Women's Health Trial put on hold

The following article updating the status of a planned major health trial concerning dietary fat and breast cancer was written by David M. Klurfeld of The Wistar Institute. It was prepared with the direction of J. Edward Hunter of Procter & Gamble, Associate Editor for JAOCS *News for Health and Nutrition.*

What had been proposed by the National Cancer Institute's (NCI) Division of Cancer Prevention & Control as a definitive test of the link between dietary fat and breast cancer may never be undertaken.

In a vote of 11 to 1 (with two abstentions), NCI's Board of Scientific Counselors (BSC) Jan. 7, 1988, recommended not to proceed with the Women's Health Trial (WHT), planned as a randomized, controlled trial of 32,000 women, ages 45–69 at enrollment, at increased risk for developing breast cancer.

In the trial, 40% of the women would have been instructed to consume a diet with 20% of calories derived from fat; the remainder (controls) would continue on their usual diets (38%–40% calories derived from fat). The women would have been followed for up to 10 years for breast cancer development. The trial, to be conducted at 20 collaborating centers, was projected to cost $130 million.

Before the BSC vote, three clinics (Cincinnati, Houston and Seattle) already had recruited about 1,500 women for the study. These volunteers will be followed without further enrollment of subjects.

BSC's major objection was the scientific basis for the hypothesis linking dietary fat with breast cancer is too weak to justify a randomized trial. Evidence was cited that recent animal studies show the increased risk from high fat diets might be due to higher caloric intake rather than to higher fat intake and that high dietary fat increased incidence of mammary cancer only under conditions of ad libitum feeding. These considerations may be especially relevant for participants in the WHT who unconsciously might restrict their caloric intake.

The BSC also concluded that epidemiologic studies (such as Willett's recent study [*New England Journal of Medicine 316*:22, 1987] reporting no association between total fat intake and breast cancer risk) do not provide strong support for the hypothesis. In addition, case-control studies provide little or no evidence in favor of the fat-cancer link. Correlation studies with positive results have serious limitations; for example, the BSC cited a study in which half the difference in risk between postmenopausal Dutch women and Japanese women could be attributed to the greater weight of the Dutch women. Increased dietary fat and calories also have been related to reduced age of menarche, and early menarche is an established risk factor.

NCI had predicted that the proposed dietary alteration would reduce breast cancer incidence by 50%; BSC considered a reduction of more than 25% highly unlikely. Statistical considerations indicated that the study would need to be four times larger or six years longer than planned to achieve a statistically significant result. Although the BSC accepted the idea that compliance with the low fat diet could be monitored using measurement of serum cholesterol, the intervention group enrolled at the three existing centers to date showed a drop of only 4% (equivalent to about 8 mg/dl). The intervention group also reduced caloric intake by 21% and had a mean weight loss of 3 kg.

Concern was expressed that as public awareness increases about the National Institutes of Health's National Cholesterol Education Program, the control subjects in the study inadvertently might decrease their fat intake. This would reduce the likelihood of seeing a significant difference in tumor development between the low fat and control groups.

In a vote intended to head off misinterpretation by the press that the recommendation not to proceed with the WHT indicates there is no relationship between fat and cancer, the BSC voted unanimously to

Omega-3 FA from algae

Omega-3 fatty acids (FA) derived from algae will cost more to produce than those from fish oil but will offer certain advantages, particularly for pharmaceutical uses, according to *Bioprocessing Technology*, a monthly newsletter published by Technical Insights Inc.

The newsletter noted that unlike fish oil concentrates, algal oil contains no cholesterol and does not accumulate high levels of heavy metals or pesticides. Also, because algaes can be grown under controlled conditions, more consistent product formation may be possible than with fish oils. In addition, strains of algae might be selected to produce specific profiles of omega-3 fatty acids.

For more details, see the January 1988 issue of *Bioprocessing Technology*.

endorse the current NCI dietary recommendations that advocate a reduction of dietary fat from 40% to 30% of calories.

It is unlikely that this is the last that will be heard of this or a similar study because top officials of NCI are committed to conducting a prospective intervention trial on diet and cancer. Those involved with WHT have suggested alterations in the study design to include multiple factors (type and amount of fat, caloric intake, energy expenditure, blood hormone levels) and multiple endpoints (types of cancer, mortality) to make it acceptable to scientific review.

A final decision on whether to proceed with a study will be made by Vincent DeVita, director of NCI. According to Maryann Roper, NCI's acting deputy director, "The trial as (originally) designed will not go forward, but we are talking with the investigators to determine what the best design might be."

Fish production

World production of fish meal in 1986/87 is estimated at 5.86 million metric tons (MT), down 8%

from the previous year, according to the U.S. Department of Agriculture (USDA). World fish oil production, meanwhile, declined to 1.3 million MT, a 12% drop from 1985/86.

USDA said most of the decline occurred as a result of reduced catch in South America, particularly Chile, Peru and Ecuador.

Peru's total fish catch is said to have dropped 27% in 1987 because of poor fishing, particularly during the last six months of the year. Fish meal production is estimated to have dropped 25% in 1987, although fish meal exports were estimated at 720,000 MT, a 3% increase, due to the use of stocks.

Ecuador's fish catch dropped nearly 37% in 1987. Reports attributed the low catch to high water temperatures experienced during the first and last months of the year. Fish meal production is estimated at 150,000 MT, down 56,000 MT from 1986.

Chile's fish meal production is estimated to have declined nearly 19% during 1987.

Denmark's fish catch in 1987 dropped nearly 14%. USDA said fishermen there have been less interested in increasing the catch because it isn't profitable.

Japan, the world's largest fish oil producer, produced approximately 370,000 MT, up slightly from the previous year. However, Peru, Chile and Ecuador combined produced nearly 210,000 MT less during 1987 than compared with 1986.

USDA forecast world production of fish meal and oil to rebound in 1987/88 as the fish catch in the major-producing countries recovers from the effects of the "El Niño" experienced during 1986/87.

International

Brazil
The Brazilian government has approved reducing the import duty on palm stearin to 10% from 70%. According to *The Cocomunity* newsletter, the move was taken to encourage more palm stearin imports as an alternative to tallow in soap production.

Chile
The government of Chile has added oilseeds to its list of agricultural products subject to minimum import prices. Vegetable oils, sugar and wheat already are subject to such pricing.

Coconuts
Coconut production is forecast to decline in the Philippines and Sri Lanka in 1988. The United Coconut Association of the Philippines said that nation's 1988 coconut production would be 1.998 million metric tons (MT) (copra equivalent), compared with 2.321 million MT in 1987. USDA estimated Sri Lankan coconut production for 1988 at less than half the 1986 output. Copra production for 1988 is forecast at 112,000 MT; oil production is estimated at 65,000 MT.

Europe
The European Economic Community (EEC) has set Maximum Guaranteed Quantities (MGQ)—the maximum threshhold for which it will offer full price support—for rapeseed, sunflowerseed and soybeans for the next three years. In 1988/89, 1989/90 and 1990/91, the EEC will grant full price support to annual production of 4.5 million MT of rapeseed, 2 million MT of sunflowerseed and 1.3 million MT of soybeans, according to an *Oil World* report.

Based on early projections, *Oil World* said European production for 1988 could exceed established MGQ. If output exceeds MGQ, support prices will be reduced by 0.45% for each 1% produced in excess of the MGQ. The new prices go into effect on Aug. 31 for rapeseed, Sept. 30 for sunflowerseed and Oct. 31 for soybeans.

Greece
The American Soybean Association (ASA) has helped launch the first cooking oil in Greece labeled as 100% soybean oil. Government regulations prohibited the sale of soybean oil in Greece before Greece's entry into the European Economic Community (EEC) as a full-fledged member.

India
In mid-February, estimates for India's edible oil imports for 1987/88 were set at 1.5 million MT, and not the 2.1 million MT predicted previously, due to favorable conditions for the summer (Rabi) oilseeds crop. Summer crop production is predicted to surpass six million MT, including more than three million MT of rapeseed and 1.7 million MT of unshelled peanuts. Last year's summer crop totaled 5.2 million MT.

In other news, the *New Delhi (India) Patriot* reported that jojoba and castor oil have been successfully hydrogenated at room temperature under atmospheric conditions for the first time in India. The report said researchers at the Central Salt and Marine Chemicals Research Center in Bhavnagar, India, were conducting the work. The lab-scale process involves the use of ruthenium. Pilot-scale work was to begin shortly, the report said.

Also, India and the Soviet Union have signed an agreement for a joint venture establishing an export and vegetable oilseeds processing unit in India, according to a report in the February 1988 *Oil Mill Gazetteer*. Under the agreement, research groups from the two countries will collaborate technically on enzyme-active soybean oil extraction, facility moderization for processing edible oils, ethyl alcohol manufacturing from non-molasses sources and commerical seed production.

Meanwhile, the European Economic Community (EEC) has said it will provide aid to India worth 45 million European Currency Units (ECU), equivalent to about U.S. $57 million, for a coconut development project in Kerala State. According to USDA, about 21.2 million ECU would be paid in foreign exchange, and the balance provided in the form of vegetable oil. The proceeds of the sale of the vegetable oil on the domestic market will finance the rest of the development project.

Also, Malaysian and Indian government officials have been discussing possible joint ventures in palm oil production and processing. The Malaysian government has asked the Indian government and private sector to consider investing in Malaysian oil palm estates to give India a stake in the palm oil industry. USDA said Malaysian firms in turn would invest in upstream palm oil projects such as soap manufacturing.

Japan
Nisshin Oil Mills Ltd. has completed a soybean extraction plant at its Isogo complex in Yokohama, according to a report in *Yushi*, a monthly Japanese trade publication. The article said the plant can produce 20,000 to 25,000 MT of defatted soy meal per year for processing into other types of soy protein products.

Malaysia
USDA forecasts Malaysian soybean meal consumption will rise to 370,000 MT in 1987/88, an 8% increase over last year. The projected increase is attributed to improved feed demand. Malaysian soybean meal imports are forecast at 190,000 MT, and soybean imports could reach 270,000 MT.

China, which supplied more than 70% of Malaysia's imported soybeans and about 80% of the meal in 1986/87, is expected to remain the major supplier. Earlier this year, the Malaysian govern-

ment announced that special licenses for goods imported from China were no longer needed. As of late January, the U.S. had sold 23,000 MT of soybeans to Malaysia. In 1986/87, Malaysia bought no U.S. soybeans or meal.

USDA said Malaysian press reports have indicated Malaysia will send a technical mission to India, Pakistan, Bangladesh, Turkey and Tunisia in April. The mission's objective is to counter the American Soybean Association's tropical fats labeling campaign. Press reports also indicated Malaysia may consider offering long-term supply contracts to major consuming nations such as India, Pakistan and China.

Meanwhile, reversing adjustments made last November, the Malaysian government has raised export duties on processed and crude palm oil to 77.60 and 58.55 ringgit per ton, respectively, USDA reported. At exchange rates in January, the new taxes would equal $30.68 per ton for processed oil and $23.15 per ton for crude oils.

Mexico

The Mexican government has eliminated the 10% ad valorem import tariff on cottonseed oil, USDA has reported.

Meanwhile, USDA said Mexico's safflower production for 1987/88 increased to 225,000 MT. This is not expected to have an impact on imports of U.S. soybeans, but U.S. sunflowerseed and Canadian canola imports may be affected. USDA estimates Mexican oilseed imports will total between 1.8 million and 1.9 million MT.

Pakistan

The Pakistani government has lowered the import duty on edible palm oil to 2,250 rupees per MT so that the government-owned Ghee Corp. can continue selling vegetable oil at a lower, controlled price. According to USDA reports, the duty was reduced from its previous level of 3,000 rupees per MT following increases in the international palm oil price.

USDA said the higher price for imported palm oil would have forced the government to raise the price of ghee, a politically sensitive issue. The increased cost of imports has forced the private sector ghee producers to raise prices, causing these producers to complain that they can not compete against government prices. USDA said local producers have criticized the government's decision because it may depress the price of locally produced cottonseed oil.

Pakistan will continue to charge a duty of 3,000 rupees per MT on all other imported edible oils and will add an additional 3,000 rupees per MT for palm oil when it is imported for non-edible uses.

Switzerland

Switzerland has announced it will provide price supports to soybean producers for the first time, accord-

ing to USDA. USDA said the Swiss government will pay farmers 205 Swiss francs per quintal (approximately $1,519 per MT, based on an exchange rate of 1.35 Swiss francs to the dollar) for soybeans in 1988.

The government's soybean support program is for a maximum area of 2,000 hectares. Although *Terre Romande*, a French-language newspaper, said the federal research station has developed two soybean varieties, USDA said other sources indicate the government only will offer price guarantees for Maple Arrow, a Canadian variety. According to *Terre Romande*, the two Swiss varieties, Silvia and Ceresia, give yields of more than 30 quintals perhectare.

In an effort to improve Swiss self-sufficiency in vegetable oils, the government also supports rapeseed. However, rapeseed has not become popular in Switizerland, and consumption is declining, USDA said.

Turkey

The Turkish Council of Ministers has reduced the import surcharge on edible oils to $10 per ton, up from $70 per ton.

United States

The U.S. Congress has approved a $10 million program to increase sunflowerseed oil exports. Under the program, USDA is instructed to use $10 million in fiscal years 1988 and 1989 to buy sunflowerseed oil to be used as an incentive to facilitate export sales at competitive prices. According to a USDA report, the intent of the legislation is to raise exports to the 1980/81 level of about 300,000 MT.

Plant purchase

Central Soya Co. Inc. has signed a contract to purchase Louisville Edible Oil Products (LEOP) and Golden Brands, a vegetable oil refinery and packaging plant in Louisville, Kentucky. The acquisition is to be completed by Aug. 1, 1988, according to Central Soya.

Central Soya currently operates edible vegetable oil refineries in Decatur, Indiana, and Chattanooga, Tennessee, an industrial and edible oil refinery in Bellevue, Ohio, and a packaged shortening plant at Decatur. The refineries all are part of larger soybean processing facilities and are generally limited to soybean oil refining because of integrated processing conditions, according to David Swanson, president and chief executive officer for

Central Soya. The acquisition of LEOP, which processes soybean, corn, cotton and peanut oil, "makes Central Soya a full-line vegetable oil refiner," Swanson said.

LEOP, the only edible oil refiner in Kentucky, supplies vegetable oils and oil blends to food processors for use in margarines, mayonnaise, cooking and salad oils and shortenings. Golden Brands supplies packaged shortening and oil. According to the company, it produced nearly one billion pounds of vegetable oil in 1987.

The existing Louisville facility, formerly a Durkee plant, is in the process of being moved about three miles to the site of a former Seagrams distillery. Central Soya will purchase a complex of buildings and approximately 14 acres of the original 56-acre distillery site.

Two to merge

Capital City Products Co. of Columbus, Ohio, and Karlshamns AB of Sweden in mid-February announced the two companies would merge, with Karlshamns buying all of Capital City Products' stock.

The transaction was expected to be completed within 30 days. Under the agreement, Capital City Products will retain its existing name, management, facilities and employees. The 105-year-old company employs a total of about 600 persons at its facilities in Columbus (Ohio), Kearney (New Jersey) and Janesville (Wisconsin) and has annual sales totaling $130 million.

Annual international sales for Karlshamns' oils and fats division equal about $190 million. The merger will provide Karlshamns with entry into American markets, particularly for products sold to the U.S. confectionery industries. Capital City Products officials said that under the merger, the new parent company will provide capital for plant improvements and program expansions, additional research and development expertise for introducing new products and international marketing opportunities.

Capital City Products manufactures and distributes vegetable oil, fat-derived chemicals and specialty fats and oils processed from domestic and imported vegetable oils. Karlshamn, founded in 1917, is a Sweden-based international manufacturer and marketer, with primary markets in Scandinavia, Eastern and Western Europe, the Middle and Far East, Africa and Latin America. It is Sweden's largest producer of vegetable oils and fats.

Crown Iron buys

Crown Iron Works Co. of Minneapolis, Minnesota, in late February announced it had acquired Wurster & Sanger Inc., a chemical engineering firm in Chicago, Illinois. Wurster & Sanger, now a division of Crown Iron Works, will continue to design and fabricate processing plants for edible oils and fats, fatty acids and glycerine.

According to Crown, "The addition of Wurster & Sanger processes extends Crown's design and production capabilities from raw seed processing through all stages of refining to finished products." Crown develops and builds continuous liquid/solid contacting systems for the solvent extraction of oil from oilseeds.

Crown named Donald M. Godell vice president of engineering and Barry V. Smith vice president of marketing for the Wurster & Sanger Division. Jeffrey Scott will serve as vice president of sales for Crown's extraction equipment division. Sales and research facilities for both divisions will be moved to Minneapolis, according to Crown.

Carver plants

Carver Inc. will provide a cottonseed preparation facility to Burma's Textile Industry Corp. and a hulling mill to the Epic Oil Mill in Johannesburg, South Africa.

According to Jack Lee, Carver's president, Carver worked with Simon-Rosedowns Ltd. to provide the plant to the Burmese company. The plant, due to be installed this year, has 70-tons-per-day delinting capacity and 30-tons-per-day decortication capacity.

The hulling mill sold to the Epic Oil Mill has a 500-tons-per-day capacity and can process both cottonseed and sunflowerseed, according to Carver. The mill is expected to be operational by late summer.

News briefs

Borden Inc. has purchased **Humpty Dumpty Foods Ltd.** from **American Brands Inc.** Humpty Dumpty, based in Montreal, Canada, is a major producer of snack foods in Eastern Canada; its snacks include potato chips, corn and tortilla chips, extruded potato and corn products and popcorn.

George F. Goebeler has been named president of the International Group of **Kraft Inc.** Goebeler previously served as vice chairman of **Chesebrough-Pond's Inc.**

Beatrice Co. of Chicago has retained First Boston Corp. to evaluate inquiries related to the sale of its domestic operations, which include **Beatrice/Hunt-Wesson Inc.**, Swift-Eckrich Inc., and Beatrice Cheese Inc.

Fred Husbands, former executive vice president of the National Cottonseed Products Association (NCPA), died Jan. 22, 1988, in Abilene, Texas. He was 75 years old. Husbands served as the NCPA chief staff officer from 1963 through 1978.

Du Pont of Wilmington, Delaware, has announced it will fund research at **DNA Plant Technology (DNAP)** to develop new varieties of canola to produce improved oils. The two companies will form a joint venture to market the products. Also, the New Jersey-based DNAP announced plans to merge with **Advanced Genetic Sciences** of Oakland, California.

Experience Inc.'s new address is 1200 Second Ave. S., Suite 400, Minneapolis, MN 55403, USA. The

company's telephone number is 612-338-7844; its telefax number is 612-338-8005.

A feature article, "The Numbers Game," in the *Chicago Tribune's Sunday* magazine Feb. 21, 1988, cited work at **Woodson-Tenent Laboratories Inc.** to show how calories are counted in frozen entrées. Photographs of and comments by three AOCS members—**Lars Reimann, Linda Littlejohn** and **Doug Bark**, all at Woodson-Tenent—were part of the article.

A new company, **Supercritical Processing Inc.**, has been formed to commercialize supercritical fluid extraction. The company has purchased the assets of the supercritical processing venture of **Air Products and Chemicals Ltd.** Founders of the company are **Zvi H. Weinman**, president, and **Raymond J. Robey**, vice president. The firm is based in Allentown, Pennsylvania.

AOCS member **Nagin Patel** has been named chief operating officer at **Alberta Terminals Canola Crushers Ltd.** in Sexsmith, Alberta, Canada.

From Washington

EPA requires hexane testing

The U.S. Environmental Protection Agency (EPA) has ruled that commercial hexane manufacturers and processors must test the chemical for its subchronic toxicity, oncogenicity, reproductive toxicity, developmental toxicity, mutagenicity, neurotoxicity, and inhalation and dermal pharmacokinetics.

Earlier, EPA had proposed that more acute toxicity research be carried out, but the agency concluded that additional studies were unnecessary after reviewing information provided by industry groups, according to the final rule published in the *Federal Register* on Feb. 5, 1988. The agency also dropped an earlier proposal that would have required manufacturers and processors to run similar tests on methylcyclopentane (MCP), the second largest constituent in commercial hexane after *n*-hexane.

The regulations, which went into effect March 21, 1988, require manufacturers and processors to test the effects of hexane on health "if the exposure giving rise to the potential risks occurs during distribution in commerce, use or disposal of the chemical." EPA defined commercial hexane as hexane containing at least 40 liquid volume percent *n*-hexane and at least 5 liquid volume percent MCP. However, for test purposes, MCP content must be at least 10 liquid volume percent.

"EPA believes that the test substance will represent a worst-case exposure to MCP and C_6 isomers other than *n*-hexane and provide a complement to existing data on *n*-hexane," the *Federal Register* rule noted.

Manufacturers subject to the new rules are required to submit either a letter of intent to perform testing or an exemption application no more than 30 days after the regulations go into effect. Under Toxic Substances Control Act (TSCA) provisions to prevent duplicate tests, EPA can allow two or more manufacturers to designate someone to conduct the research for them. Processors only are required to submit the letter or application if manufacturers fail to submit a letter or sponsor the required tests.

According to the ruling, anyone violating the testing rules would be subject to criminal and civil liabilities under TSCA. Civil and criminal penalties could result in fines up to $25,000 for each violation. "Knowing and willful violations" also could result in imprisonment for up to one year. Among those who could be subject to penalties are "persons who submit materially misleading or false information." Failure to submit the letter of intent or the exemption request could result in civil penalties, according to the rule.

EPA estimated testing costs for the study would range from $2.2 million to $2.9 million. Figures from 1985 indicate that approximately 83,000 workers have actual exposure to hexane solvents. Details: *Federal Register*, Feb. 5, 1988, pp. 3382–3395.

Patent Office hears appeal

Lawyers for Harold N. Barham and Harold N. Barham Jr. have appealed a U.S. Patent Office decision to reject the Barhams' patent for the use of soybean oil in dust suppression. The U.S. Patent Office's rejection of Patent 4,208,433, "Method for the Adsorption of Solids by Whole Seeds," was the result of an American Soybean Association (ASA) request that the patent be reexamined.

ASA had claimed that for a patent to be valid, an invention must be novel, nonobvious and useful. The Patent Office determined that the use was not novel and that there was a history of prior art (meaning that oil had been used for dust suppression), according to David Erickson, ASA's director of technical services. When contacted, the patent examiner would not explain the reason for the rejection.

"Although the examiner essentially has taken the position that the invention was obvious, our position still is that its use was nonobvious," according to George Matava of Sheridan, Ross and McIntosh, the Denver, Colorado, patent firm representing the Barhams. "One way to establish that the invention was nonobvious is to present commercial success evidence."

Matava explained this meant that if companies weren't using oil to suppress dust on a commercial scale before the patent's issue, then the use of oil was nonobvious. "Everyone in hindsight can say the (dust