FDA ponders fat substitutes

The Food and Drug Administration (FDA) may need to establish guidelines for human testing of emerging fat substitutes such as Simplesse and Olestra, according to F. Edward Scarborough, acting director of the Office of Nutrition and Food Sciences in FDA's Center for Food Safety and Applied Nutrition. Scarborough spoke at the American Dietetic Association's annual meeting on Oct. 24.

"Because humans are the intended consumers of these additives and because part of the safety factor is an expression of our uncertainty of extrapolating animal test data to humans, human clinical studies seem to be a logical alternative for reducing the traditional safety factor," Scarborough said. "Another fundamental question remains. How much animal safety data is needed before going to clinical testing in humans?"

Scarborough said the fat substitutes pose nutritionally related questions not typically posed for other food additives: "What would be the effect of the fat substitute on vitamin and mineral status? Will the fat-soluble vitamins be partitioned into the fat substitute and be flushed throughout the body, thus limiting a person's ability to absorb these vitamins?"

Scarborough also noted "an explosive growth in the use of fiber, particularly soluble fiber, in foods, and bulking agents such as polydextrose are being more widely used . . . . How do we as regulators deal with the cumulative effects, and potential interactions, associated with this rather significant change in overall dietary patterns?" he asked. From Food Chemical News, Nov. 6, 1989, pp. 51-52.

Rapeseed planting may increase

The Disaster Assistance Act of 1989, recently signed into law by President Bush, allows farmers greater flexibility in planting high erucic acid rapeseed (HEAR) and canola. The act has a provision which allows farmers to plant up to 20% of their permitted 1990 program acres to a variety of small oilseed and industrial crops, including HEAR and canola. Farm program benefits will not be paid on the substituted acreage, but it will be "considered planted" to the relevant program crop for purposes of determining a farmer's program base in future years. Without this assurance, many farmers would be reluctant to plant alternative "non-program" crops. Source: Calgene Chemical Update, November 1989.

Modified bentonite, hectorite okayed

The Food and Drug Administration (FDA) has cleared bentonite and hectorite (each modified by reaction with benzyl dimethyl alkyl ammonium chloride, where the alkyl groups are derived from hydrogenated tallow) for use as modifiers in resinous and polymeric coatings for food packaging.

The action was in response to petitions by N.L. Industries (for modified bentonite and hectorite) and United Catalysts (for modified bentonite). FDA determined that the additives are not pigments but rheological agents used in coatings to control flow, viscosity and pigment suspension. Contact: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW, Washington, DC 20204. Telephone 202-472-5960. From The Federal Register, Nov. 17, 1989, pp. 47764-47766.

In addition, FDA is considering a petition filed by ICI Americas Inc. proposing that the food additive regulations be amended to provide for the safe use of polyethylene glycol/poly(12-hydroxystearic acid) copolymer as a stabilizer in the preparation of polyacrylamide retention and drainage aids used to make paper and paperboard used in contact with aqueous and fatty food. Contact: Andrew D. Laumbach at the above address. From The Federal Register, Nov. 17, 1989, p. 47828.
FROM WASHINGTON

Olestra not toxic in beagle study

Research presented at the annual meeting of the American College of Toxicology in Williamsburg, Virginia, on Oct. 29–Nov. 1, 1989, showed that olestra is not toxic to beagles when fed at 10% of the diet for 90 weeks.

The researchers, K.W. Miller and C.L. Alden, of the Procter & Gamble Company, fed the fat substitute to three groups of beagles at 0%, 5% and 10% of the diet for 90 weeks. The diets were supplemented with vitamins A and E "at levels designed to compensate for any potential effects on the absorption of these vitamins by the high levels of olestra."

Aside from isolated incidences of soft stools (not diarrhea) in 17 of the 20 treated dogs, the researchers reported no ill effects. They found no biologically significant change in the status of fat-soluble vitamins A, D, E, and K. From Food Chemical News, Nov. 6, 1989, p. 48.

Hershey testing ‘light ice cream’

The Food and Drug Administration has issued a temporary permit to Hershey Creamery Co. to test market a “light ice cream” deviating from the U.S. standard for ice cream. The milkfat content of the ice cream is reduced by at least 50%, with vitamin A palmitate added. The product is designed to be nutritionally equivalent to ice cream, but containing fewer calories and less fat.

The permit is effective for 15 months, allowing a total of 500,000 cases of two half-gallon containers to be distributed in 16 states. Contact: Joanne Trav- ers, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW, Washington, DC 20204. Telephone 202-485-0324. From The Federal Register, November 17, 1989, p. 47829.

APHIS okays test of new cotton

The Animal and Plant Health Inspection Service (APHIS) has found that field testing of cotton plants genetically engineered to be Bromoxynil-tolerant will not have a significant impact on the quality of the environment. The finding allows Calgene Inc. of Davis, California, and Monsanto Agricultural Co., of St. Louis, Missouri, to field-test the cotton plants in Hawaii. Contact: James White (Monsanto inquiries), Biotechnologist, or Sivramiah Shantharam (Calgene inquiries), Biotechnologist; Biotechnology Permit Unit, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Rm. 841, Federal Building, 6505 Belcrest Rd., Hyattsville, MD 20782. Telephone 301-436-7612. From The Federal Register, Nov. 28, 1989. pp. 48921–48922, and Nov. 16, 1989, pp. 47700–47701.

U.S.-Mexico review begun by ITC

The United States International Trade Commission has begun a study of Mexico’s recent trade and investment reforms. (Continued)

Handbook of Soy Oil Processing and Utilization

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FROM WASHINGTON

The study is to be divided into two phases. Phase I will provide a comprehensive review of recent trade and investment liberalization measures undertaken by Mexico, and a description of the implications for U.S. exporters and investors. Phase II will provide a summary of the prospects for future U.S.-Mexican trade relations. This survey will explore such proposals as a free trade area, an enhanced dispute settlement mechanism, possible sectorial approaches, the recently established Framework of Understanding, and other options for enhanced bilateral trade relations.

A public hearing in connection with phase I of the study was held Dec. 4, 1989; a separate public hearing for phase II of this study will be announced later. Contact: Constance A. Hamilton, Trade Reports Division, Office of Economics, U.S. International Trade Commission, Washington, DC 20436. Telephone 202-252-1263.

Army evaluating reconstituted milk

The U.S. Army Natick Research and Development Center is evaluating proposals from potential contractors to enhance reconstituted milk by replacing the current coconut-based product with one based on an unsaturated oil.

The Natick Center said that the contract "shall determine the most successful combination of oils (including blends of oils) and emulsifying agents/homogenization that will result in a product that is equivalent to the current coconut-based product."

The Natick Center will evaluate samples, using microbiological, chemical, sensory and physical tests, over a three-week period. The oils demonstrating the best results will be selected for more extensive evaluation to provide confirmation of the performance. From Food Chemical News, Nov. 13, 1989, pp. 10-11.

Court upholds FDA

The Food and Drug Administration (FDA) recently obtained summary judgement of the U.S. District Court for the Central District of California in a contested seizure of evening primrose oil.

FDA claimed the oil contained an unapproved food additive. This action was one of a number of seizures made by FDA of evening primrose oil. In this case, 45 drums of the oil were seized from a California company. The claimant was the manufacturer, Efamol Ltd., a British company. In its motion to throw out the contested seizure case, Efamol stated that a panel of experts concluded that FDA's concerns about evening primrose oil were scientifically unfounded and invalid. From Food Chemical News, Nov. 6, 1989, pp. 22-23.