Trade complaint goes to GATT

The U.S. Trade Representative in June was scheduled to resubmit a request that the General Agreement on Tariffs and Trade (GATT) Council establish a panel to investigate charges that European Economic Community (EEC) subsidies are unfair to U.S. soybean exporters. The U.S. made a similar request in May, but the EEC blocked the formation of an investigative panel.

Unfair trade practice charges against the EEC originated with the American Soybean Association (ASA), which filed a Section 301 trade complaint with the U.S. Trade Representative's office last year. ASA claimed that European subsidy programs had nullified the agreement between the U.S. and Europe that allowed duty-free imports of U.S. soybeans and soybean meal into Europe. The subsidies caused U.S. farmers to lose $1 billion in European sales annually, according to ASA. The EEC claims U.S. losses were due to increased imports of Brazilian and Argentine soybean and soymeal rather than to EEC agricultural policies.

"The EEC strongly opposes the U.S. taking the ASA complaint to a GATT panel since it is very likely such a panel will rule in favor of the U.S. on the issue," according to John Baize, ASA's staff vice president for trade and export policy. Baize explained that under GATT rules, the establishment of a dispute settlement panel requires the approval of all GATT-member nations, including the nation charged with violating GATT rules. If the EEC blocks the establishment of an investigative panel at three GATT meetings, the U.S. can act unilaterally to adopt retaliatory sanctions, Baize said.

FDA takes on omega-3 claims

The U.S. Food and Drug Administration (FDA) has asked its district offices to take action against marketers of omega-3 fatty acid products who make unfounded health claims about their products.

In a health fraud bulletin to the districts, FDA said, "There is no general recognition of the therapeutic role of omega-3 fatty acids in human nutrition and health at this time." Advertising and labeling claims for omega-3 products have been based on interpretation of preliminary data by commercial interests, FDA's health fraud staff said.

An FDA survey conducted in 1987 found that labels on omega-3 products made claims about the prevention or treatment of arthritis, atherosclerosis, cancer, diabetes, eczema and psoriasis. Others claimed to lower cholesterol, triglyceride levels and blood pressure. Products for which these kinds of claims are made generally are considered prescription drugs by the FDA and as such must go through the agency's drug approval system. However, FDA said, "Adequate and well-controlled clinical studies have not been completed (on omega-3 products) under the investigational new drug and new drug application procedures, and there is no general recognition by qualified experts to warrant these marketing claims at this time."

Rather than use enforcement methods such as seizures, injunctions and criminal prosecution against marketers making health claims on their omega-3 fatty acid products, FDA told the district offices to use regulatory letters instead. The letters will inform marketers of FDA's legal position and allow them a chance to respond, FDA said.

Shaklee Corp., a Sacramento, California, company that markets products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), was the first company to receive one of these letters.

FDA said the health fraud bulletin deals only with dietary supplement products that make therapeutic claims for marine lipids; it will not affect the Generally Recognized as Safe (GRAS) petition for menhaden oil, which is before the agency.

Meanwhile, the National Fish Meal and Oil Association (NFMOA) has asked FDA to confine its determination of GRAS status for refined menhaden oil to food product uses. In a letter to FDA, NFMOA's Roy Martin said the affirmation of refined menhaden oil in fish oil capsule products "might present additional difficulties with respect to a safety assessment, because such capsules may be consumed in excessively large quantities by certain persons."

To speed the affirmation process, NFMOA said it is willing to have the agency limit the GRAS affirmation for refined menhaden oil in foods other than dietary supplements provided the refined menhaden oil in the finished food composes no more than 30% of the total weight of the finished food. FDA previously said it will rule separately on the GRAS status of partially hydrogenated menhaden oil.

FDA also has said it is concerned about the potential health effects of all fish oils, not just menhaden oil, which is presently under evaluation. Details: *Food Chemical News*, April 25, 1988, pp. 3-5; May 2, 1988, pp. 26-27; May 16, 1988, pp. 9-10.

FDA considers olive oil needs

The Food and Drug Administration (FDA) has told the International Olive Oil Council (IOOC) that FDA "was not in a position to establish a standard for olive oil products."

FDA officials met with representatives from the Association of Food Industries, the Tunisia National Vegetable Oil Office, the Turkish Olive and Olive Oil Exporters Union, the Turkish Embassy, the Moroccan Ministry of Agriculture and IOOC earlier this year to consider an IOOC request that a food standard be developed.

FDA has not published any new food standards in the past year, and according to a memo about the meeting by David Firestone of FDA's Center for Food Safety and Applied Nutrition, "The U.S. is moving away from commodity standards."

IOOC has asked FDA if it would consider establishing a practice code, even if it did not establish a standard. Fausto Luchetti, IOOC executive director, suggested that olive oil be divided into three grades: extra virgin oil, which would have an acid content of less than 1%; olive oil, which would be a blend of refined and virgin olive oil; and olive pomace oil. He also asked that the label include information about cholesterol and monounsaturated fatty acid levels.

FDA said it would consider the IOOC proposal "in light of marketplace needs, as well as evaluate the Codex standard versus the current IOOC International Olive Oil Agreement." FDA added that it would continue to work with representatives of the olive oil industry to control olive oil adulteration and to develop better methods to determine when adulteration has occurred. Details: *Food Chemical News*, May 16, 1988, pp. 52–54.

In other olive oil-related news, a three-judge panel in Madrid is expected to hand down a decision in July in the trial of eight businessmen charged in the 1981 Spanish toxic oil incident. The death toll in that case now totals 605 persons. The prosecuter has asked that the eight businessmen be sentenced to 61,500-year terms on a number of charges, including 605 counts of homicide.

Linseed oil firm replies to FDA

Lawyers for Flora Distributors Ltd. of Burnaby, Canada, continue to assert that their client's linseed vegetable oil product is a food rather than a food additive and that it has been consumed for centuries.

The vegetable oil distributed by Flora could not be a food additive using "applicable parameters of the federal Food, Drug and Cosmetic Act," according to Kirkpatrick Dilling. Dilling is a member of Dilling, Gronek and Armstrong, the Chicago law firm that represents the Canadian company.

FDA has detained imports of the company's linseed oil due to concern that it may not be fit for use in human food. "We do not believe that the currently available information allows us to conclude that linseed oil is Generally Recognized as Safe," according to Robert Lake, director of the Office of Compliance in FDA's Center for Food Safety and Applied Nutrition.

Lake said the data supplied by the company did not establish clearly that linseed oil was commonly used as a food before 1958. Lake also expressed concern about the company's failure to submit data showing that long-term linseed oil consumption is safe. Details: *Food Chemical News*, May 2, 1988, p. 16; April 18, 1988, p. 37.

OSHA upheld on cotton dust rule

The U.S. Supreme Court has declined to review, and thereby affirmed, a lower court's ruling upholding regulations requiring medical surveillance of workers exposed to cotton dust in cottonseed oil mills.

The National Cottonseed Products Association had argued that no significant risk of health impairment in cotton oil mills had been shown, and therefore the Occupational Safety and Health Agency (OSHA) should not require such surveillance.