DAVID R. LINEBACK, PH.D
Host Organizer & Opening Speaker

Dr. Lineback, Director, Joint Institute for Food Safety and Applied Nutrition (JIFSAN), University of Maryland at College Park is a food scientist with extensive academic experience. He has been dean, College of Agriculture, University of Idaho and head of the Departments of Food Science at Pennsylvania State University and North Carolina State University. He has served on the faculty of the University of Nebraska and Kansas State University. He is active in the American Association of Cereal Chemists and the Institute of Food Technologists, having been President of both. He has been active in the Council for Agricultural Science and Technology (CAST), serving on the Board of Directors, the Executive Committee, and as President. He has provided leadership in several public and private sector food-related organizations. He has been involved in international activities for many years, and currently serves on the Governing Council, the Management Committee, and as chair of the Scientific Council of the International Union of Food Science and Technology (IUFoST).

PROFESSOR MICHAEL ROBERTS, PH.D
Opening Speaker and Session 4 Chair

Professor Roberts has gained a broad background in land use and environmental sciences through lectureships at the Universities of Toronto and Liverpool and research management in the power industry and the UK Research Councils (NERC). He was Director of NERC's Institute of Terrestrial Ecology for 10 years from 1989. He was Director of NERC's Centre for Ecology and Hydrology from 1989 to 2001 during which period he implemented a major restructuring programme. He has managed a wide range of research projects in land use, conservation of biodiversity and environmental pollution. He has published over 50 papers on the ecological effects of air pollution, contaminated land and land use change. He was Chairman of the UK 'Man and the Biosphere' Committee from 1990-2000. Representational duties on government committees include the Advisory Committee on Genetic Modification (ACGM), the Advisory Committee on Pesticides (ACP) and the Advisory Committee on Hazardous Substances (ACHS). Professor Roberts is currently the Chief Executive of Defra's premier laboratory with responsibility for research on the sustainable management of agriculture and provision of safe, wholesome food.

PETER AGGETT, PH.D

Dr. Aggett is Head of the Lancashire School of Health and Postgraduate Medicine at the University of Central Lancashire, Preston, England. His previous posts include being Assistant Director of the Institute of Food Research at the Institute of Food Research, Norwich. He was a Member of the Steering Groups and Consensus Groups for the ILSI co-ordinated EU Concerted Actions on Functional Food Science in Europe, and on the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)

He has served on a number of WHO/FAO/IAEA/International Programme on Chemical Safety/UNU, European Union and United Kingdom Expert Panels and Task Forces on Nutrient Requirements, Environmental and Nutrient Risk Assessment, and Food Safety.

Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM)

Peter J. Aggett
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ABSTRACT

PASSCLAIM involved more than 160 experts from academia, industry, public interest groups and the regulatory environment and was supported by the Fifth European Community Framework Programme, and was co-ordinated by ILSI Europe. It had the following objectives:

- to evaluate existing schemes which assess scientific substantiation;
- to produce a generic tool for assessing the scientific support for health claims for foods;
- to establish criteria for markers which can be used to explore the links between diet and health.

As a basis for the development of the criteria, seven comprehensive reviews were produced covering examples of areas of diet, health and performance in which health claims are likely to be made. An eighth paper reviewed existing processes and regulations. Finally a consensus view was developed of criteria which would assure that scientific data underpinning health claims made for foods are adequate for the purpose and that the claims can be considered valid.

The criteria describe the standards by which the quality and relevance of the scientific evidence including new data should be judged, and thus the extent to which claims based on them can be said to be scientifically valid. As the view of a broad-based partnership of scientific and other experts, the criteria provide a basis for harmonizing the requirements for, and the assessment of, scientific data supporting health claims made on foods which has a potential for positive impact across a spectrum of stakeholder activities, including those of interest groups within (consumers, health professionals and industry) and across (national and international regulatory agencies) geographic regions.

Criteria for the scientific substantiation of claims

1. **The food or food component to which the claimed effect is attributed should be characterized.**

2. **Substantiation of a claim should be based on human data, primarily from intervention studies the design of which should include the following considerations:**
   - **2(a) Study groups that are representative of the target group.**
   - **2(b) Appropriate controls.**
   - **2(c) An adequate duration of exposure and follow up to demonstrate the intended effect.**
   - **2(d) Characterization of the study groups' background diet and other relevant aspects of lifestyle.**
   - **2(e) An amount of the food or food component consistent with its intended pattern of consumption.**
   - **2(f) The influence of the food matrix and dietary context on the functional effect of the component.**
   - **2(g) Monitoring of subjects' compliance concerning intake of food or food component under test.**
   - **2(h) The statistical power to test the hypothesis.**

3. **When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers.**

4. **Markers should be:**
   - **biologically valid in that they have a known relationship to the final outcome and their variability within the target population is known;**
   - **methodologically valid with respect to their analytical characteristics.**

5. **Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported.**

6. **A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence.**

ELKE ANKLAM, PH.D

Dr. Anklam studied food chemistry (Münster - D) and has received her PhD in organic chemistry in 1984 (Hamburg – D). She had grant-holder contracts for a post-doctoral position in 1985 (Strasbourg – F; Alexander von Humboldt foundation), for a scientific position from 1986-1989 (Berlin – D; Arbeitsgemeinschaft Grossforschung), and 1989 (Berlin – D: Deutsche Forschungsgemeinschaft). She was professor for food chemistry and chemistry at an Engineering School from 1990 – 1991 (Fulda – D). Since 1991 she is working at the Joint Research Centre Ispra (Italy) of the European Commission where she was Head of the Food Products and Consumer Goods Unit (Institute for Health and Consumer Protection) from 1998 – 2002. After the transfer of the activities on food and feed analysis from Ispra to Geel (Belgium; Institute for Reference Materials and Measurements) in 2002, she is Head of the Food Safety and Quality Unit and also the Institute's Deputy Director.

Dr. Anklam has published more than 180 papers in scientific journals, more than 70 reports and has given more than 240 oral and poster presentations in international workshops and conferences.

Allergenicity as a Future Challenge

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ABSTRACT

Food allergies represent a significant health problem in industrialised countries. They are supposed to affect up to 2 % of the adult population and up to 7 % of children. Even the intake of minute amounts of allergens may provoke reactions in sensitised individuals. As no effective treatment for food allergic individuals exists, the only approach is total avoidance of the allergen-containing food. However, this is not an easy task considering the large variety of ingredients (including allergenic foods) in food products. Due to unintentional contamination of food products during processing, transportation, or storage and therefore lack of adequate labelling, total avoidance is sometimes not possible. For food authorities and the food industry it is therefore of utmost importance to have reliable analytical methods at hand to detect even trace amounts of food allergens that may be present in food products in order to ensure compliance with food labelling and to improve consumer protection. Despite the fact that numerous food allergens have been identified, there are not many analytical approaches available so far to detect them at low levels (e.g. 1-10 mg kg^{-1} range) in a variety of food matrices [1]. Legislation has been established world-wide to label food allergens. About 90 % of all food allergens are caused by eight food groups: milk, egg, soy, peanut, tree-nuts and almonds, wheat, fish and crustaceans. However it must be kept in mind that those food commodities can be present in different processed forms, e.g. from milk there may be whey protein, casein, full and skimmed milk or milk powder. In addition, those food commodities may contain even several allergens, e.g. there are presently 8 allergens known from peanuts. Peanuts and nuts are mostly consumed toasted and not raw. The technological treatment has shown to influence the allergenicity of the various food of concern.

One of the most potent allergens derives from peanuts a common source of proteins due to their ubiquity and severity of reactions. They may be present in traces in many food commodities such as chocolate, ice cream, breakfast cereals or biscuits. The capability to detect any unintentional contamination of food products that usually do not contain peanuts is especially important for

peanut allergic patients. Recent results from in-house and collaborative trial studies demonstrated that peanut (protein) processing leads to different analytical results when using the currently available enzyme linked immuno-sorbent assay (ELISA) technology. Not only the recoveries varied between 44 and 188 %, but also the reproducibility showed figures between 22 and 86 % for the various test kits [2]. In addition, a strong decrease in detectability was observed, and this effect became even more significant, when the peanut material was distributed in a finely ground form within the food product prior to baking.

In order to verify findings of Maleki et al. [3] who observed that peanut roasting might even lead to increased allergenicity, biscuits were made using various recipes and baking times and were analysed not only by ELISA but also by using human sera-based immunoassay (HsbI) techniques. It could be demonstrated that the allergenic potential of peanut-containing biscuits was enhanced with increasing baking time and remained stable after 20 min of baking at 180 °C whereas the detectability/recovery for peanut by using ELISA test kits decreased with increasing baking time. A repeated analysis of the biscuits by using various commercial peanut ELISA test kits showed that the allergenic food (peanut) was only detectable in biscuits that had been processed/baked for less than 10 min; typically biscuits are baked for a longer time period (e.g. 12-20 min) [4]. These findings demonstrate very clearly that the commonly used ELISA technique does not give reliable quantitative results. Alternative techniques such as DNA based methods involving PCR (polymerase chain reaction), as well as new approaches in the field of proteomic or LC-MS technology may lead to the availability of allergen specific test methods in the near future, which are more independent of the processing history of the allergenic food. Improvement of the sensitivity of DNA based methods using the PCR technique is currently under way. The rapid development in the field of proteomic-based approaches is promising. However, the sensitivity of current protein analysis methods using chromatography coupled to mass spectrometry needs to be improved by a factor of 20-100.
The pros and cons of the various methods will be discussed in this paper.

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WAYNE R. BIDLACK, PH.D.

Dr. Bidlack, is Dean, College of Agriculture, at California State Polytechnic University, Pomona, and is Professor in both the Department of Animal and Veterinary Science and the Department of Nutrition and Consumer Sciences.

Dr. Bidlack received his Bachelor of Science degree in Dairy Science and Technology from Pennsylvania State University (1966), his Master of Science degree in Food Science from Iowa State University (1968), and his Ph.D. Degree in Biochemistry from the University of California, Davis (1972). In addition, he was a postdoctoral fellow in Pharmacology at USC School of Medicine (1972-1974). He received his academic appointment at the University of Southern California (1974), served as Assistant Dean of Medical Student Affairs (1988-1991), as Professor and Interim Chair of Pharmacology and Nutrition, 1992. Dr. Bidlack also served as Chairman and Professor of Food Science and Human Nutrition and as Director of the Center for Designing Foods to Improve Nutrition at Iowa State University, Ames, Iowa, from 1992-1995.

Dr. Bidlack has been a member of the Institute of Food Technologists for more than 25 years, serving in many capacities; currently, Chair of the Strategic Planning Committee. He is past President of the Food Safety Specialty Section of the Society of Toxicology, and still serves on many committees. He has served as a member of the Board for the CBNS and actively contributed to the creation of the national certification exam. He is currently serving on the Editorial Board and as Book Editor for the Journal of the American College of Nutrition. He continues to review grants for several agencies and universities.

Dr. Bidlack has received many prestigious awards: Meritorious Service Award from the California Dietetic Association and the Distinguished Achievement Award from the Southern California Institute of Food Technologists; honorary membership in the Golden Key; National Honor Society and in Gamma Sigma Delta; Bautzer Faculty University Advancement Award for Cal Poly Pomona; CSU WANG Family Excellence Award for Administrators and the Cal Poly Pomona Chapter of Gamma Sigma Delta's Outstanding Faculty-Administration Award.
Dr. Bidlack has been elected to several national scientific societies, including the American Institute of Nutrition (American Society of Nutritional Science), the American College of Nutrition (Certified Nutrition Specialist), the Institute of Food Technologists, the American Society of Pharmacology and Experimental Therapeutics, and others.

His research interests are varied; but, integrate the general areas of nutrition, biochemistry, pharmacology and toxicology. From these efforts, Dr. Bidlack has published more than 55 publications, 12 book chapters, and edited 5 books.

Functional Foods to Enhance Health

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ABSTRACT

Man has selected a broad variety of foods of plant, animal and microbial origin to provide the nutrients needed for his existence. As a complex mixture of chemicals, food provides essential nutrients, requisite calories, and other physiologically active constituents needed for life and health. Yet, very little is known about the physiologic effect of most substances found in foods.

During the past 25 years, epidemiological studies have consistently correlated diet as a factor in the etiology of the five leading causes of death in the US: heart disease, certain types of cancer, stroke, non-insulin dependent diabetes mellitus and atherosclerosis. A new paradigm for “optimal nutrition” continues to evolve that would place emphasis on the positive aspects of diet, identifying components in addition to known nutrients that are physiologically active (bioactive) and contribute to the prevention of disease onset. Even though genetic predisposition increases susceptible people's risk for some of these chronic diseases, especially with advancing age, optimal nutrition should enable people to achieve their maximum genetic potential and decrease their susceptibility to disease. Understanding the mechanisms by which individual nutrients, and non-nutrient constituents, function physiologically should allow food scientists to truly design food products to support a healthy diet.

Most epidemiological evidence continues to correlate positive effects of fruits, vegetables and grains with lower incidence of cancer and coronary heart disease, and other diseases. The most consistent finding has been an inverse relationship between the risk for certain cancers and the consumption of fruits and vegetables, whole grains, fiber and some types of fats. Fruits and vegetables appear to be most effective against cancers involving epithelial cells such as cancer of the lung, cervix, esophagus, stomach, colon, and pancreas, and for hormone-related cancers.

The plant foods having the highest anti-cancer activity include garlic, soybeans, cabbage, ginger, licorice and umbelliferous vegetables (carrots, celery, cilantro, parsley, and parsnips). While more modest effects have been shown by onions, flax, citrus, turmeric, cruciferous vegetables, broccoli,

brussels sprouts, cabbage and cauliflower, solanaceous vegetables (tomatoes and peppers), brown rice and whole wheat.

Interestingly, the positive health correlations do not always agree solely with nutrient content. Non-nutrient constituents have been identified to contribute beneficial effects that may delay or prevent disease as well. Specific examples include allyl sulfides in garlic and onion, phytates in grains and legumes, lignans in flax and soy beans, isoflavones in soybeans, saponins in legumes, indoles and isothiocyanates in cruciferous vegetables, ellagic acid in grapes, strawberries, raspberries, and nuts, and a range of flavonoids, carotenoids and terpenoids in various plant foods. Surprisingly, many of these have appeared on natural toxicant lists, indicating as Parcelsus noted “the dose makes the poison”.

The functional foods concept has unified the medical, nutritional and food sciences in long term disease prevention. In the recent IFT Expert Panel Report, functional foods were defined as “foods and food components that provide a health benefit beyond basic nutrition (for the intended population)”. The promise of functional foods has emerged at a time when consumer interest in diet and health is at an all time high. The average consumer has been willing to pay a higher price for health foods, nutritional and herbal supplement products.

The new generation of functional foods represents an opportunity to apply food technology to enhance production of specific functional ingredients using gene transfer, genetic engineering, bioengineering, cell culture and specialized breeding programs. Many of these processes have been used over the last decade in efforts to enhance the nutritional quality of the food supply; for example, breeding of meat animals to have lower body fat in an effort to control calories and cholesterol content per serving; altering plant fatty acid content to achieve desired ratios of beneficial fatty acids in the extracted oil; and to improve the nutritional quality of plant proteins. These efforts continue as a means to improve the diet without necessarily labeling them as functional foods.

Functional foods, food products and supplements that deliver a physiological benefit in the management or prevention of disease, continues to present an opportunity and an interesting challenge for the future of the food industry, an industry which must constantly adjust its products to meet the needs of an ever changing society. To market these health products, promotional guidelines need to be made that enhance the understanding of the product and its health benefits. Health claims and the related health

benefits need to be substantiated by scientific evidence. The use of observational epidemiological studies, animal studies, and intervention trials provide the scientific evidences needed to establish health benefit relationships. Scientific data can be changeable and contradictory at times, so the quality of a health claim requires consistent substantiation from multiple studies.

Although significant evidence continues to accumulate that many phytochemicals may contribute to disease prevention and better health, very little effort has been made to test the long term, or possible toxic, side effects of these agents. In addition to the phytochemicals, herbals and other combinations of botanical components to food or taken as a dietary supplement has inherent risk simply because the numbers of consumers using the products are very high. In essence the use of these products without testing, dose controls or identification of possible contaminates has rapidly become a large uncontrolled human experiment. As the argument goes, the majority of these materials have been consumed for thousands of years; unfortunately, most have little recorded history and the outcomes of the consuming population are not available.

Another aspect of self treatment with plant materials is how it may affect other therapeutic regimens. Similar issues arose between drug-nutrient interactions 15-20 years ago and package inserts now warn to avoid certain foods or the timing of ingestion that can diminish (or enhance) absorption of drugs which may alter their efficacy or safety. A similar case is expected to be made for specific phytochemicals, the form in which they are ingested, the foods they may interact with (affecting nutrient utilization), and the timing of consumption relative to drug therapy regimens.

The General Accounting Office has raised concerns about the safety of functional foods, primarily noting a lack of regulations to guide companies on testing and presentation on product labels. The FDA has noted that the vast majority of these ingredients have not been cleared as GRAS nor approved as food additives for most of the cases in which they are being used. Aggressively promoting such products place the consumer at health risk and the food industry at financial risk. A potentially beneficial bioactive agent/functional food could be eliminated from the marketplace due to a negative incident that may have been avoided with a more development work. Thus, the use of plant materials and phytochemicals in functional foods to enhance the promotion of natural components for health may be premature and should be used with caution.

Given the consumers' preference for more convenient and healthful foods, an improved knowledge of human nutritional and physiological needs, and technological developments, the US food industry has been able to develop a wide variety of healthy food products. These include fortified foods, low fat and low calorie foods, functional foods, and most recently, foods produced by the emerging techniques of biotechnology such as cereal grains with greater nutritional value. Taking a raw commodity, such as wheat or soybeans, and making it more nutritious, safer, more convenient, more acceptable, easier to prepare, or specific to the needs of special population groups, adds immense value to the commodity.

It remains important to integrate a well balanced diet, healthy lifestyle habits, environmental factors, and heredity. Without this connection, the designer-functional foods concept might be misinterpreted as offering some form of magic bullet. In the end the consumer remains responsible for maximizing their own health potential, while the food industry must deliver specific functional products that enable the consumer to optimize their genetic potential for long term health and well being. Perhaps the food industry will finally be recognized for its contribution to a healthy, safe diet for the mutual benefit of everyone.

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(Material described in the abstract and in the slide presentation was obtained from the following articles, which contain specific reference citations).

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WILLIAM J. BURKHOLDER, PH.D

Dr. Burkholder received his D.V.M. in 1985 from the Virginia-Maryland Regional College of Veterinary Medicine and his Ph.D. in 1994 from Virginia Tech. He is a Diplomat by examination of the American College of Veterinary Nutrition. He was a member of the faculty of the College of Veterinary Medicine in the Department of Small Animal Medicine and Surgery at Texas A&M University from 1994 to 2000. He currently is a Veterinary Medical Officer with the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds, Nutrition and Labeling Team where he deals mostly with issues related to labeling and content of pet foods.

Challenges Facing Regulation of Pet Foods Containing Bioactive Components

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ABSTRACT

The proposed definition for a bioactive food component published in the *Federal Register*[1] read: "Bioactive food components are constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs that are responsible for changes in health status."

The Notice for the proposed definition requested comments on it and whether certain broad categories of compounds should be considered bioactive food components. Although none of the comments suggested that the definition should be broadened beyond "human nutritional needs," because physiological responses of animals to food components are not completely dissimilar from those of human beings, it is reasonable to presume that if there are constituents in foods other than those needed to meet basic nutritional needs that are responsible for changes in health status of people, then the same would generally be true for animals. If certain human food products gained a promotional advantage from having bioactive food components, it can be anticipated that pet food manufacturers will try to take advantage of the same promotional appeal for various "bioactive food components" in pet food products because the promotional and marketing strategies for pet foods parallel closely those for human foods.

The challenges presented for regulating food components identified as those that do not meet basic nutritional needs but which are identified as being responsible for changes in health status in animal feeds reside in upholding the regulatory regimens for foods versus drugs as required by the Federal Food, Drug, and Cosmetic Act and supporting regulations; upholding the rights of commercial free speech guaranteed by the First Amendment to the United States Constitution; and, applying the spirit of the Nutrition Labeling and Education Act (NLEA) of 1990, the specifics of which apply only to human foods. As for bioactive food components being constituents of dietary supplements, the Food and Drug Administration (FDA) has determined

[1] Federal Register 2004; 69(179):55821-2.

that the Dietary Supplement Health and Education Act of 1994 was not intended to apply to animals[2] because of safety concerns regarding the potential for residues from supplements in meat, milk, and eggs from food producing species fed dietary supplements, and because of the lack of a history of safe use of many dietary supplement ingredients in pet foods or other animal feeds. Thus, bioactive food components in animal feeds or animal feed supplements would be limited to constituents of acceptable ingredients or bioactive components that are themselves acceptable ingredients for use in animal feeds.

The criteria in the definition that bioactive food components effect "changes in health status" presents a significant hurdle for regulating products containing such components. Drugs are defined in large part by their intended use with part of the statutory definition for a drug being, "(B) articles intended for use in the diagnosis, cure, mitigation, treatment or ***prevention*** [emphasis added] of disease in man or other animals; …."[3] Although several comments on the proposed definition noted that, as written, a change in health status could be negative, companies generally do not promote a product on the basis that it contains a component that is bad for overall health, and an intention to affect a positive change in health status is likely to be closely aligned with preventing, treating, or mitigating a disease condition. Under the NLEA, human foods are allowed to make "health claims" that the FDA has judged to be valid based on significant scientific agreement among multiple scientific studies addressing the effects of a particular food or food component on the health of people. It is exceedingly rare for the quantity and quality of data needed to demonstrate significant scientific agreement to exist for validating a health claim for animal species, and health claims for people are not necessarily applicable to other species because of physiological differences. A good example of inapplicability of human health claims for pets are the health claims for whole oat and soluble fiber-containing foods reducing the risk for coronary heart disease. Dogs and cats do not suffer from coronary heart disease, atherosclerosis, or effects of cholesterol in the way that people do. Thus, to claim similar benefits for dog or cat foods containing whole oats or soluble fiber would be false and misleading because the same benefit does not exist for these species.

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[2] Federal Register 1996; 61(78):17706-8.
[3] Title 21 United States Code, Section 321(g)(1)(B).

The criteria in the proposed definition that bioactive food components are "other than those needed to meet basic […] nutritional needs" presents another significant hurdle for regulating products containing such components, particular for isolated or purified components added to foods to increase the content of those components in food products. Another part of the statutory definition for a drug is, "(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; …."[4] Case law has helped to further define the meaning of "(other than food)" as being substances that provide taste, aroma, or nutritive value.[5] Thus, something that affects the structure or function of the body in a manner other than by taste, aroma, or nutritive value is a drug, as reflected by the statutory definition, case law, and the Center for Veterinary Medicine Program Policy and Procedures Manual Guide 1240.3605, Regulating Animal Foods with Drug Claims.[6] Until better definitions are in place for terms such as "nutritive value," and non-basic nutritional needs (i.e., requirements), regulators and industry will be at odds on where and how to split the regulatory hair between a bioactive food component and its associated claims and a drug.

The determination for where and how to divide claims to affect the structure or any function of the body of man or other animals between those appropriate for food and bioactive components of food versus a drug is not trivial and has consequences regarding guarantees for commercial free speech under the First Amendment to the United States Constitution. Drugs require approval by the FDA prior to marketing to be legal products in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Products with claims that establish their intended use to be that of a drug, but which do not have approval as a drug are illegal products and speech that promotes an illegal activity or product is not protected under the First Amendment, no matter how accurate or true it may be. Several comments to the notice of the proposed definition for bioactive food components noted that the definition provided for no new regulatory structure for foods, components, and appropriate claims.

Finally, just because a food may have a safe history of use such that the food is generally recognized as safe (GRAS) for a particular use does not mean that components of that food when isolated, purified, or synthesized for reincorporation into foods for some other use are also

[4] Title 21 United States Code, Section 321(g)(1)(C).
[5] Nutrilab v. Schweiker. 713 F.2d 335 (CA 7, 1983).
[6] http://www.fda.gov/cvm/FOI/ppindex.html

GRAS. Apples are GRAS and yet apples contain small, generally insignificant quantities of cyanide in their seeds which is obviously not GRAS. Although the notice of the bioactive food component definition noted that green tea, soybeans, broccoli, and red grapes, which are undeniably foods considered GRAS for their typical uses and consumption by people, contain the components of, epigallocatechin gallate, isoflavones, sulphorophane, and resveratrol, respectively, these components themselves are not GRAS compounds.

DON CLARKE, PH.D

Dr. Clarke joined the UK Ministry of Agriculture Fisheries and Food (MAFF) as a senior analytical chemist in 1999. He has extensive experience of chemical analysis and food safety, specialising in trace analysis of food for chemical contaminants. From 1999 to the present he has been a part of the Food Safety & Quality group (FSQ) of the Central Science Laboratory in York. He has responsibility for staff who are currently working in the areas of phytoestrogen analysis for clinical trials and perfluorinated alkyl sulphonic acids (PFOS) environmental contaminants.

Dr Clarke obtained a PhD in organic synthesis & natural products chemistry in New Zealand and held a post doctoral fellowship in chromatography (supercritical fluids) at the University of Nottingham. He previously spent 5 years conducting ADME studies for agrochemical registration at Huntingdon Life Sciences and Inveresk Research International.

Dr Clarke has published 17 scientific papers, principally on phytoestrogen identification and analysis in food and clinical studies, analysis of acrylamide, and identification of natural products from New Zealand trees.

Phytoestrogens in Food

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ABSTRACT

Phytoestrogens are plant hormone mimics that interact with the mammalian estrogen receptors. They have been used in folk medicine throughout history and have many clear and measurable effects. In previous decades there has been commercial incentive to understand the undesirable effects on animal reproduction and productivity. Currently the focus is on the rapidly expanding human nutraceuticals and functional foods markets, with numerous products available on the market place making often unsubstantiated health claims. This has led to an extensive programe of clinical trials in an attempt by manufactures and government agencies to prove/disprove the many possible beneficial/harmful effects in man. This presentation will describe work we have conducted on the analysis of phytoestrogens in food and in support of UK clinical trials. A dietary intake calculation for the UK will be presented [1] and the sources of phytoestrogens will be explored [2]. An analytical method for determination of isoflavone urinary conjugates [3] has been used to determine that habitual exposure to isoflavones (100 mg/day) does not affect overall excretion or the conjugation profile [4].

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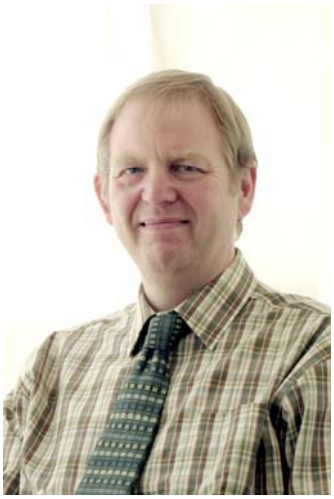

JOHN DENNIS, PH.D

Dr. Dennis leads CSL's Food Safety and Quality Group of 80 scientists, applying a formal risk management process to identify and ameliorate business risks and maximize the potential of the unit.

Dr. Dennis has key experience in: Application of NMR to metabolite profiling; Analysis for Genetically Modified Organisms; Methods to authenticate species, origin and processing of foods; Isotopic analysis; Bromate and azodicarbonamide in bread; Polycyclic aromatic hydrocarbons; and N-Nitrosamines and Ethylcarbamate

He key activities include: (1) Ensuring Health and Safety of staff through production of appropriate COSHH assessments and risk assessments; (2) Developing the annual business plan and ensures a sufficient financial contribution is achieved through a detailed planning and management process; (3) Approving all Group research proposals and high value commercial proposals and seeks to identify new opportunities through an annual marketing plan; (4)Ensuring efficient utilisation of staff and equipment resources regularly reviewing priorities; (5) Ensuring staff are empowered to take advisory roles in UK and EU committees, to present their scientific achievements at National and International conferences and to publish in the most significant peer reviewed journals; and (6) Advising Government and other customers on food safety and quality issues.

Dr Dennis is a member of the following national and international committees: EU Wine Databank Advisory Group; DTi Measurement Advisory Committee to the National Measurement System (2003-presnt); DTi Measurements for Biotechnology Steering Group (2002-present); MAFF/FSA - Food Authenticity Working Party and Chairman of the Methods Sub-committee (1993 to present); and Food Chemistry Group, Royal Society of Chemistry (1995-1998)

"OMICS" Reviewed – With Applications to Food Science

John Dennis
Central Science Laboratory
York, United Kingdom

ABSTRACT

In the last 10 years there have been enormous development and applications for three closely related technologies – **Geneomics, Proteomics and Metabolomics** (sometimes termed **Metabonomics**). These technologies all refer to the analysis of components of living organisms, cells, and biofluids. They are related by far more than their name. They are related at a structural level because the DNA template provides the information source for the three dimensional structure of proteins, the choice of those expressed, their amount, their modification and their subsequent digestion and recycling. The metabolome refers to the range and concentration of the small molecules present in biofluids. The composition of this chemical soup is derived from the action of enzymes forming part of the proteome as well as from environmental influences (e.g. source of food). Thus the genome, proteome and metabolome are inextricably linked at a functional level.

However the concept of "omics" is more than a convenient label for parts of cell systems. On the contrary, these technologies are linked philosophically. In each case the technologies can be used to compare a "normal", healthy or untreated population of organisms with a "challenged" sick or treated population. The technologies are then applied to rapidly identify differences between these populations. The information gained can then lead to diagnostic tests, to more effective, targeted treatments or to better informed advice. The rapid nature of these experimental approaches enables large numbers of tests to be performed so that low frequency divergences within populations can be identified with statistical validity.

In this presentation I will briefly review common technologies in geneomics, proteomics and metabolomics and identify examples of relevance to food science and nutrition.

KATHLEEN ELLWOOD, PH.D

Dr. Ellwood is the Director for the Division of Nutrition Programs and Labeling, Office of Nutritional Products, Labeling and Dietary Supplements, U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN). This Division is responsible for scientific review of nutrition labeling, such as health claim petitions, nutrient content claim petitions, and overall diet and health issues. Prior to joining FDA, Dr. Ellwood was the National Program Leader for Human Nutrition for the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS). Prior to joining ARS, Dr. Ellwood was the Director of the Human Nutrition and Food Safety Competitive Grant Programs for USDA's Cooperative State Research, Education, and Extension Service (CSREES). Dr. Ellwood has held research scientist positions at FDA, CFSAN and USDA, ARS. She received her B.S. in biology from Old Dominion University, an M.S. in animal science and Ph.D. in nutritional biochemistry from the University of Maryland. Dr. Ellwood has numerous publications and is a member of several professional societies.

Food Labeling and Health Claims: U.S. Perspective

Kathleen C. Ellwood
Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD

ABSTRACT

The Nutrition Labeling and Education Act (NLEA) passed in 1990 was to assist consumers in maintaining healthy dietary practices, provide a level playing field for claims and encourage innovations in food products. NLEA permits authorization of health claims under the significant scientific agreement standard. Significant scientific agreement standard is when it has been determined, based on the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles, that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (1). This standard applies equally to conventional foods and dietary supplements. Prior to NLEA the US Food and Drug Administration (FDA) considered claims made about disease on a food to be drug claims. Health claims are about a causal relationship between a substance (food or food component) and a disease or health-related condition for the general U.S. population or subpopulation.

Several court cases known as the Pearson Court Decisions favored "disclosure over suppression" for claims that did not meet significant scientific agreement standard. This dealt with first amendment protection of free speech. FDA was to provide for the claim as long as it contains qualifying language as not to mislead the consumer. These cases pertained only to dietary supplements.

In December, 2002, Commissioner of FDA, Dr. Mark McClellan, announced a major new initiative, "The Consumer Health Information for Better Nutrition Initiative". This initiative was to make available more and better information about foods and dietary supplements, to help American consumers prevent diseases and improve their health by making sound dietary decisions. It was designed to encourage producers of conventional foods and dietary supplements to make accurate, up-to-date, science-based claims about the health benefits of their

products. This initiative provided for the use of qualified health claims for both conventional foods and dietary supplements when there is emerging evidence for the claim.

An FDA Task Force was established and a report was released on July 10, 2003 (2). The Task Force Final Report established interim procedures for qualified health claims on conventional food and dietary supplements; developed guidance for interim evidence-based ranking system for scientific data; and developed a consumer studies research agenda. The guidance for interim evidence-based ranking system consists of defining the substance/disease relationship, identifying relevant studies for the claim, classifying studies (i.e., intervention/observational), rating the studies for quality, rating for strength of body of evidence (i.e., quantity, consistency and relevance), then reporting a rank.

An Advanced Notice of Proposed Rulemaking (ANPRM) published in November, 2003 to seek comments on the process for regulating qualified health claims and the appropriateness and nature of dietary guidance statements (3). In addition, FDA conducted consumer studies to look at the wording or graphic that would be required for conveying to the consumer information that would be truthful and not misleading. FDA is reviewing comments to the ANRPM and evaluating consumer study data to develop a strategy for regulating qualified health claims, and will publish final guidance on the evidence-based ranking system for health claims and qualified health claims.

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1. Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements. U.S. Food and Drug Administration. 1999. http://www.cfsan.fda.gov/~dms/ssaguide.html
2. Consumer Health Information for Better Nutrition Initiative. Task Force Final Report. U.S. Food and Drug Administration. 2003. http://www.cfsan.fda.gov/~dms/nuttftoc.html
3. DHHS/FDA. "Food Labeling: Health Claims; Dietary Guidance." November 25, 2003, Volume 68 Federal Register, p. 66040.

LYNN FREWER, PH.D

Dr. Frewer is Research Professor in Food Safety and Consumer Behaviour at the University of Wageningen in the Netherlands. She was previously head of the Consumer Science Group at the Institute of Food Research at Norwich in the UK. Lynn has research interests in various aspects of consumer food choice, including those focusing on understanding public responses to food risk issues, emerging technologies, and investigating the impact of traceability on consumer attitudes and food choices, as well as risk communication and evaluating stakeholder and public engagement, and how this relates to food risk policy and optimizing risk analysis practices. She has a particular interest in developing research activities spanning the social and natural sciences.

Consumer Perspectives and Attitudes in the EU

Lynn Frewer
Wageningen University
Wageningen, The Netherlands

ABSTRACT

Recent food safety incidents in Europe and beyond have resulted in consumer disquiet associated with various food production practices. Prominent examples include the BSE and dioxin crises, as well as consumer concern regarding the introduction of new food processing technologies such as genetically modified foods and other novel food technologies. However, consumers are not homogenous, and individual consumer acceptance of novel foods is dependent on the interaction between different attitudinal factors. These include trust in regulatory institutions and scientific processes, as well as the food industry and different actors in the food chain. For a novel product to be acceptable, consumers must perceive that the perceived benefits outweigh the risk, although what is perceived as a benefit may vary between different consumers. Different consumer values (for example, concern about the integrity of nature) may also be influential determinants of food choices. Consumers must also perceive personal control over which foods they eat if consumer confidence is too be maintained, which implies that there is a need to introduce traceability systems into different food chains which reflect consumer, as well as regulatory, requirements.

In order to develop consumer trust in risk management, it is important to revisit the risk analysis framework. European research directed towards developing an integrated approach to food risk analysis will be presented. Future challenges lie with the development of effective risk-benefit communication with consumers, as well as overcoming barriers to changing unhealthy food consumption patterns. The introduction of nutrigenomics, functional foods and other potentially beneficial food products will be contingent on effective communication about risk and benefit associated with products and production technologies, and developing targeted information delivery focused on the needs of specific groups of consumers.

WENDY REINHARDT KAPSAK, MS,RD

Ms. Reinhardt Kapsak is Associate Director for Health Communications at the International Food Information Council (IFIC) in Washington, DC, and specializes in effective consumer communications on a variety of food safety and nutrition issues such as, obesity and weight management, functional foods, food biotechnology, low-calorie sweeteners and food allergies and sensitivities.

Wendy is a registered dietitian and a member of several professional organizations, including the American Dietetic Association and the Society for Nutrition Education.

Ms. Reinhardt received her Bachelors degree from the University of Missouri, Columbia in Nutrition and Physical Fitness, and received her Masters degree from James Madison University in Nutrition and Physical Activity. She completed her dietetic internship at Yale-New Haven Hospital in New Haven, Connecticut.

Her research endeavors have included nutrition and physical activity interventions related to childhood obesity. Ms. Reinhardt presents regularly on a wide range of food safety and nutrition topics.

IFIC is a nonprofit organization that communicates sound science-based information on food safety and nutrition topics to health professionals, journalists, government officials, and consumers. IFIC's programs are primarily supported by the broad-based food, beverage, and agriculture industries.

Functional Foods: Communicating Challenges & Opportunities

Wendy Reinhardt Kapsak
International Food Information Council
Washington, DC

ABSTRACT

In the current research environment, scientific knowledge of the health benefits of foods and food components is developing rapidly. Consumers obtain nutrition information from a variety or resources, including the media, food labels, and health professionals, which can contribute to confusion and frustration. Based on nine years of consumer research conducted by the International Food Information Council, attendees will learn to effectively address the challenges and opportunities in communicating the health benefits of functional foods to patients and other consumers.

MICHELE KELLERHALS, PH.D

Since mid May 2005, Dr. Kellerhals is responsible for Scientific and Regulatory Affairs of Non Carbonated Beverages in Coca-Cola European Union Group, encompassing the EU25, Russia, Turkey and some other Central European Markets. Within this growing area involving juices, waters, tea and coffee, energy drinks and sport drinks, his role is to work with health platforms in the area of Health and Wellness and to interface Science, Regulatory Affairs and Marketing for the development of sustainable business propositions. In his previous assignment with Beverage Partners Worldwide (BPW), the Joint Venture between Coca-Cola and Nestlé for RTD Tea and RTD Coffees, Dr. Kellerhals worked as a Technical Manager for Europe, Africa and Middle East and managed the Technical/Scientific interface between the parent companies, R&D, Regulatory Affairs and Commercialization in one of the fastest growing beverage market segments. Dr. Kellerhals joined the Coca-Cola Company in 1998 as a Technical Manager for Switzerland. In this role he was responsible for all technical aspects of the business, including Regulatory Affairs and R&D. In 2001 he was transferred to BPW as part of the European Management Team.

Dr. Kellerhals holds a Masters in Food Science and a PhD from the Institute of Biotechnology, both at the Swiss Federal Institute of Technology (ETH) in Zürich. His personal interest is in strengthening the dialogue between different stakeholders such as Regulators, Industry, Academia and Consumer Organizations in order to foster Innovation, Technology Transfer and appropriate and safe consumer centric business propositions.
In his free time Dr. Kellerhals enjoys the time with his family and can be found either trekking on glaciers in the Swiss Alps or Scuba Diving in the Mediterranean Sea.

The Science Behind Labeling Issues and Health Claims

Michele B. Kellerhals, PhD.
Coca-Cola European Union Group,
Brussels, Belgium

ABSTRACT

Although the functional food market in Europe has been one of the fastest growing food market segments and is now approaching 10 billion Euros, it is significantly lagging behind Japan and the US. One of the main reasons for this shortfall is the lack of harmonized EU legislation on labelling of bioactive-containing functional foods and lack of agreed guidelines on substantiation of nutrition and health claims. As a consequence, these are currently regulated at national level and several countries have already established multi-stakeholder voluntary codes to bridge this gap. Concomitantly, the European Union, as many others, is facing a tremendous challenge in order to manage the rapid raise of the obesity epidemics: in this context labelling, as a tool of both public interest and marketing, plays a pivotal role on the Agenda of the recently established EU Platform for Action on Diet, Physical Activity and Health.

Only recently the Commission has proposed two important regulations with the intent to harmonize nutrition labelling requirements and establish uniform science-based approval processes in the area of health claims in Food. In spite of this sought after harmonization attempt, Food in Europe is still viewed as a stronghold of cultural diversity, and as such, Member State positions in this matter tend to diverge dramatically. As an example, South Europe tends to reject health claims and the functional food approach as a whole, as food is generally regarded as wholesome; in many Northern European countries instead, people will embrace the idea if it can be scientifically proven.

Eventually, the addition of well-known bioactive compounds that are easily recognized by consumers such as vitamins and minerals and certain other substances will be permitted under certain conditions with details still to be defined. Substance bioavailability must be assessed within the proper target group and dietary context, and, if only nutrient content or comparative claims are made, no proof of efficacy will be required.

As far as nutrient function and health claims are concerned, the proposal text is currently extremely fluid: nevertheless, cornerstones such as the requirement for scientific substantiation or the concept of nutrient profiles are almost certain to be included in the final regulation. While it seems there is wide stakeholder consensus on the benefits of the evidence-based approach, no definition of “evidence” and “generally accepted scientific data” was included in the proposal. In this context, scientific criteria for claim substantiation developed by PASSCLAIM will hopefully provide invaluable experience and a common language to companies, academia and regulators.

The measurement of dietary exposure patterns across European Markets, the development of a harmonized approach to risk assessment and the development of appropriate markers of intermediate endpoint will heavily influence the research agenda in Europe. Additionally, scientific breakthrough in emerging technologies such as nutrigenomics or nanotechnology will soon enable new and superior consumer benefits.

On the other side of the spectrum, the scientific hypothesis will largely be dictated by the wording of the claim; a critical balancing act between public interest and private advertising at the service of consumer understanding. Only with participation and close collaboration between the scientific, the commercial and regulatory environments will these changes be possible and mutually beneficial to society.

TODD KLAENHAMMER, PH.D

Dr. Klaenhammer was born in St. Paul Minnesota, 1951. Graduated from the University of Minnesota in 1978 with a Ph.D. in Food Science. Joined North Carolina State University as an Assistant professor in 1978. Currently, a Distinguished University Professor and named a William Neal Reynolds Professor with faculty appointments in the Departments of Food Science, Microbiology, and Genetics. The major field of study is on the genetics of lactic acid bacteria and their bacteriophages with emphasis on genomics of probiotic lactobacilli. Elected into the US National Academy of Sciences in 2001.

Probiotics in Functional Foods

Todd R. Klaenhammer
Department of Food Science & Genomic Sciences Program
North Carolina State University
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ABSTRACT:

The lactic acid bacteria are Gram-positive fermentative microorganisms known primarily for their roles as starter cultures and probiotics. The food industry represents one of the largest manufacturing industries in the world and recent trends are rapidly expanding the use of probiotic cultures within functional foods. Understanding and control of probiotic lactic acid bacteria is now being revolutionized by genomic sciences and the appearance of the complete genome sequences for *Bifidobacterium longum*, *Lactobacillus johnsonii*, *Lactobacillus plantarum*, *Lactobacilluls acidophilus,* and draft sequences for *Lactobacillus gasseri* and *Lactobacillus casei.* This explosion of DNA sequence information, accompanied by the development of bioinformatic tools for nucleic acid and protein analysis, now allows rapid characterization of probiotic strains for their genomic content and expression profiles across the entire genome. Comparative genomics has already revealed important similarities and differences in strains, species, and genera and will likely identify key genetic features responsible for the beneficial properties ascribed to probiotic lactic acid bacteria. Practical genomics promises to establish the genetic landscape, correlate genotypes with desirable phenotypes, establish genetic criteria for strain selection, improve culture stability by stress preconditioning, provide opportunities for metabolic engineering, and uncover a mechanistic basis for the beneficial activities of probiotics when delivered in various foods. This presentation will examine the genomic and comparative genomic content of probiotic *Lactobacillus* cultures used as probiotics. In addition, expression profiling by whole genome microarrays will illustrate how environmental conditions encountered in biomanufacturing, fermentation, and the gastrointestinal tract can impact gene expression and probiotic functionality.

GILBERT A. LEVEILLE, PH.D

Dr. Leveille was born in Fall River, Massachusetts and educated at the University of Massachusetts-Amherst and Rutgers University-New Brunswick, where he received his Ph.D. Early in his career Dr. Leveille became Professor of Nutritional Biochemistry, Department of Animal Science, and University of Illinois at Urbana-Champaign. Other positions included: Professor and Chairman of the Department of Food Science and Human Nutrition at Michigan State University where his duties included the administration of the department, teaching and research; Director of Nutrition and Health Sciences at General Foods Corporation, where his responsibilities related to corporate research in the areas of Nutrition, Physiology, Dental Health and Toxicology, as well as clinical studies.

From 1986 until his retirement in 1996 Dr. Leveille was Vice President, Research & Technical Services, Nabisco Foods Group, responsible for Fundamental Science and Bioanalytical Sciences. In 1996 Leveille Associates was founded, a firm providing consultation in scientific and regulatory areas related to food, nutrition and the emerging field of functional foods (nutraceuticals). He was also a founding member of Life-Sciences-Alliance, a consortium of consultants. Dr. Leveille was Worldwide Vice President, Regulatory and Scientific Affairs at McNeil Consumer Healthcare in Fort Washington, PA. He retired from this post in August 2001. In January 2002 he became Vice President, Technology for Cargill's new Food System Design unit. He retired in June 2004, but continues to represent Cargill as a Sr. Consultant of Scientific and Regulatory Affairs.

Dr. Leveille is a member of numerous professional organizations, participates in numerous professional symposia, and lectures world wide. He has authored over 300 scientific papers and books including ***Nutrients in Foods*** published in 1983 and ***The Setpoint Diet,*** a New York Times non-fiction best seller, published in 1985. He is an inventor listed on several issued patents.

Awards and honors include: Mead Johnson Research Award, AIN (1971); election to Phi Kappa Phi (1979); Michigan State Distinguished Faculty Award (1980); inclusion in American Men of Science, Who's Who in America, Who's Who in Medicine and Healthcare, Who's Who in Executives and Businesses and Who's Who In the East; Distinguished Service Award, Philadelphia Section of IFT, (1980); IFT Fellow Award (1982), Tanner Award, Chicago Section of IFT, (1989); Endresen Lecturer, University of Massachusetts, (1992); Carl R. Fellers Award, IFT (1992); IFT Industrial Scientist Award (2004).

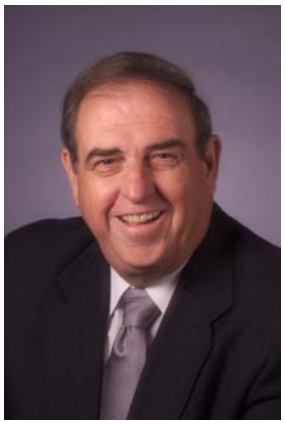
Where Do We Go From Here?

Gilbert A. Leveille, Ph.D.
Senior Consultant Scientific and Regulatory Affairs, Cargill Inc.
Denville, NJ

ABSTRACT

This presentation will attempt a futuristic look to identify issues that will be associated with the implementation and commercialization of functional foods. The lack of an adequate business model for full commercialization of the products emanating from the advancements of the "omics" developments will be discussed. How these issues will/might relate to existing food/pharma businesses will be considered.

Regulatory impacts on the evolution of the science and its implementation will be discussed; specifically, attention will be directed to ways in which regulatory policies can provide impediments or incentives to commercialization.



JOHN MILNER, PH.D.

Dr. Milner is chief of the Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute. Dr. Milner earned a Ph.D. from Cornell University in nutrition, with a minor in biochemistry and physiology and a B.S. in Animal Sciences from Oklahoma State University. Dr. Milner is a member of several professional organizations, including the American Society for Nutritional Sciences, American Association of Cancer Research, the American Society for Clinical Nutrition, the American Chemical Society's Food and Chemistry Division and the Institute of Food Technology. He is a fellow in the American Association for the Advancement of Science.

He has served in an advisory capacity as a member of the U.S. Department of Agriculture's Human Nutrition Board of Scientific Counselors, Joint USDA/HHS Dietary Guidelines Committee, and for the Food, Nutrition and Safety Committee within the International Life Sciences Institute (ILSI). Dr. Milner has served as president of the American Society for Nutritional Sciences (formerly the American Institute of Nutrition) and has testified before the Subcommittee on Appropriations in Washington, D.C. and the Presidential Commission on Dietary Supplement Labels in Baltimore, Maryland. He has served as a member of the National Academy of Sciences Committee on Military Nutrition Research, the U.S. Olympic Committee Dietary Guidelines Task Force and the External Advisory Board for the Pennington Biomedical Research Center. He is currently a Member and Vice-Chair for the Counsel of Experts of United States Pharmacopeia Committee on Bioavailability and Nutrient Absorption, a member of the Global Board of Trustees for ILSI, and chair of the World Cancer Research Fund/American Institute for Cancer Research Mechanisms Working Group and a member of the External Advisory Board for the European Commission SeaFood Plus initiative.

Dr. Milner has published more than 300 abstracts, book chapters, and journal articles. He serves on the editorial boards for the *Journal of Medical Food, Journal of Nutritional Biochemistry, Nutrition and Cancer, An International Journal, Comprehensive Reviews of Food Science/Food Safety and Nutrition, and The Journal of Nutrition.* In his current position he promotes research that deals with the physiological importance of dietary bioactive compounds as modifiers of cancer risk and tumor behavior. Much of his own current research focuses on the anticancer properties of garlic and associated allyl sulfur compounds. In addition to presentations about garlic and health he has been an invited to speak about nutrition and genomics, selenium nutriture, antioxidants and health, functional foods and health promotion, and nutrition for cancer prevention.

Biomarkers and Surrogate Endpoints for Evaluating Health Benefits of Food Components: Promises and Perils

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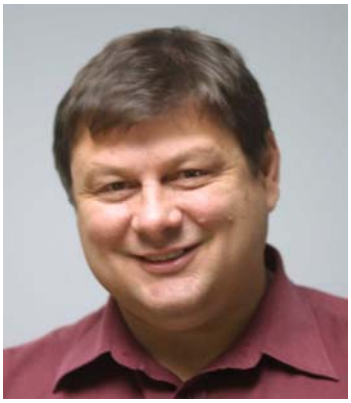
National Cancer Institute
Nutritional Science Research Group
Division of Cancer Prevention
Rockville, MD

ABSTRACT

While dietary habits continue to surface as a significant factor influencing health, there is considerable scientific uncertainty about how to identify those who might benefit most from intervention. Three types of biomarkers (exposure, effect and susceptibility) are likely required to predict responders from non-responders to dietary change. Each type has its own unique characteristics that may necessitate the monitoring of more than one indicator to develop a predictive model. Several factors may ultimately influence the amount of a bioactive food component that reaches a target site. Thus, knowledge about an individual's genetic background (nutrigenetics), epigenomic homeostasis (nutritional epigenomics), responsiveness of genetic expression profiles to bioactive food components (nutritional transcriptomics), the amount and activity of specific proteins (nutritional proteomics) and/or the dose and temporal changes in cellular small molecular weight compounds within and bathing cells (metabolomics) are fundamental to deciphering who will be a responder. Without doubt, a fundamental issue remains about how best to estimate dietary exposure(s). Some suggest that blood measurements may not always be the best indicator of events occurring within other tissues. Thus, interest continues to mount about the usefulness of cell scrapings, exfoliated cells, or body fluids as possible predictors of a response in target tissues. Since health concerns tend to increase as a function of time, a single measurement is likely inadequate to predict overall benefits and/or risk. Ultimately, biomarkers will be needed that are sensitive and reliable predictors of specific processes which influence health, including cell division, foreign compound metabolism, DNA repair, apoptosis, immunocompetence, hormonal homeostasis, etc. Since these are normal cellular events, it is critical to establish the balance and harmonization that must continue to exist across processes when evaluating the physiological significance of food components. Deciphering the importance of each of these potential sites of regulation will be particularly challenging, but does hold promise in explaining many of the inconsistencies in the literature, reducing health care costs, and most importantly improving health and longevity.



ROBERT PREMIER, PH.D.

Dr. Premier is currently employed as the section leader of the plant physiology and food science section of the Department of Primary Industry in the State of Victoria, Australia. He has a B.Sc. degree, a Master of Environmental Science degree, a Master of Biotechnology Degree and a PhD from the University of Melbourne. His interests for the past ten years have been in the are of food science related to agricultural foods, especially horticulture. He pioneered food safety at on farm level in Australia and has authored and co-authored many publications in Australia that have shaped the direction of food safety in agricultural commodities. More recently he has had an interest in phytochemical and health and has published a number of papers in this area. His team has worked on the quantification of health related phytochemicals in brassica species and they have studied production of these phytochemicals in whole plants. As part of an FAO/WHO expert team he has investigated the potential use of high phytochemical vegetables in the food chain and the issues that need to be addressed when using these as part of normal nutrition in humans. His section is involved in a $25M joint project with Food and Crop of New Zealand which aims at developing new vegetable varieties that are high in health promoting phytochemicals.

Value Adding to Horticultural Plants Foods through Enhancement of Nutritional Parameters

Robert Premier
Postharvest Physiology and Food Science
Victoria, Australia

ABSTRACT

Although plant-based foods have been eaten since the existence of mankind, there are many drivers for modern man's consumption of plant foods. Plant foods have an incredible range of tastes and aromas. The smell of a fresh apple or the taste of a ripe tomato have been entrenched in our minds as very distinctive and specific sensations. The diversity of texture found in plant foods is also something that is quite unique. Plant foods may have a crisp, granular or creamy texture. The combination of texture, aroma and taste often leads to a unique sensation in plant food consumption. Many plant products however are consumed because of their real and perceived importance for health and well-being. It is well established that plant foods have been shown to contain important nutritional compounds. Both macronutrients and micronutrients are found in fruit and vegetables. The importance of plant products in the human diet has led to the five-a-day and the seven-a-day campaigns which are driven by the nutritional importance of plant foods in terms of essential vitamins, essential trace elements, sources of energy and fibre. Dieticians recognize that some vitamin intake is linked directly to consumption of plant foods. An example of this is the carotenoids, which are precursors to vitamin A. Plants supply the only source of carotenoids to the animal kingdom and more than 80% of the world's vitamin A is supplied by horticultural crops. Plant breeding has not concentrated on nutrition as a quality parameter. This presentation will focus on the hidden health treasures of plant foods and where the future lies in the nutritional dimension of the plant food industry and its significance for value adding at on farm level and at post harvest.

ALAN RULIS, PH.D

Dr. Rulis is currently Senior Advisor for Special Projects, at the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN).

Dr. Rulis began working at FDA in 1977 in the then Division of Food and Color Additives. From 1995 until assuming his current position last year, he was Director of the agency's Office of Food Additive Safety. Dr. Rulis' experience at FDA ranges across the areas of food chemical safety assessment, risk management, public policy, premarket approval, and recently, applied nutrition.

As a Senior Advisor in CFSAN, Dr. Rulis works on the immediate staff of the CFSAN Center Director, and collaborates with several program offices in CFSAN on a range of project areas. He served on the FDA's Consumer Health Information for Better Nutrition Initiative Task Force (July 2003) developing approaches for the premarket review of qualified health claims on conventional foods and dietary supplements. In 2003-04 he served on FDA's Obesity Working Group whose resulting report, "Calories Count," released in March of 2004, announced steps within FDA's purview to help reverse overweight and obesity in the U.S.

Dr. Rulis' doctoral degree in chemistry is from the University of Wisconsin, Madison.

"Nutritional Risk" Associated with Food Safety: Case Study

Alan M. Rulis, FDA/CFSAN
Center for Food Safety and Applied Nutrition
Food and Drug Administration
College Park, MD

ABSTRACT

This presentation will focus on FDA's scientific criteria for the safety assessment of bioactive food ingredients. The current framework is rooted in the agency's traditional approach to evaluating the safety of new food additives, a toxicologically based framework. In recent years, that framework has been expanded and adapted to situations where certain additives may have "nutritional effects" that must be addressed in the overall safety evaluation when considering a "bioactive" substance for use as a food ingredient. This was the case for the agency's safety evaluation of the food additive "olestra" a macro-nutrient substitute for fat in the production of savory snack foods. Several aspects of this safety assessment will be reviewed.

More recently the agency has been evaluating uses of a variety of food ingredients with "bioactive" properties under its "Generally Recognized As Safe" (GRAS) notification program. In that context, several precedent setting cases will also be mentioned.

As the safety assessment framework for food ingredients has expanded beyond the realm of mainly "toxic" responses to include consideration of nutrition related phenomena, we see the outlines of a field of "nutritional risk assessment" as a new tool to use in evaluating the safety of a broad array of foods and food constituents.