FDA INTERNATIONAL UNITS TO WORK IN TANDEM

The Food and Drug Administration's Office of Policy in a memo clarified that the International Policy Staff headed by Linda Horton (See FOOD CHEMICAL NEWS, Aug. 9, Page 38) will work closely with the International Affairs Staff headed by Walter Batts.

"The International Affairs Staff in FDA's Office of Health Affairs will work closely with the International Policy Staff and will continue to carry out its responsibilities for coordinating the FDA's international activities with foreign governments, international organizations and other U.S. government agencies, including participation in international trade discussions," the memo said.

It added that "the International Affairs Staff will work with the International Policy Staff to help identify policy issues and develop policy options and recommendations."

Explaining the need for an International Policy Staff, FDA said its "interest and involvement in international harmonization has increased significantly in the last several years." It added:

> "FDA believes this area provides an opportunity to enhance the efficiency and effectiveness of its regulatory activities. Further, FDA has become a key participant in international trade discussions, and FDA's activities have a broad impact on international trade. The International Policy Staff is being created to support and coordinate the international harmonization activities of FDA's operating Centers and to assist the Deputy Commissioner for Policy in providing Commissioner-level leadership on international policy issues."

The memo also said "the Centers and the Office of Regulatory Affairs will continue to carry out their international activities in coordination with the International Affairs and International Policy Staffs."

THRESHOLD OF REGULATION PROPOSAL TO BE ISSUED BY FDA

The long-pending Threshold of Regulation proposal, unveiled late last week and expected to be published in the Federal Register on Oct. 12, will exempt from food additive requirements indirect additives which migrate at negligible levels.

The Food and Drug Administration said it will exempt indirect additives if they meet criteria specified in the upcoming Federal Register document. A food additive Petition would not be required for exempted uses.

Barred from the Threshold of Regulation proposal would be substances which are carcinogenic or which contain a carcinogenic impurity with a TD_{50} (the feeding dose that causes cancer in 50% of test animals) or less than 6.25 mg per kg body weight per day. Also prohibited would be indirect additives suspected of carcinogenicity because of chemical structure.

Key Figure for Threshold Is 0.5 P.P.B.

The key figure in the proposal is a dietary concentration at or below 0.5 p.p.b., which would correspond to dietary exposure levels at or below 1.5 micrograms person/day,

based on a diet of 1,500 grams of solid food and 1,500 grams of liquid food per person per day.

The proposal also would approve a regulated direct food additive if the dietary exposure to the substance resulting from the proposed use is less than 1% of the Acceptable Daily Intake (ADI).

FDA proposed that the substance would have no technical effect in food to which it may migrate, adding that the substance would not have a significant adverse impact on the environment.

However, FDA will reserve its right to decline to grant an exemption when information indicates a public health risk.

Criteria for exemptions for indirect additives would include chemical composition, conditions of use, and whether the article will be a one-time or repeated-use article.

Data will include validated migration data under worst-case conditions, levels of the substances used in the manufacture of the article and residue levels that are present. For repeated-use articles, FDA proposed an estimate of the amount of food that contacts the specific unit of surface area over the lifetime of the article.

If these data are provided only as manufacturing-use levels or residual levels, FDA said it will calculate the worst-case dietary concentration level assuming 100% migration. Analytical methods must be submitted.

When there is no detectable migration into food or solvents but when there is no suitable analytical method, the agency said it will consider the validated detection limit of the method to analyze for the substance.

Firms were urged to obtain guidance from FDA on appropriate protocols, the agency said.

The proposal said that an abbreviated environmental assessment may be required for an indirect additive meeting the threshold. It added that all data must be reviewed and submitted to the agency.

FDA said it will inform a firm by letter whether the specific food-contact application is exempt from the regulation. Although such articles will not be listed in regulations, the agency said it will maintain a list of substances exempted from regulation, including the name of the company, the name of the chemical, the use for which there is an exemption and any needed limitations.

If a request for an exemption is denied, FDA said the firm may submit a petition for reconsideration.

If the agency receives significant new information raising questions of safety, FDA said it would reconsider the decision. The company would be given an opportunity to discuss the substance with FDA-ers. If an exemption is rejected, there would be a notification on public display at FDA's Dockets Management Branch.

In several regulations, FDA has proposed granting requests for exemption from regulation as an indirect food additive.

Comments Requested on Threshold Proposal

Providing for 60 days of comment on the proposal, FDA asked for comments on the 0.5 p.p.b. dietary concentration level for substances not currently regulated for direct additives and the 1% of the ADI threshold level proposed for regulated direct additives.

The agency also requested information on making decisions publicly available under the proposed policy. FDA said decisions must be made available for the public, but the agency said it also recognizes its obligation to protect trade secret information. It asked for comments on how to inform the public, while at the same time protecting proprietary information.

●

FDA PROPOSES FOLIC ACID ENRICHMENT OF GRAIN PRODUCTS

The Food and Drug Administration on Oct. 7 proposed requiring the addition of folic acid to flour, breads and other grain products in order to lower the risk of neural tube birth defects (See FOOD CHEMICAL NEWS, Sept. 27, Pages 2 and 37).

In three separate notices to be published in the Oct. 14 Federal Register, FDA proposed amending: the standards of identity for enriched grain products, food additive regulations and food labeling regulations in regard to folic acid.

The written comment periods on all three proposals will end 60 days after publication.

The U.S. Public Health Service last year recommended all women of child-bearing age consume 0.4 milligrams daily of folic acid as a way of reducing spina bifida and anencephaly in their babies. There are about 2,500 live-birth cases annually.

"Women of child-bearing age may reduce the risk of neural tube birth defects by increased folate intake," said FDA Commissioner Dr. David Kessler in the FDA announcement. "This proposal is designed to provide for that increased folate intake while avoiding problems that can result from overconsumption. This is an important balance to strike."

Overconsumption of folic acid can mask symptoms of such vitamin B-12 deficiencies as pernicious anemia, which can lead to nerve damage if untreated. FDA said the proposed fortification levels are designed to stay within safe levels even for heavy consumers of grain products.

The agency said PHS estimated that if all women of child-bearing age consumed 0.4 mg of folate daily, the incident of neural tube defects could be cut in half, saving $651 to $788 million in health and other costs annually.

On the other hand, FDA said it believes it will cost industry approximately $4 million to add folic acid annually, testing would be about $2.5 million and required label changes would cost about $20 million. However, the agency said it could not estimate how much it would cost to do separate production runs to export products to countries, such as Canada, that do not allow folic acid fortification.

The agency said it will hold a meeting of its Food Advisory Committee, including its Folic Acid subcommittee, on Oct. 14 and 15 to discuss the proposals.