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FDA ISSUES INDIRECT ADDITIVE "DISCUSSION DRAFT" PROPOSAL

The Food and Drug Administration has formalized its staff paper on easing regulation of indirect food additives to the extent of sending it as a "discussion draft notice of proposed rule making" to representatives of trade associations which took part in the 1968 FDA-industry conference on indirect additives (See FOOD CHEMICAL NEWS, Feb. 19, 1968, Pages 3, 10, and 18).

The proposal, on which comments were requested, is essentially the same as an FDA staff paper which was circulated last year within the agency (See FOOD CHEMICAL NEWS, Aug. 19, Page 3).

Key point in the FDA proposal is an exemption from Food Additive Law clearance procedures for substances used "as components of food-contact articles provided any substance so used contributes no more than 0.05 p.p.m. of additive to the contacted food as determined by analysis of the food, or by appropriate extraction studies, or by calculation assuming 100% migration."

The key industry proposal, propounded by Hercules' Dr. John Frawley, would exempt from clearance procedures substances that migrate into the food supply at not more than 0.1 p.p.m. These, under the Frawley proposal, would be indirect additives used at less than 0.2% by weight of the food container.

FDA Sticks to Need for Extraction Tests for Contacted Foods

The key difference between the Frawley proposal and the FDA proposal is that the Frawley recommendations would exempt substances which can migrate to the food supply at no more than 0.1 p.p.m. -- without the need for extraction studies. The FDA proposal would require extraction studies to show that the substance could not migrate at more than 0.05 p.p.m. into a specific food contacted.

Thus, there will be some industry dissatisfaction that the FDA plan would still require extraction studies. However, there will also be some satisfaction that FDA has at least opened the door to the theory of toxicological insignificance so far as food additives are concerned.

FDA undoubtedly was influenced in preparing the draft proposal by the report of a National Academy of Sciences Task Force which recommended adoption of a philosophy of toxicological insignificance (See FOOD CHEMICAL NEWS, Feb. 3, Page 29; and April 14, Page 2). The report recommended that additives used for at least five years at a level up to 0.1 p.p.m. of the total diet be considered "toxicologically insignificant." The Task Force suggested that substances

used at higher levels than 0.1 p.p.m. or for less than five years be weighed by analogy with similar substances for which data is available.

The agency did not go to the Task Force philosophy based on the level of an additive in the total diet. However, it did embrace the concept of toxicological insignificance.

The NAS Task Force report was not mentioned by FDA in its draft proposal, since the language of the report has become embroiled in some controversy in an NAS publications committee. Thus, the report - - already well circulated - - has not officially been issued yet by NAS.

FDA endorsement of a concept of toxicological insignificance, although limited in this case to indirect additives, may eventually have some significance for the field of direct food additives. Industry representatives with a stake in flavor substances hope that adoption of the "toxicologically insignificant" philosophy may influence European experts who have tended to take a strict view of flavors in the past (See FOOD CHEMICAL NEWS, April 21, Page 3).

In addition to indirect additives migrating at no more than 0.05 p.p.m. to contacted food, the FDA proposal would exempt from clearance procedures, the following:

(1) Components of articles intended for use in contact with dry solids with the surfaces containing no free fat or oil, provided the finished food-contact surface contains no free oils not otherwise permitted for such use.

(2) Components of articles intended for repeated use in contact with bulk quantities of food, provided the finished food-contact article is thoroughly cleansed prior to first use in contact with food.

(3) Components of defoaming agents employed prior to or during the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food.

(4) Components of food-packaging adhesives complying with the Food Additive Order for adhesives (§121.2520).

These exemptions, if proposed in the Federal Register and finalized, would mean the deletion from the Subpart F Food Additive Regulations of a number of lists of substances. Among the Orders which might disappear, at least in part, are §121.2520 for adhesives, §121.2519 for defoaming agents used in the manufacture of paper and paperboard, §121.2571 for components of paper and paperboard in contact with dry food, and §121.2562 for rubber articles intended for repeated use. The proposed exemptions also may make unnecessary Food Additive Order proposals under consideration for colorants for packaging materials.

Excluded from the exemptions would be: (1) Heavy metals, as identified under Heavy Metals Test in the Food Chemicals Codex, and compounds of such heavy

metals; (2) Substances prohibited under the Delaney Clause of the Food Additive Law, which bars clearance for potential carcinogens; and (3) "any other substances that have been demonstrated to produce toxic reactions when present at levels of 40 p.p.m. or less in the diet of man or animals."

The "40 p.p.m." level for toxic reactions is a new section, replacing a more generally worded exclusion in the FDA draft of last year. Basically, it is intended to bar exemptions for agricultural chemicals and other biologically active substances. The NAS Task Force said that "no commercial compound has been demonstrated to produce toxic reactions below a dietary concentration of 40 p.p.m.," a calculation also made by Frawley.

In letters from FDA's L. L. Ramsey, Assistant Director of the Bureau of Science for Regulatory Programs, the trade associations which received the document were told it is a "first response to comments received in connection" with the conference on indirect additives. Ramsey invited comments, and said the agency is willing to meet with trade association representatives on an industry-by-industry basis.

FDA had been urged to establish an industry advisory committee to help deal with the problem of indirect additives, but this approach was rejected.

In the draft of the exemption proposal, FDA said:

> "Having evaluated comments received in connection with the . . . conference, and other relevant information, the Commissioner . . . proposes that the food additive regulations be amended . . . to provide for use of additional substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food. Under the proposed conditions of use, these additional substances are not expected to become components of food in any toxicologically significant amount."

The exemptions would be added to §121.2500(d) of the regulations governing indirect additives. This section now exempts substances which are "generally recognized as safe" for use in or on food or in food packaging, substances granted "prior sanctions," and substances cleared under Food Additive Orders.

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NEW "NADER RAIDERS" TO PROBE CPEHS, FDA IN SUMMER

A new team of "Nader's Raiders," composed of eight medical students from schools around the country, is expected in Washington this summer to concentrate on activities of the Consumer Protection and Environmental Health Service with particular emphasis on food purity and air pollution.