NTP reports on chemical studies

The National Toxicology Program (NTP), announcing the availability of the "NTP Annual Plan for Fiscal Year 1987," is encouraging interested parties to nominate chemicals for possible toxicological studies.

NTP's two-part report covers current NTP research in applied studies, methods development and validation efforts. It also lists chemicals under study by various Department of Health and Human Services agencies, including the Food and Drug Administration, National Cancer Institute and the National Institutes of Health; the Department of Energy and the Environmental Protection Agency. The major research areas are carcinogenesis, cellular and genetic toxicology, reproductive and development toxicology, and characterization for cardiac, cutaneous, immunologic, neurobehavioral and renal toxicologies.

NTP has asked that in making requests, nominators include the name of the chemical, the rationale for its nomination and a recommendation as to the type of study. Additional information on its chemical and physical properties, production, use, occurrence, toxicity and chemical disposition also is sought.

Copies of the "NTP Annual Plan for Fiscal Year 1987" and the "FY 1987 Review of Current DHHS, DOE, and EPA Research Related to Toxicology" are available from the NTP Public Information Office, PO Box 12233, Research Triangle Park, NC 27709. Comments on the report or chemical nominations should be addressed to Larry Hart at the above address. Details: *Federal Register*, Oct. 21, 1987, pp. 39286-39288.

FDA receives fish oil data

At the request of the U.S. Food and Drug Administration (FDA), the National Fish Meal and Oil Association (NFMOA) has submitted additional information to support its petition for Generally Recognized as Safe (GRAS) status for menhaden oil.

FDA had requested more information on specifications for heavy metals such as mercury and for selected hydrocarbons, including polychlorinated biphenyls (PCB) and certain pesticides. The agency also recommended that the Iodine Value (IV) range of 10–149 suggested by the association for partially hydrogenated menhaden oil be narrowed because it "would be more representative of the oil intended for use in food."

In response to FDA's concerns about heavy metal concentrations, NFMOA indicated it expected that menhaden oil and partially hydrogenated menhaden oil would have specifications similar to the GRAS limits for low erucic acid rapeseed oil of 40 parts per million (ppm) for heavy metals, 10 ppm for lead and 3 ppm for arsenic "except in instances where higher levels cannot be avoided." The association said determining levels for chlorinated pesticides and PCB "is more problematic" because there are no established levels for these in the Food Chemicals Codex. However NFMOA recommended maximum levels of 2 ppm for toxaphene and 0.5 ppm each for other pesticides that have action levels for fishery products.

The fish meal and oil processors organization noted that "it would be a disservice to the U.S. industry to restrict potential new uses by narrowing the IV range." It noted that partially hydrogenated menhaden oil in the IV range of 35–85 is used for margarine and shortening in Europe. Oil in the 20–35 IV range is used for feedstock margarine and shortening. According to the group, fish oils in South America are hydrogenated to IV 110–120 for use in cooking oils and to IV 18–25 for use as an anti-staling agent in bread dough in South Africa.

Asked whether natural toxicants are present in refined menhaden oil, NFMOA said the chemical characteristics of marine toxins may prevent their accumulation in extracted oil. Details: *Food Chemical News*, Nov. 2, 1987, pp. 11–13.

FDA action on GRAS request

The U.S. Food and Drug Administration has granted glyceryl behenate generally recognized as safe (GRAS) status for use as a formulation aid in foods prepared as tablets. Glyceryl behenate is a mixture of glyceryl esters of commercial behenic acid produced from hydrogenated rapeseed oil.

The request for GRAS status came from Gattefosse Etablissements, Saint Priest, France. The company proposes to use the compound as an excipient at levels of 1–4% of total tablet weight. In some cases, such as in sustained release formulations, the levels may be 10–20%.

FDA affirmed the use of glyceryl behenate based on the material's similarity to fully hydrogenated rapeseed oil and superglycerinated fully hydrogenated rapeseed oil. Both oils have GRAS status. Details: *Federal Register*, Nov. 5, 1987, pp. 42429-42430.

Microbial safety committee formed

The U.S. Department of Agriculture (USDA), in conjunction with the Department of Health and Human Services (DHHS), has announced the establishment of the National Advisory Committee on Microbiological Quality Standards for Foods.

The committee will advise the Departments of Agriculture and Health and Human Services on the development of microbial criteria to determine the safety of foods. Those criteria will include standards for microorganisms that indicate whether foods have been processed in accordance with good manufacturing practices. Details: *Federal Register*, Nov. 10, 1987, p. 43216.

Meanwhile, USDA has announced there will be a 12.5% acreage reduction for the 1988 upland cotton program. The established target price will be 77 cents per pound; the loan level will be 51.8 cents per pound for the base quality of upland cotton.

Delaney versus 'de minimis'

A U.S. Court of Appeals' unanimous ruling that the U.S. Food and Drug Administration (FDA) cannot use its de minimis policy to approve color additives may indicate the end of FDA's ability to reinterpret the Delaney clause. According to Raymond Gill, deputy director of the Office of Compliance in FDA's Center for Food Safety and Applied Nutrition, the decision "could very well mean that administrative solutions to create flexibility in dealing with food additive petitions may have been exhausted."

The three-judge decision by the District of Columbia Court of Appeals in October overruled FDA's decision to allow Orange 17 and Red 19 to remain on the market despite evidence that they cause cancer in laboratory animals. FDA had argued that because the dyes present such a small risk (de minimis interpretation) to humans, a strict interpretation of the Delaney clause was unreasonable. The Delaney clause of the Color Additive Law prohibits the use of additives that induce cancer in appropriate and relevant animal studies.

Although the judges wrote that "we hold that the agency's de minimis interpretation of the Delaney clause of the Color Additive Amendments is contrary to law," they stressed that congressional action might be needed. Critics of the Delaney clause claim the rule is too rigid and does not make allowances for advancements in ability to detect carcinogenic materials in quite small amounts. Late last year, 13 Republicans on the House Committee on Government Operations called the clause "a terribly outmoded and inflexible law."

USDA and FDA appointments

Frank A. Shank, director of the office of physical sciences in the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition, has been named acting deputy director of the center. Raymond W. Gill will serve as deputy director of the Office of Compliance in the center.

At the U.S. Department of Agriculture's Food Safety and Inspection Service, Ronald Prucha has been appointed associate administrator and Marvin Norcross has been named deputy administrator of science.