

SNN's Botanicals & Bioactives Update "A World Class Event"

On October 25th, the Saskatchewan Nutraceutical Network held the **Botanicals & Bioactives Update** conference at the Radisson Hotel in Saskatoon. Included in the day's events were presentations from renowned nutraceutical and functional food experts who provided up-to-the-minute information on market, consumer and product trends, new research results, marketing and business strategies as well as the latest on national and international health claim regulations. A panel presentation included nine of Saskatchewan's industry leaders who provided insight into the scale of activities within a sampling of SNN's 90 member organizations.

One hundred and thirty industry delegates were in attendance, travelling from across North America and beyond. Mr. William Tonks of Park Tonks flew in from Cambridge, UK to take in the event. His company is involved in the development of nutraceuticals for both veterinary and human applications. Conference attendees were highly impressed with the excellent

topic coverage. Speakers of international prominence provided high-quality and timely information. Dr. Clare Hasler's keynote address on the latest trends in nutraceutical development was particularly well received, and many attendees expressed an interest in making high-calibre seminars such as this an annual event.

There were 14 trade show exhibitors. The Saskatchewan Trade and Export Partnership highlighted their services that are directed towards the growth of Saskatchewan's export industry through specially tailored programs. The Crop Utilization Program of Agriculture & Agri-Food Canada's Saskatoon Research Centre provided information on their research expertise in the investigation of alternative commercial applications for prairie crops. Agriculture & Agri-Food Canada's Market and Industry Services Branch of Saskatoon promoted their Agri-



Dr. Clare Hasler

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Food Trade Service, an international business development service. Biopharmaceutical Research, Inc. of Burnaby, BC supplied information on analytical and research services for botanicals, nutraceuticals and pharmaceuticals. Buffaloberry product development was the focus of information provided by Extropian Agro Forestry Ventures, Ltd. of Beaubier, SK. The POS Pilot Plant Corporation highlighted their expertise in the areas of processing research and development, food and ingredients and milling, extraction and purification.

Bioriginal Food and Science Corporation of Saskatoon displayed samples of their nutraceutical product lines including essential fatty acid supplements and herbs. CANTOX Health Sciences International, based in Mississauga, ON, supplied information on their firm's specialization in scientific and regulatory issues. The Canadian Institute for Scientific and Technical Information (CISTI), of the National Research Council of Canada, provided an overview on their information services. Canadian Emu Oil, Ltd. of Carlyle, SK displayed their "Songlines" products that include lip balm and enriched soaps, and provided information on provincial emu oil processing activities. Canada Seabuckthorn Enterprises displayed numerous seabuckthorn products ranging from wines to jellies.

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Identifying the Next "Hot" Nutraceutical Trend

Dr. Clare Hasler, Executive Director of the Functional Foods for Health Program at the University of Illinois provided the Keynote Presentation at the **Botanicals and Bioactives Update** conference. She noted that with increasing health care costs, technical advances and an aging population, the growing trend toward self-care is no surprise and with this, the increasing interest in functional foods. A 1998 Consumer Magazine survey reported that 66% of consumers are purchasing products to reduce the risk of illness and 63% for managing illness. The top five factors motivating food purchase decisions, according to the results of this survey, are ensuring overall good health, reducing fat intake, following a physician's advice, and to control weight and cholesterol intake. In a focus group study, the International Food Information Council found that 9 out of 10 consumers believed they have control over their health.

In the U.S., several health claims are allowed that link nutrients or food groups to the reduction of particular diseases. Such claims have the power to steer consumers' perceptions and purchasing trends. Dr. Hasler expects the sales of soy products to double with the approval of a risk reduction claim for soy protein. The U.S. Food and Drug Administration (FDA) officially announced the new claim on October 20, 1999. The allowable claim states that consumption of 25 grams of soy protein daily, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. The FDA based its decision, in part, on a meta-analysis of 38 controlled clinical trials involving 730 individuals which showed a consistent lowering of total and low-density lipoprotein (LDL) cholesterol following the consumption of isolated soy protein, textured soy protein, or a combination of both (Anderson *et al.*, 1995. NEJM. 332:276). In order to display the claim, a food must contain at least 6.25 grams of soy protein per RACC and meet the nutrient requirements for a "low saturated fat" and "low cholesterol" food. "Whole soybeans in foods will still qualify as low fat," stated Hasler, "so long as the fat source is soy based." This is the first food protein claim accepted by the FDA.

The high concentration of isoflavones, among other components in the soybean, may contribute to its cholesterol lowering effects. "The FDA is not persuaded that the isoflavone component of soy protein is a relevant factor," said Hasler; however, "... evidence from a wide range of studies using differently processed soy protein is supportive of a relationship between soy protein and reduced risk of coronary heart disease."

Soy isoflavones may help to reduce bone loss in postmenopausal women at a rate comparable to hormone replacement therapy, suggesting a possibility for combating osteoporosis. In turn, calcium and isoflavone supplements for women are gaining popularity. A cross-sectional comparison of Japanese and Canadian women reported a much lower rate of hot flashes and night sweats in the former group, effects that were attributed to high levels of soy intake (Lock, 1991. *Lancet*. 337:1272). Hot flashes were reduced by 45% in women who consumed a soy protein isolate beverage for 12 weeks in comparison to a control group who drank milk (Albertazzi *et al.*, 1998. *Obstet. Gynecol.* 91:6). Of interest, isoflavone levels in the diets of the soy group still represented 1/3 the average daily intake of Japanese women. Foods supplemented with soy such as bread and crackers are being marketed in Europe.

In 1998, the U.S. FDA approved a health claim for psyllium, stating that soluble fibre from foods such as psyllium as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. As for soy protein, the claim was approved based upon the blood cholesterol-lowering effects of the soluble fibre in psyllium. Foods bearing the health claim must provide at least 1.7 grams of soluble fibre from psyllium seed husk per RACC. Clinical research also suggests that psyllium has a positive effect on moderating post-prandial glucose levels and could prove beneficial for diabetes (Anderson *et al.*, 1999. *Am. J. Clin. Nutr.* 70:466).

Dr. Hasler reported that the most frequently performed surgery among the elderly in the U.S. is for cataracts, accounting for the largest single item in Medicare expenditures. Lutein and zeaxanthin are the only carotenoids that accumulate in the retina and the risk of cataracts has been shown to decrease with increased intake of these carotenoids. In the Beaver Dam Eye Study, lutein intakes were assessed in 1,354 persons aged 43 to 84 for 5-years. The results showed that persons in the highest quintile of lutein intake were half as likely to develop cataracts (Lyle *et al.*, 1999. *Am. J. Epidemiol.* 149:801). The authors concluded that lutein, zeaxanthin and foods rich in carotenoids may decrease the risk of cataract development.

Moving on to herbs, Dr. Hasler described the results of a recent meta-analysis that assessed the efficacy of Ginkgo Biloba, the third highest selling botanical in 1998, on cognitive function in Alzheimer disease. Of 57 studies analyzed, only four met the inclusion criteria. "Ginkgo Biloba has shown a small but statistically significant effect on dementia and intellectual stimulation," stated Dr. Hasler, "but many food products with ginkgo simply do not contain enough of the herb to make any difference." Studies are continuing to

determine the effective level of intake for ginkgo.

In 1996, St. John's Wort was not well known in the mass market. However, in 1997 following a story on television's 20/20, sales soared by over 11,000%. St. John's Wort is currently listed at #2 on the 1998 top 10 botanical sales list. Clinical trials have shown a positive effect of St. John's Wort on the treatment of mild to moderate depressive disorders with fewer side effects than prescribed medications (Linde *et al.*, 1996. *Brit. Med. J.* 31:253). Recent clinical studies on *Echinacea purpurea* and *angustifolia*, 1998's #1 selling botanical, support a modest reduction in the rate and duration of upper respiratory tract infections following treatment with the herbs (Melchart *et al.*, 1998. *Arch. Fam. Med.* 7:541). Also in the top 5 botanicals sold in 1998 is Saw Palmetto, which is being studied for the reduction of symptoms related to benign prostatic hyperplasia (BPH). Less expensive than drug therapy, this herb may become the preferable treatment for BPH.

Fenugreek, a legume cultivated in Saskatchewan, has been shown in human trials to significantly lower blood glucose and blood lipids in diabetic subjects. Fenugreek has achieved "generally recognised as safe" (GRAS) status in the U.S., and is marketed in several medical foods.

Functional foods with added herbs have been appearing in increasing numbers on the North American market. According to a recent Position Statement on Functional Foods released by the American Dietetic Association, these foods may have a positive effect on health if consumed regularly at an effective level.

Dr. Hasler emphasized a continued focus on self-treatment in the new millennium. "The outlook for healthy foods is bright," she said. "We need good, clinical research to demonstrate efficacy and well-publicized results for consumers to make well informed choices." She concluded that commercial success of functional foods is expected to continue with increased availability of healthy and flavourful products, consumer awareness of benefits, increased scientific support, appropriate media attention and FDA-approved health claims.

As Executive Director, Dr. Hasler has been fundamental in developing the internationally recognized Functional Foods for Health research and education program at the University of Illinois. Dr. Hasler is currently an Assistant Professor of Nutrition at the Department of Food Science and Human Nutrition at the University of Illinois and a Visiting Assistant Professor at the Department of Medicinal Chemistry and Pharmacognosy. Dr. Hasler received her M.Sc in Nutrition from Pennsylvania State University and a dual Ph.D. in Environmental Toxicology and Human Nutrition from Michigan State University.

For more information on the Functional Food for Health Program at the University of Illinois, link in through the SNN website www.nutranet.org or directly at <http://ag.uiuc.edu/~ffh/ffh.html>.



Ms. Audra J. Davies

The Dietary Supplement Industry – Growth into the New Millennium

As Manager of Nutrition Science and Services at Nutrilite Division of Amway Corporation, Ms. Audra Davies is responsible for overseeing clinical research, nutrition education and stability programs as well as researching new ingredients to support Nutrilite's Nutrition & Wellness Business Line. At the October 25th Conference, Ms. Davies shed some light on trends within the dietary supplement industry.

In the early 20th century, the focus of the health care profession and consumers was principally related to the control of disease, primarily prevention of deficiency-related diseases. Over the years, as advances were made in health technology and research, that focus has shifted towards achieving and maintaining optimal health and fitness. "Today's consumers have high expectations for their own health and product availability, and they are seeking alternatives to costly pharmaceuticals," stated Davies. A growing number of consumers now take herbal supplements, increasing from 20% in 1997 to 33% in 1998 while the number taking a vitamin supplement has risen from 30% to greater than 50%. The most frequently used herbals include Echinacea, Ginkgo, Garlic, Ginseng and St. John's Wort. Ninety-five percent of supplement consumers use these products to maintain or enhance overall health and 85% take supplements to prevent specific health problems. The average age of consumers of vitamins and minerals is 37 years and for herbals and supplements, 46 years.

A tremendous market opportunity exists within the dietary supplement industry. In Canada alone, annual sales of \$1 billion have been reported (Nutrition Business Journal, 1998). On a global scale, market estimates for functional foods, natural and organic foods, dietary supplements and nutraceuticals range anywhere from \$76 to \$200 billion. Given the current trend towards health care cost reduction and a growing consumer interest in preventive health, it is expected

that the dietary supplement industry will continue to exhibit strong growth.

Davies reported that many in the industry are expecting a move from the current generic supplementation model towards a greater emphasis upon condition-specific, age-related and/or gender-associated product development as well as a shift to very specific maintenance and preventive supplements. In addition, many speculate that as clinical research continues, we may see supplement usage evolve for curative purposes.

In the United States, a staggering \$367 billion is spent on direct and indirect costs for the treatment of cardiovascular disease, cancer and osteoporosis. Epidemiological and clinical studies are improving our understanding of the relationships between dietary constituents and health and illness. Ms. Davies gave several examples of science supporting the use of various levels and combinations of vitamins, minerals and phytochemicals in reducing the risk of conditions ranging from macular degeneration to cancer. She indicated that "...many people find it difficult to consume optimal amounts of nutrients necessary for health through diet alone." Not only are supplements proving necessary to reduce serious health problems in the population, but also preventative strategies are proving to be less expensive than treating disease.

For optimal success of a new dietary supplement, Davies noted that certain criteria must be met. In order to establish a need for supplementation with a particular ingredient, a well-recognised link between the reduction in the risk of a specific disease state and the intake of the particular ingredient must be evident. The disease state should affect a significant portion of the population and an assessment of the cost to the health care system should be available in order to establish the market opportunity and cost effectiveness of the proposed supplement. Ms. Davies reiterated that a rigorous code of ethics must be maintained at all times in order to ensure that consumers are using products of consistently high quality with proven safety and efficacy. The industry is rapidly moving towards providing a greater number of products that have been standardised for purity and potency with attention to consistent quality and proven efficacy based on well-designed clinical trials. Products must be processed under good manufacturing processes and informative product labelling must be utilised. But above all else, Ms. Davies stressed that the priority must always remain in delivering safe products to consumers.

The dietary supplement industry faces many challenges as it enters into the 21st century including the ever-increasing importance of scientific evidence, the need for proprietary positions, an ever-changing business environment as a result of mergers and acquisitions, a

changing regulatory environment and the need for consumer education and comprehensive public relations programs. The industry is taking many responsible steps toward self-regulation. One example includes the recent formation of the Institute for Nutraceutical Advancement Method Validation Program (www.nutraceuticalinstitute.com) by 30 leading botanical manufacturers and suppliers in the U.S. The objective of the program is to develop validated analytical testing procedures for herbal raw materials in order to ensure that products can meet their label claims.

Consumers can be quick to jump on the latest supplement bandwagon, when in fact many aspects of one's overall lifestyle must be considered. In conclusion, Ms. Davies reiterated that although supplementation provides a significant contribution toward the prevention of many degenerative disease states and dietary deficiencies, they are only one component to achieving overall optimal health and vitality. "After all," she said, "there are no magic bullets."

Audra Davies studied at the University of Manitoba, where she received her M.Sc. in Food Chemistry with an emphasis on phytochemistry, and her B.Sc. in Nutritional Science. Nutrilite is a division of Amway Corporation; its offices are located in Buena Park, California.

The Road to a New Regulatory Framework for Natural Health Products

The Canadian Health Food Association (CHFA) was established in 1964 to support members in their efforts to make appropriate claims for natural health products and to be able to sell them in traditional health food stores. The industry believed that foods, as part of a healthy lifestyle, could impact positively on health and disease prevention. The Association, though one step closer, is still trying to secure the right for Canadian natural health products to carry appropriate health claims; a large undertaking due to current restrictive regulations.

According to Ms. Anne Ledger Wilkie, CHFA's Director of Science, natural health products (NHPs) can be generally defined as those substances and combinations of substances which can be found in nature, they can be in whole food form or in supplement/dosage form and are traditionally used within the context of an holistic model of health. This would include vitamins, minerals, herbs and botanicals, supplements and organic foods, among others. In 1997, there were 1,700 retail outlets in Canada whose primary sales were of NHPs, 50% of which have been established within the past ten years. By 1998, 70% of Canadian households were using one or more alternative complimentary medicines (Canada Health Monitor, August 1998). The tremendous market growth

is due to Canadians' desire to take greater control over their health and well being.

"The largest demographic are the baby boomers," said Wilkie. "They're everywhere and they don't want to get old, and if they have to they want to do it gracefully."

The current regulatory framework was established in the mid-50's with the Food and Drugs Act, created to protect consumers against health hazards and fraud within the food, drug, cosmetics and medical devices industries. Today, this framework is in need of an overhaul as regulatory confusion and overlap creates difficulty in categorizing a NHP as a food or a drug. Wilkie gave the example of garlic, which is traditionally defined as a food. However, if it is put into capsule form with labeled health claims, it becomes a drug.

Within the Food and Drugs Act, NHPs regulated as foods cannot have any pharmacological activity, and, except for those defined as novel foods, require no pre-market notification. Most NHPs without health claims are marketed in Canada as foods. NHPs defined as drugs must meet pharmaceutical profile definitions and processing requirements in addition to undergoing rigorous safety assessments. Drug regulation fees are generally high, which can delay the product's market entry and cause financial burden to small and large Canadian companies. According to Wilkie, confusion with product definition and labeling has resulted in decreased NHP availability in Canada as compared with, for example, the U.S.A. "The use of either the food model or the drug model doesn't work for many NHPs," stated Wilkie.

The CHFA pushed for regulatory changes including defining NHPs as a separate category from foods or drugs and instituting a regulatory framework appropriate for NHPs. On March 26, 1999 the Federal Health Minister, Alan Rock, accepted all 53 recommendations made by the Standing Committee on Health in the document, "Natural Health Products: A New Vision." In accordance with the Standing Committee's recommendations, the Minister created a new Office of Natural Health Products (ONHP) along with a 3-year funding commitment of \$7 million for the ONHP and \$3 million for research activities. To implement the NHP strategy, a transition team of three government and 14 industry members has been set up. The ONHP is setting a global precedence by aiming to establish NHPs and regulations through the new Office on equal footing with the food and drug directorates.

The proposed mission statement of the ONHP reads, "to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity." The Office will

establish a regulatory framework using the Standing Committee on Health's 53 recommendations. This framework will encompass product-licensing, protocol for good manufacturing practices, research policies, communication strategies, and more. Scheduled to open by spring of 2000, the Office will also incorporate an Expert Advisory Committee.

Wilkie stressed several current factors to be aware of. Provinces still have the power to decide whether a product is sold as a prescription or behind-the-counter product. It will also be important to ensure that functional foods and nutraceuticals fit into appropriate categories as food and drug components separately to make way for natural health products.

With a membership of over 1,200, the CHFA is no longer a fringe movement. "The CHFA, together with its stakeholder partners lobbied long and hard for regulatory changes," Wilkie said. "There's still a lot of work to be done. Most importantly, we must all work together to ensure that these new regulations serve all of us and not just a few."

Ms. Wilkie's responsibilities at the CHFA include all regulatory and scientific affairs affecting natural health products, foods, drugs and cosmetics that impact upon the industry. Ms. Wilkie is fundamental in the implementation of the Random Testing Program and other quality assurance initiatives within the industry. She comes to the CHFA with many years of experience as a Nutrition Program Specialist at the Canadian Food Inspection Agency and as a Chemistry Analyst and Food Inspector with the Health Protection Branch, Health Canada.

International Regulations & Trends

In 1996, the regulatory status of functional foods and dietary supplements within CODEX came under review, as did nutraceuticals and functional foods in Canada. "There has been little change since then," stated Dr. Karen Lapsley, Senior Nutritionist for the Almond Board of California, "but the need to define functional foods and nutraceuticals has evolved." Lapsley described current regulations for dietary supplements, nutraceuticals and functional foods in Japan, Europe and the U.S.

In Japan, health claims are allowed for food under FOSHU (Foods for Specified Health Use) status that is regulated by the Japanese Ministry of Health and Welfare. "We consider these to be soft claims, primarily focused upon drinks, fermented products and table sugars," said Lapsley. Of the 154 approved FOSHU products, 110 have claims related to gastrointestinal function, with ingredients such as dietary fiber, oligosaccharides, lactobacillus and bifidobacterium. Forty-five are liquid or powder drinks, another 40 are yogurts and fermented drinks, and 18 are table sugars. "Basically," said Lapsley, "a majority of the 154 FOSHU approved products are in some way related to gut

function or GI tract health," which appears to be a significant Japanese health concern. In regard to the market for functional foods, drinks comprise the largest category due to the number of commuters purchasing quick meals and take-along drinks. In addition, en route vending machines make drink products an easy way to test market a new product.

FOSHU status is not the only way to market foods with health properties in Japan. In fact, of the total Japanese functional food market of \$8B U.S., products carrying FOSHU claims represent only \$1.5B U.S. of this market. This is due in part to an abundance of creativity within the food industry, combined with a more adventurous Japanese consumer and a tolerant government. Regarding new product trends, antioxidants are very popular. The latest product development focus in this area has been polyphenol fortification in products including water, wine and candies.

"The FOSHU system has gained a level of credibility over the past 10 years," said Lapsley. However, it has been suggested that standards may need to be tightened. For example, the level of fat, cholesterol, sodium and sugar content may need to be limited in products carrying FOSHU claims. Also, there is concern that conventional food consumption may be under-emphasized in the total diet. Still, Lapsley believes that the FOSHU system presents a good model for the regulation of functional foods.

Lapsley discussed functional foods in Europe, and indicated that regulations as well as health concerns are not consistent among countries. A 1999 survey by Leatherhead found that in the UK, France and Germany, health concerns included cancer, stress, heart disease and fatigue, but in differing orders of importance. These findings suggest that it may be difficult to develop products for all markets within the European community, and that differing health care priorities may make it difficult to formulate all-encompassing EU regulations.

Recent developments within the EU regarding developing a framework for regulating functional foods include the appointment of a new Commissioner of Foods from Finland, who carries a broader view of health claims. Also, five European countries (France, Netherlands, Belgium, Sweden and UK) have developed voluntary codes of practice on health claims, all of which have documented plans to make health claim regulatory changes. In each of these countries, the food industry is the most involved participant in the establishment of codes of practice. Government agencies, public interest groups and scientific expert committees are involved to a lesser extent. Also, the EC Concerted Action on Functional Food Science and the Confederation of the Food & Drink Industries of the EU (CIAA) is working towards claims regarding

enhanced function and disease risk reduction.

In the United States, there are no regulatory definitions for nutraceuticals and functional foods. Allowable health claims for dietary supplements and foods can be described in four levels. The first level permits nutrient content claims. Level two permits positive health claims for a nutrient. Level three allows a statement regarding the effects of consumption of a nutrient or food constituent on the structure or function of a particular body system. Level four is the most sophisticated claim, and requires the greatest level of scientific support relating to the ability of a particular nutrient or compound to reduce the risk of disease. In Canada to date, disease risk reduction health claims have been disallowed. Instead, the label may list nutrient content, leaving the consumer to make a health connection. As an example, Lapsley asked, "Can you tell the consumer about Vitamin E's antioxidant qualities? That's the leap we're trying to make."

In 1997, a significant change in the potential allowance of risk reduction claims in the U.S. occurred with the passage of FDA's Modernization Act (FDAMA). Under FDAMA, disease prevention claims on food labels may be "based on an authoritative statement by a scientific body of the U.S. government or the National Academy of Sciences using significant scientific agreement." Recently, a claim for whole grains and cancer risk reduction was approved under the FDAMA. However, FDA has been reluctant to approve several other claims under this new guideline.

In January 1999, the US Court of Appeals handed down a decision determining that "the FDA's blanket refusal to permit preliminary health claims violated the commercial free speech protections of the First Amendment to the US constitution. The Courts indicated that FDA "needs to articulate and define the criteria that it relies on for significant scientific agreement, and must use the least restrictive means to regulate health claims" (Pearson vs. Shalala, decision #98-5043, D.C. Cir. Jan. 15/99).

"I don't think we should be scared away by varying international regulations," stated Lapsley, "but instead, we should be encouraged by the significant headway that's been made globally toward appropriate claims regulations."

As one of Canada's top functional foods experts, Dr. Lapsley has been a member of the Health Canada Advisory Panel for Health Claims for Foods (1996 - 99), the Canadian Institute of Food Science and Technology and the Swiss Food Science Association. Dr. Lapsley received her Ph.D. in Food Science from ETH in Zurich, Switzerland.



Dr. Alison Stephen

Proposals for the Regulation of Nutraceuticals and Functional Foods in Canada

Dr. Alison Stephen, the newly appointed Director of Nutritional Sciences for CANTOX Health Sciences International, learned through her pet's encounter with a barbed wire fence that there are some obstacles in life that we must tread around very carefully. Such is the case with initiatives related to the regulation of nutraceuticals and functional foods in Canada. The Food and Drugs Act states that "no person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."

"Canadian consumers have different expectations from the government than do consumers in the United States," said Stephen. "We are much less tolerant of mistakes and therefore, the government must be very careful."

In Canada, there are eight classifications for products taken internally, ranging from ingredients to drugs, and including nutraceuticals and functional foods. The classification of a product depends on the source and form of the product and the degree of processing that the product has undergone. Some of these classifications are undergoing regulatory definition, including natural health products (NHP), nutraceuticals and functional foods. The definition of novel foods has recently been amended. An approval process involving notification and a submission of safety and status as a novel food has been established by the Health Protection Branch (HPB).

In February of 1998, the HPB initiated a lengthy process to develop a new food labelling scheme for Canadian products. Implementation of these new policies will begin, as will an education strategy, in early 2000. Under the proposal, it may become mandatory for companies to declare on labels a list of core nutrients,

including energy, fat, protein, carbohydrates, dietary fibre, saturated fatty acids, trans fatty acids, sodium, calcium and iron.

Vitamin and mineral food fortification was the subject of another HPB initiative that began in the winter of 1997 with a consultation of stakeholders. In March of 1999, new policies began to take shape to ensure that the government's decision to allow vitamin and mineral fortification would be based on the best available scientific evidence. In addition, such fortification must improve the nutritional quality of the food, and not result in health hazards due to nutrient excess, deficits or imbalances. The new fortification policy will attempt to prevent any misleading, deceiving or confusing practices, while at the same time facilitating consumer choice. In October of 1999, the policy paper was completed and implementation is scheduled for 2000.

In the U.S., health claims are defined as "Any claim on the package or label or other labelling (such as an ad) of a food, including fish and game meats, that characterizes the relationship of any nutrient or other substance in the food to a disease or health-related condition." Several generic health claims that link nutrients or food groups (such as fruits, vegetables, fat and fibre) to the reduction of particular diseases (such as cancer or coronary heart disease) are approved in the U.S. More recently, food-specific claims have been allowed, such as those describing oats, psyllium and soy protein and their relationship to lowering coronary health disease risk.

Regulatory initiatives related to nutraceuticals and functional foods are currently underway in Canada. In the summer of 1996, the Food Directorate of HPB began deliberations, which resulted in a proposal for more accurate definitions of nutraceuticals and functional foods. The proposed definition of a nutraceutical is a product that has been isolated or purified from foods and generally sold in medicinal forms not usually associated with food. Nutraceuticals have been shown to exhibit a physiological benefit or provide protection against chronic disease. According to Health Canada's proposal, a functional food would be similar in appearance to a conventional food and is consumed as part of the usual diet. These foods would have demonstrated physiological benefits, and/or reduce the risk of chronic disease beyond basic nutritional functions. By fall of 1997 the Food Directorate and the Therapeutic Products Program initiated a joint project resulting in a final policy paper that was released in late 1998. Recommendations were made to permit structure/function and risk reduction claims for foods and to continue to regulate therapeutic claims as drugs. More significantly, Health Canada has proposed allowing product-specific claims associated with a single commercial product

in which the research supports the claim. Another food with the same "active ingredient" would not be able to make the claim unless supported by research.

Health Canada currently has three initiatives underway in the area of health claims for foods: 1) to adopt U.S. generic health claims within a Canadian context; 2) to develop scientific standards of evidence and a guidance document for supporting the validity of product-specific claims; and 3) to develop an overall regulatory framework for functional foods. There is uncertainty as to whether all U.S. generic health claims for foods should be adopted in Canada, as the science upon which the approved criteria for some of these claims appears to be out-dated. Experts are currently reassessing both the original and current science related to the U.S. claims as well as the criteria which would be required in order that a food may carry a health claim.

What are the perceptions of Canadian consumers regarding health claims? In order to answer this question, the National Institute of Nutrition conducted 901 face-to-face interviews over the summer of 1998. The objectives of the study were to determine how accurately claims communicate health benefits, their value to consumers, their influence in food selection and the value of third party endorsements. Potential health claims in the areas of fibre and cancer, calcium and osteoporosis, saturated fat and coronary heart disease, and folic acid and neural tube disorders were assessed. A number of interesting observations were found. The survey determined that Canadian consumers were familiar with diet and disease relationships for coronary heart disease, cancer, hypertension and diabetes, and were most comfortable with a "may reduce" or "helps reduce" rather than a "can reduce" health claim. Canadians appreciate endorsements from Health Canada or agencies such as the Canadian Cancer Society that they considered trustworthy. This finding differs from American consumers who indicate less trust in governmental regulatory bodies. For those concerned about a particular health issue, claims were seen as interesting and relevant, and could influence a decision among purchasers already using similar products, but were not as likely to initiate product use.

Dr. Stephen also described the findings of an Agriculture and Agri-Food Canada (AAFC) round table discussion that was held in March 1999 to facilitate the development of the nutraceutical and functional food industries in Canada. The participants identified several challenges to industry development including insufficient resources available for research; a lack of awareness of research capabilities in Canada; an uncertainty about the regulatory framework; and insufficient scientifically-trained personnel. "We have

some very good scientists in Canada and should be making better use of them,” stated Stephen. “We need more scientists, especially at the junior level.” Participants also indicated that the industry faced marketing challenges, such as a poor understanding of the relationship of diet and disease by the public, and a poor acceptance of nutraceuticals and functional foods by health professionals. Also, manufacturers appear to be unclear about the most effective ways to market functional foods and nutraceuticals.

Dr. Stephen stated that it has been an uphill battle to get to this point in the regulatory renewal process, and the challenges are far from over. Once federal regulations are implemented, there may still be confusion within provincial government jurisdictions. However, Dr. Stephen used the example of the persistence of her pet Dalmatian as she concluded, “If you keep at the opposition for long enough, they will eventually agree!”

Dr. Stephen, an international authority in human clinical nutrition, specializes in the effects of dietary constituents on human gastrointestinal function and lipid metabolism. Among her many involvements, Dr. Stephen is a member of the Editorial Boards of the British Journal of Nutrition and the Journal of Nutraceuticals, Functional and Medical Foods. Dr. Stephen received her B.Sc. in Physiology from the University of Edinburgh as well as a Ph.D. in Nutrition from the University of Cambridge, UK.

Value-Added Opportunities in Nutraceuticals

In the second presentation of the “New Product Development” session, Dr. Stephen McCurry, Manager of Biochemistry in the Nutraceuticals Department of Cargill, Inc. described his company’s recent focus upon nutraceutical development. Minneapolis-based Cargill is a 135-year-old, privately-owned raw material



Dr. Stephen McCurry

processing and supply company with over one thousand facilities in 75 countries. Many of Cargill’s businesses are about taking agricultural products apart and selling the constituents. As a result the company has developed expert separation technology (also applicable to their fermentation businesses). The company began processing flaxseed in 1946, then expanded to include soy in 1966. Today, 60 of Cargill’s facilities across the globe process a variety of oils.

Originally a commodity/trading company, Cargill evolved into the value-added nutraceutical business through joint ventures such as that with Hoffman LaRoche (all of Cargill’s natural source vitamin E is committed to Roche).

Stated simply, large commodity companies such as Cargill are interested in the nutraceutical market for its potential to add significant value to minor by-products of processing (some of which were essentially “throw-away” in years past). These include oil-based tocopherols, phospholipids and phytosterols, the health benefits of which are of growing interest to the health community and consumers.

Cargill’s vision statement reads, “to raise living standards around the world by delivering increased value to producers and consumers.” Cargill customers can expect value, as well as a high standard of product safety, quality and business integrity.

“Supplements aren’t regulated like drugs or food additives, but they are regulated. Consumers deserve safe products that meet any claims,” said McCurry. This includes claim substantiation supported by solid data as well as safe products.

Identifying future opportunities in the nutraceutical area and weeding out consumer fads is a difficult task, according to McCurry. Customers will often demonstrate huge interest for the “latest ingredient,” even before the necessary substantiation of safety or efficacy has been done. “For a company such as Cargill to react to market demands often takes a huge amount of money,” stated McCurry. “We want to know the product will be safe, meet any claim and have market longevity, among other things, before making a huge investment and modifying existing processing facilities.”

McCurry is excited about the increased efforts underway to substantiate the health effects of nutraceuticals and other supplements. On October 6, the National Institutes of Health (NIH) announced their commitment to establishing two Dietary Supplement Research Centres. The Centres will specialize in studying botanicals to determine safety,

effectiveness and biological action, and will be located at the University of California and the University of Illinois. These Centres will impact health professionals and consumer awareness of botanical ingredients; they will be an invaluable resource to companies for identifying whether new supplements are a fad or a trend. In addition, the new IBIDS (International Bibliographic Information on Dietary Supplements) provides a significant scientific, credible database on dietary supplements including vitamins, minerals and botanicals. "This is a very good place to find out substantive, technical information," said McCurry. The IBIDS web site is available through an SNN link (www.nutranet.org) or directly at: <http://odp.od.nih.gov/ods/databases/ibids.html>.

"We have a number of nutraceutical projects going through different stages of evaluation," stated McCurry when asked about Cargill's future plans. "We are cautious in deciding what to do, but I'm not concerned about our ability to execute once we have decided."

Dr. McCurry received his B.Sc. and M.Sc. in botany at the University of Nebraska and his Ph.D. in biochemistry from Michigan State University. McCurry conducted his postdoctoral work in chemistry at MIT in Boston.

Phytrol™ – A Cholesterol-Lowering Functional Food

Almost 2,500 years ago Hippocrates was the first to advocate the importance of proper diet and plant medicine (phytochemicals) for disease prevention and cure. According to Dr. Jerzy Zawistowski, Director of Food Product Development at Forbes Medi-Tech, plant-based phytosterols represent the future for functional foods. The company has developed a tall-oil-based sterol ingredient, Phytrol™, for both functional food and pharmaceutical applications. Dr. Zawistowski described the health benefits of phytosterols during the first of two "New Product Development" presentations at the October 25th Update.

According to Zawistowski, high plasma cholesterol levels have been established as a major risk factor for the development of coronary heart disease (CHD). In the U.S. alone, as many as 98 million individuals have borderline to high plasma cholesterol levels. The majority of preventable CHD deaths occur in people with borderline plasma cholesterol levels (levels that do

not present a direct risk for a heart attack but require monitoring). Studies have suggested that lowering plasma cholesterol levels may reduce the incidence of first heart attacks, overall deaths from heart disease and the need for heart surgery. In fact, epidemiological studies and long-term clinical trials have indicated that a 10% lowering of plasma cholesterol levels can result in up to a 30% reduction in the incidence of deaths related to heart disease.

Plants synthesize phytosterols instead of cholesterol. In the Western diet, vegetable oils are the principle source of phytosterols that include beta-sitosterol, campesterol and stigmasterol. In addition to sterols, coniferous trees also contain stanols - hydrogenated counterparts of sterols. The level of phytosterols consumed in an average Western diet is about 250 – 500 mg/day, similar to dietary cholesterol. Plant sterols and stanols are similar in their chemical structure to cholesterol and appear to compete with cholesterol in the formation of mixed micelles required for cholesterol absorption. This interaction can lead to a reduction in the amount of cholesterol absorbed and a lowering of serum cholesterol levels.

"Forbes has conducted a number of clinical studies that showed efficacy of Phytrol™. In addition, several studies using Phytrol™ in various food matrices are still ongoing," stated Zawistowski. He also discussed a study that was recently published (Jones et al., *Am. J. Clin. Nutr.*, 1999, 69:1144-50). In a 30-day, placebo-controlled, randomized study of 16 hypercholesterolemic subjects (> 250 mg/dl plasma cholesterol) consuming 1.75 g/day of Phytrol™, total and LDL cholesterol levels were significantly reduced by 10% and greater than 14% when compared to a group consuming a control margarine. The study was



conducted by Dr. Peter Jones of the Department of Nutrition at McGill University. Phytrol™ supplementation has also been shown to reduce the onset of atherosclerotic (fatty) lesions in Apo E knockout mice, a model of severe atherosclerosis. Similar results were seen with hypercholesterolemic rabbits.

The scientific findings regarding Phytrol confirm that the product is both safe and effective. Dietary phytosterols are much less expensive than cholesterol-lowering pharmaceuticals. Therefore, Zawistowski believes the opportunity for Phytrol is great, and he foresees no major marketing obstacles.

The Raisio Company of Finland was the first to market a phytosterol-enriched margarine under the “Benecol” trademark. It now represents 15% of the Finnish margarine market. The Finnish government recently conducted a survey of over 140,000 people who regularly consumed the margarine product, with no reported adverse side effects. “Take Control” margarine marketed by Unilever is another phytosterol-enriched product that has been recently introduced in the U.S. According to Zawistowski, “The

“Benecol” and “Take Control” products have already received a letter of no objection under the GRAS (Generally Recognized as Safe) notification process from the FDA and have been successfully launched at premium prices.” In addition, unlike its competitors, Forbes is exploring the use of Phytrol in various low and no-fat foods.

Novartis Consumer Health, in partnership with Forbes, is responsible for marketing Phytrol™, as well as clinical trials and regulatory approval. Novartis has recently acquired the global rights to Phytrol™ for use in nutrition supplements, over-the-counter markets and other ingredient options. The two companies expect regulatory approval and a launch of Phytrol™-based products by mid-2000.

Dr. Jerzy Zawistowski received his M.Sc. in Human Nutrition from the Warsaw University of Agriculture in Poland and a doctoral degree in Food Biochemistry from the University of Manitoba. Forbes Medi-Tech, Inc. is located in Vancouver, B.C., where Dr. Zawistowski is responsible for functional food and nutraceutical technology and product development.

CONFERENCE PROCEEDINGS AVAILABLE – contact the SNN office.

2nd Annual General Meeting, October 26th

Election of New Members to the SNN Board

At the Second Annual General Meeting of the SNN, held on October 26th, three Directors were elected from a slate of five candidates to fill industry vacancies on the Board. These Directors, listed below, will serve a two (2) year term (October, 1999 to October, 2001) or until their respective successors are elected or appointed:

- ◆ Mr. Mark Pickard,
InfraReady Products
- ◆ Mr. Roy Sangster,
Sangster Health Centres
- ◆ Dr. Alison Stephen,
CanTox Health Sciences International

In addition to those listed above, the Board is comprised of:

- ◆ Mr. Jerome Konecni, Bioriginal Food & Science,
CHAIR
- ◆ Mr. John Christensen, Fytokem Products,
VICE-CHAIR

- ◆ Mr. Don Hrytzak, Taiga BioActives,
SECRETARY-TREASURER
- ◆ Ms. Maryellen Carlson, Saskatchewan Agriculture
and Food, MEMBER, EXECUTIVE COMMITTEE
- ◆ Dr. Dennis Gorecki, College of Pharmacy &
Nutrition, University of Saskatchewan
- ◆ Mr. John Hyshka, Saskatoon Regional Economic
Development Authority
- ◆ Ms. Melody Machmer, Mid Northern Growers
- ◆ Dr. Gopalan Selvaraj, Plant Biotechnology Institute

Annual Report

Copies of the 1998/99 SNN Annual Report including Messages from the Chairperson, the President and the Secretary-Treasurer and the Reviewed Financial Statements for the thirteen-month period March 1, 1998 to March 31, 1999 were approved by the Membership at the AGM. Copies are available by contacting the SNN office.

Up-Coming Events

Marketing Functional Foods, Natural Health Products and Nutraceuticals in a Changing Regulatory Environment

February 4, 2000

Marriott Hotel

Richmond, British Columbia

Presented by the British Columbia Functional Food and Nutraceutical Network

Contact: Christine Watt

Tel: (604) 822-6920, Fax: (604) 822-5143

E-mail: bcffnn@hotmail.com

Nutraceuticals and Functional Foods Short Course

A four-day practical short course is being offered by the Food Science and Technology Program and Food Protein Research and Development Center of the Texas A&M University in College Station, Texas, **February 20-24, 2000**. Herbal Products, Functional Ingredients, Food Sources, Extraction, Separation/Purification, Market Toxicology and Regulations are some of the topics to be covered in the extensive program. Conference organizers indicate that the course is the "...only practical, hands-on nutraceutical and functional foods short course offered internationally." The conference cost is \$1,495 U.S. However, a special rate of \$1,050 U.S. is available for Canadian-based members of the SNN. Please contact the SNN office for more information on the short course and how to take advantage of this special rate.

Nutraceuticals - New Directions for Agri-Foods

St. Boniface Research Centre

Winnipeg, Manitoba

Tel: 1-800-870-1044



Canada

Saskatchewan

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For more information or to submit articles, contact:

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Saskatoon SK S7N 4L5 Canada

Nutraceuticals Workshop

March 5 -7, 2000

Hotel Gander, St. John's, Newfoundland

Contact: Ronda Dillon

NRC - IRAP

Memorial University of Nfld

Tel: (709) 778-0554, Fax: (709) 778-0695

E-mail: ronda.dillon@nrc.ca

First International Symposium on Antler Science and Product Technology

April 9 - 12, 2000

Banff, Alberta

Contact: Dr. Hoon Sunwoo

Tel: (780) 492-0378, Fax: (780) 492-9130

E-mail: hsunwoo@ualberta.ca

Internet: www.afns.ualberta.ca/asptsymp

43rd Annual Meeting of the Canadian Federation of Biological Societies

June 22-24, 2000

Ottawa Congress Centre

Ottawa, Ontario

Contact: CFBS

Tel: (613) 225-8889, Fax: (613) 225-9621

E-mail: wantonious@cfbs.org

Internet: www.cfbs.org

International Herb Conference and World Council Meeting

July 18-21, 2000

Delta Bessborough Hotel

Saskatoon, Saskatchewan

Contact: Mr. Grant Wood

Tel: (306) 966-5586

Herbfest 2000

July 22-23, 2000

The Saskatchewan Irrigation Diversification Centre Outlook, Saskatchewan

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