy metals, no compounds were found to be toxic at less than 10 p.p.m. Applying the 100-to-1 safety ratio, Frawley concluded that up to 0.1 p.p.m. in the human diet would be safe. He said that use of 0.2% by weight of a component in a food container will result in less than 0.1 p.p.m. in the diet. Later Frawley expanded his proposal to include an exemption for substances which can contribute no more than 0.1 p.p.m. migration to the diet, even if they are used at levels above 0.2%.

Although Frawley had disclosed his proposal previously, it was formally enunciated after FDA proposed a revision of the food additive procedural regulations (See FOOD CHEMICAL NEWS, August 14, 1967, Page 3). The proposals inevitably led to a challenge of the coverage of indirect additives, and Frawley's proposal was one of a number made in comments. His exemption proposal was widely endorsed (See FOOD CHEMICAL NEWS, November 6, Page 20; November 13, Page 13; November 20, Page 4; January 15, Page 2; and February 5, Page 18).

FDA responded by promising a reappraisal of the indirect additives problem (See FOOD CHEMICAL NEWS, December 4, Page 9). At a meeting of the Food Protection Committee, FDA Associate Commissioner Kirk indicated that his agency would not accept the Frawley proposal, as such, but hinted that the amount of data required might be reduced (See FOOD CHEMICAL NEWS, December 4, Page 18).

After the indirect additive problem was called to the attention of the House Small Business Regulatory Agencies subcommittee, FDA agreed to call the national conference (See FOOD CHEMICAL NEWS, January 22, Page 21). At that meeting, FDA agreed to consider the Frawley proposal, although with some obvious reluctance (See FOOD CHEMICAL NEWS, February 19, Page 3).

FDA Science Bureau Director, Dr. William H. Summerson, called the paper he delivered at the conference a "justification" of current FDA policy. However, FDA-ers modified their stance during the meeting and finally said they were willing to seek a "middle ground." Contrasting the FDA and Frawley positions, Summerson commented: "Somewhere in between will be a position that both Dr. Frawley and FDA can live with."

Ad Hoc Committee Still Working on "Insignificance" Definition

An ad hoc committee of the National Academy of Sciences-National Research Council's Food Protection Committee is working on a definition of "toxicological insignificance," to apply across-the-board to other additives and pesticides as well as to indirect additives (See FOOD CHEMICAL NEWS, March 18, Page 21). However, no final report has been issued, and the ad hoc committee deliberations have had no relationship with FDA's deliberations on indirect additives.

Part of the problem of bulky Subpart F sprang from an FDA policy decision that if a firm runs extraction tests on a substance, the substance is presumed to be a

"food additive." Thus, a Food Additive Petition must be filed regardless of the results of the extraction study (See FOOD CHEMICAL NEWS, Jan. 22, 1962, Page 8).

An FDA report early this year to the House Small Business Regulatory Agencies subcommittee indicated a shift in policy saying that packaging materials do not have to be covered by an Order if extraction data show no migration to food (See FOOD CHEMICAL NEWS, January 22, Page 21). Some FDA-ers, commenting on the report, indicated there had been a change of policy, and other FDA-ers flatly denied there was a change in policy (See FOOD CHEMICAL NEWS, February 19, Page 18). It became apparent that there was a gray area, and that Petitions had been required in all but a few cases.

Adoption of either the Frawley or the FDA proposal, or a variation of them, would eliminate the problem of Petitions for packaging materials which do not actually migrate to food.

FDA SEIZES MYCONOX AGAIN; NAREMCO CASE UP FOR RE-TRIAL

The Food and Drug Administration recently made another seizure of Myconox, Medicated, this time on food additive charges, as part of a continuing battle between the agency and Naremco, Inc., Springfield, Missouri, which has gone on for more than a dozen years.

A re-trial is scheduled next month in Texas of a case which FDA won, in part (See FOOD CHEMICAL NEWS, February 27, 1967, Page 3; October 30, Page 2; November 13, Page 24; and March 25, Page 6). Implied in the cases is the question of whether FDA can decide a prior sanction is no longer valid and that a feed additive requires an approved New Drug Application and clearance under a Food Additive Order,

In the recent seizure of the product shipped from Naremco to Animal Health Sales, Inc., Selbyville, Delaware, FDA charged that methylrosaniline chloride and sodium propionate are not cleared under the Food Additive Law for control of avian mycosis in broilers and market turkeys, fatty liver syndrome in poultry, and avian leucosis complex in poultry.

The Tyler, Texas, case also involves a Naremco product containing phthalylsulfacetamide. The firm has repeatedly said that if FDA has questions about veterinary sulfas it should act against all of them instead of picking out its products.

FDA recently made two more seizures of mixed nuts on the charge that the label vignettes showed a large percentage of nuts other than peanuts but that the products contained a large percentage of peanuts. Seized were mixed nuts shipped by Pittsburgh Snax Co., Pittsburgh, Pa., to Liggett Drug Co., Jacksonville, Fla., and Kelling Brand Mixed Nuts with Peanuts, shipped by Kelling Nut Co., Paterson, N. J., to Carpel Food Distributors, Washington, D. C.