

Scientific Symposium: 3 July 2010
Geneva, Switzerland

Scientific Issues Related to Codex Goals

- The role of science in consumer health and fair practices in food trade
- Scientific standards for label claims
- Risk assessment methods consistent with Codex guidelines and WTO agreements

presented by:

Council for Responsible Nutrition



CRN-I™

INTERNATIONAL

Bringing together international regulators, government bodies, nutrition scientists and academics to share information, perspective and rationale surrounding Codex issues relating to science-based risk management and developing scientific standards for health claims. (Program in English)

Today's speakers *in order of appearance*



Mark LeDoux
Natural Alternatives International, Inc.

Mark A. LeDoux, J.D., is founder/chief executive officer/chairman of Natural Alternatives International, Inc., (NAI) an organization with facilities in the U.S., Switzerland and Japan engaged in the research, design and manufacture of nutritional supplement programs and products for multinational clients. Mr. LeDoux is considered a leader and spokesperson for the nutritional supplements industry. He assumed chairmanship of the Council for Responsible Nutrition (CRN) in December 2008, serving through 2010, and is a member of the Board of Directors and Executive Committee of CRN. He is a recognized participant of the Codex Alimentarius Commission, the United Nations' food and dietary supplement standard-setting body under joint supervision of its Food and Agriculture Organization and World Health Organization. Mr. LeDoux is president of the Marie A. LeDoux Charitable Foundation and a member of the Young Presidents Organization Graduates.



Arpad Somogyi, D.V.M., Ph.D.
Consultant to the European Commission, Brussels, Belgium

During the past four decades Professor Somogyi participated as chairman, vice-chairman, rapporteur, adviser and member of expert panels in countless national and international activities pertaining to risk assessment and risk management in the course of the safety evaluation of a large variety of products, processes and substances. On these subjects, he has authored more than 150 communications that appeared in international scientific periodicals or published as book chapters. In addition to his earned doctoral degrees he is holding two honorary doctorates and is a member of several learned societies, including an external membership of the Hungarian Academy of Sciences. Professor Somogyi served in the European Commission in Brussels where he became Head of the Unit *Evaluation of Health Risks* in the Directorate-General for Health and Consumer Protection. In 2002 he was entrusted by the European Commission with the EU Project Leadership aimed at establishing and developing the Hungarian Food Safety Office in Budapest. Since 1987 he has been serving as vice president of European Affairs of the Toxicology Forum.



Peter Prock, M.D.
*European Nutraceutical Association
Basel, Switzerland*

Dr. Peter Prock, a medical doctor focusing on preventive medicine, and scientific advisor for nutraceutical research and medical communications, is a founding member and current president of the European Nutraceutical Association, an expert association devoted to providing a scientific platform for nutraceuticals. He speaks and educates regularly on issues of preventive and lifestyle medicine, nutrition and nutritional supplements, weight management, and hypertension and has been published in numerous peer-reviewed journals.



Hans-Konrad Biesalski, M.D., Ph.D.
*University of Hohenheim,
Stuttgart, Germany*

Prof. Dr. Biesalski is currently head of the department of Biological Chemistry and Nutrition at the University of Hohenheim, a position he has held since 1995. He serves on the boards of several scientific journals, including *Nutrition*, *Nutrition and Metabolism*, the *International Journal of Vitamin and Nutrition Research*, *Aktuelle Ernährungsmedizin* and the *European Journal of Nutrition*. He is a member of the executive board of the German Society of Nutrition Medicine, the scientific advisory board of the U.S. Pharmacopeia, the FAO/WHO Joint Expert Group on nanotechnology and food, and the scientific board of the German Society for Vitamin Research, among other key organizations. Prof. Dr. Biesalski has published more than 350 scientific papers in peer-reviewed journals.



**Jeffrey Blumberg, Ph.D., F.A.C.N.,
F.A.S.N., C.N.S.**
Tufts University, Boston, USA

Dr. Blumberg is a professor in the Friedman School of Nutrition Science and Policy and also serves as the director of the Antioxidants Research Laboratory at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. His research has focused on the biochemical basis for the role of antioxidant nutrients and their dietary requirements in promoting health and preventing disease during the aging process via changes in status of oxidative stress. He has published more than 265 scientific articles and serves on the editorial boards of several scientific journals. Dr. Blumberg also participates in activities relevant to the incorporation of sound nutrition science into public health policy and has served as a member of the Surgeon General's Workshop on Health Promotion and Aging, Sports Medicine Committee of the U.S. Olympic Committee, WHO/FAO Consultation on Preparation and Use of Food-Based Dietary Guidelines, Food Advisory Committee of the U.S. FDA, and other committees.



Jean-Michel Antoine, M.D., Ph.D.
Danone Vitapole, Palaiseau, France

Dr. Jean-Michel Antoine is a physician by training, specializing in internal medicine, with a Ph.D. in Nutrition. He worked for ten years as resident and resident-in-chief in University hospitals in France before joining Danone in 1983 to create the department of Nutrition and implement clinical research on the effect of food on humans. Actively involved in ILSI Europe since its creation in 1986, he has contributed to many functional food projects. Dr. Antoine is one of the founding fathers of the European Nutrition Leadership Programme and has published more than 90 papers on nutrition and foods, many on probiotics.



John Hathcock, Ph.D.
*Council for Responsible Nutrition (CRN)
Washington, D.C., USA*

Dr. Hathcock is senior vice president, Scientific & International Affairs at the Council for Responsible Nutrition (CRN) and is responsible for scientific review and regulatory interpretation, specializing in safety and international issues. He has decades of experience in the field, having served as a professor at Iowa State University and a senior scientist at U.S. FDA before joining CRN in 1995. He has made numerous presentations on the safety of vitamins and minerals and other dietary ingredients to the U.S. Food and Nutrition Board and is the author of CRN's *Vitamin and Mineral Safety* (1997 and 2004). In addition to publishing numerous peer-reviewed scientific articles, he regularly presents at major national and international conferences on food safety and regulatory issues, analyzes and develops CRN policy positions, and speaks on international regulations and issues, including those pertaining to the Codex Alimentarius, the European Commission, and the ASEAN health supplements harmonization of maximum levels.



Wolfgang Gaissmaier, Ph.D.
*Max Planck Institute for
Human Development,
Berlin, Germany*

Dr. Wolfgang Gaissmaier is chief research scientist at the Harding Center for Risk Literacy at the Max Planck Institute for Human Development, Berlin. In 2007, he finished his dissertation on how memory shapes decision making. His current research focuses on the intersection between basic research on decision making and memory and how it can be applied to medicine, health care, politics, finance and other (risky) domains. In particular, Dr. Gaissmaier is interested in cognitive and emotional mechanisms that explain how people make decisions under uncertainty and how they deal with risks. He has applied many principles investigated by the Harding Center in further education for physicians and entrepreneurs.



Corrado Galli, Ph.D.
University of Milan, Milan, Italy

Professor Galli's professional studies and career have dynamically contributed both nationally and internationally to the promotion, continuous development and use of risk assessment using a robust scientific approach and strongly supported the use of mechanistic toxicology to improve the risk assessment process. In developing an original research program with emphasis on molecular and cellular mechanism for toxicity, including in vitro toxicology, Prof. Galli has assisted numerous students and professionals in the field by demonstrating how exposure to chemicals causes adverse effects under various situations and in certain populations. His key research area includes exposure to low levels of chemicals in combination with other chemicals and environmental factors (i.e. food additives, food allergens, pesticides, contaminants) and use of state-of-the-art molecular biology tools (genomics and proteomics) to facilitate research in the prediction of how exposure to chemicals affects the host. Prof. Galli is author of more than 200 publications, and a member of numerous national and international scientific committees.



Gareth Edwards, B.Sc., M.Sc., FRSH
*Gareth Edwards Consultancy,
Reading, United Kingdom*

Gareth Edwards has worked as an independent consultant since 2003, after 35 years in the food industry. He has considerable experience in the safety and regulatory issues associated with novel foods, and is currently an adviser to the ILSI Europe Task Force on Novel Foods and Nanotechnology and co-authored its paper on History of Safe Use. Mr. Edwards previously chaired the ILSI Europe Expert Group on the Safety Assessment of Novel Foods, which reported in 2003. He also sits on a number of food industry committees in the United Kingdom and Brussels, including the UK Food and Drink Federation's Novel Foods Group. While working at the large UK food group RHM (now Premier Foods), he was responsible for Regulatory Affairs and Nutrition, providing advice to group companies on nutrition, food legislation and regulatory issues. During RHM's development of mycoprotein, the first new food to obtain a formal approval in the UK, now sold under the brand name "Quorn," Mr. Edwards was responsible for the safety evaluation and was heavily involved in obtaining regulatory approvals.

Today's agenda

08:00 BREAKFAST

09:00

Introduction and purpose of CRN International

Mark LeDoux

Natural Alternatives International, Inc.

09:15

Keynote address—The role of science in consumer health and fair practices in food trade

Arpad Somogyi, D.V.M., Ph.D.

Consultant to the European Commission, Brussels, Belgium

Dr. Prof. Somogyi will describe the preeminent role of science in the decisions of Codex that focus on its primary aims—consumer health and fair practices in food trade. He brings a wealth of experience as chairman of the Codex Committee on Nutrition and Foods for Special Dietary Uses, the principal risk assessor for the European Commission, and other key top-level appointments.

Session 1: Scientific standards for label claims

Moderator: Peter Prock, M.D.

*European Nutraceutical Association
Basel, Switzerland*

10:00

Different types of claims—equal or different standard of evidence?

Hans-Konrad Biesalski, M.D., Ph.D.

University of Hohenheim, Stuttgart, Germany

Health claims sometimes include nutrition content and structure function statements. How should the required evidence relate to the type of claim being considered?

10:30

Clinical trials for benefits—evidence-based medicine or nutrition?

Jeffrey Blumberg, Ph.D., F.A.C.N., F.A.S.N., C.N.S.

Tufts University, Boston, USA

The differences in feasible research protocols for drug and nutrition research will be described as related to data requirements for firm conclusions. Are current research paradigms appropriate for nutrients?

11:00 BREAK

11:30

Evaluation of benefit claims and veracity of claims—what evidence is sufficient and feasible?

Jean-Michel Antoine, M.D., Ph.D.

Danone Vitapole, Palaiseau, France

How should the evidence required depend on the strength of the claim? What evidence standards are feasible for nutrients and food ingredients?

12:00

DISCUSSION—Session 1

Speakers, Moderator and Audience

12:30-14:00 LUNCH

Session 2: Risk assessment methods consistent with Codex guidelines and WTO agreements

Moderator: John Hathcock, Ph.D.

Council for Responsible Nutrition, Washington, D.C., USA

14:00

Public (mis-)perception of food risks

Wolfgang Gaissmaier, Ph.D.

Max Planck Institute for Human Development, Berlin, Germany

The data, logic, and scientific support demanded to reach public policy decisions vary greatly with the institution and issue. Rigid requirements would seem to protect consumers but can be escalated until no conclusion can be reached. How do we identify the best choices?

14:30

Establishing causality and managing uncertainty

Corrado Galli, Ph.D.

University of Milan, Milan, Italy

What evidence is needed to establish a causal relationship? How are uncertainty about cause and quantitative uncertainty managed in assuring food safety?

15:00 BREAK

15:20

History of safe use: Application in novel food safety assessment

Gareth Edwards, B.Sc., M.Sc., FRSH

Gareth Edwards Consultancy, Reading, United Kingdom

The term “history of safe use” is widely used by risk assessors and risk managers. Most conventional foods and some purified ingredients have not been subjected to toxicological study. What evidence is needed to establish a history of safe use? Should application of the concept be increased or decreased?

15:50 DISCUSSION

Speakers, Moderator and Audience

16:20 ADJOURN