

Progress of Health Claims in Europe: A New Perspective

23-February-2010

**10:00 am - 4:30 pm Workshop
4:30pm - 5:30 pm Reception**

**Crowne Plaza Hotel
BRUSSELS-EUROPA**

Workshop Highlights

- Hear directly from EFSA, Health Canada, and the U.S. FDA
- Get updated on the latest developments
- Learn about the most common fatal flaws made in submissions
- Find out how to ensure your biomarkers and outcome measures are valid



Government Representatives



Cantox is pleased to welcome the following distinguished guest speakers:

Juliane Kleiner, Ph.D, European Food Safety Authority

Dr. Juliane Kleiner has contributed to many important scientific initiatives related to food safety and nutrition in Europe. As the head of the Unit on Dietetic products, Nutrition and Allergies (NDA) at the European Food Safety Authority (EFSA), Dr. Kleiner coordinates, amongst other scientific activities, the evaluation of health claim submissions.



Paula Trumbo, Ph.D, U.S. Food and Drug Administration

Dr. Paula Trumbo is a supervisory nutritionist at the U.S. Food and Drug Administration (FDA) where she oversees the scientific review of health claims using an evidence-based review system developed by her team. This review system has been used to evaluate approximately 75 petitioned health claims in the U.S. Dr. Trumbo is recognized internationally as an expert on the scientific substantiation of health claims.



Lydia Dumais, R.D, Food Directorate, Health Canada

Ms. Lydia Dumais is Section Head, Nutrition Labelling and Claims, in the Bureau of Nutritional Sciences at Health Canada. Ms. Dumais manages the development of policies and regulations that govern the use of nutrition information and health claims on foods. She played a major role in the development and implementation of mandatory nutrition labelling, including that for *trans* fat.

Cantox Speakers



Nigel Baldwin, B.Sc, CSci, Director, Scientific & Regulatory Consulting, Europe

Mr. Nigel Baldwin heads Cantox's European Office, which is conveniently situated in the United Kingdom just outside of London. He is a recognized scientific and regulatory expert in the area of health claims and novel food ingredients and supplements. Mr. Baldwin is well-versed in European food regulations, has extensive experience with their practical implementation across the EU, and keeps abreast of recent regulatory developments.



Kathy Musa-Veloso Ph.D, Associate Director, Food & Nutrition Group

Dr. Kathy Musa-Veloso oversees a team of nutritionists and scientists who are dedicated to the conduct of scientific evidence-based systematic reviews for health claims. Her specific areas of expertise include comprehensive evaluations of scientific data to determine sufficiency for health claim substantiation; identification of data limitations and gaps; and assistance in the design, placement, and management of clinical trials. Dr. Musa-Veloso has assisted several companies with the compilation of health claim submissions to regulatory authorities in the United States, the EU, and Canada.



Andrea Wong, Ph.D, Scientific & Regulatory Consultant

Dr. Andrea Wong critically evaluates and interprets clinical and non-clinical study data used for health claim substantiation and safety assessments of food ingredients, food additives, and dietary supplements. Dr. Wong has played a key role in numerous successful petitions evaluated by regulatory authorities in the United States, EU, and Canada. She has experience in preparing documentation for health claim submissions, GRAS determinations, and novel food petitions.

Agenda: February 23, 2010

- 9:00 – 10:00 am** **Registration**
- 10:00 – 10:15 am** **Welcome and Introduction** (Mr. Nigel Baldwin)
- 10:15 – 10:45 am** **How the Regulatory Picture is Evolving - from EFSA Opinions to Regulations and Everything in Between** (Mr. Nigel Baldwin)
Topics covered will include an update on the proposed progressive adoption timetables of the positive and negative Community lists, nutrition claims and nutrient profiles and how they interface with other relevant EU legislation, such as food labelling, dietary reference values, PARNUTS, food supplements and fortified foods legislation. The objective of this presentation will be to show, with practical examples, how it is all progressing and changing the regulatory landscape for functional foods in the EU.
- 11:00 – 11:45 am** **Health Claims Reviewed Thus Far: What Have We Learned?** (Dr. Andrea Wong and Dr. Kathy Musa-Veloso)
The current status of all submitted Article 13.1, 13.5, and 14 health claims will be presented. The 300+ health claims that have been reviewed will be analysed according to food/food constituent, health outcome, and the evaluation outcome. The session will conclude with the requirements for a successful health claim application, drawing on examples from published Opinions, both favourable and unfavourable.
- 11:45 – 12:30 pm** **Lunch**
- 12:30 – 3:00 pm** **The World is Watching as Health Claims Unfold in the EU** (Dr. Juliane Kleiner, European Food Safety Authority; Dr. Paula Trumbo, U.S. Food and Drug Administration; and Ms. Lydia Dumais, Food Directorate, Health Canada)
In this session, regulatory authorities from the EU, U.S., and Canada will discuss how health claims are regulated as well as the scientific requirements for their approval. This session will put into perspective the expectations for health claim substantiation in Europe and North America. Hear about the most common fatal flaws made in health claim submissions and how to avoid them. You also will learn about potential opportunities outside of Europe.
- 3:15 – 3:45 pm** **Health Outcomes and Biomarkers – Part I** (Dr. Kathy Musa-Veloso)
Are the health outcomes you are measuring relevant to the proposed claims? In this session, you will learn how to ensure congruency between the outcome being measured and the claimed effect.
- 3:45 – 4:15 pm** **Health Outcomes and Biomarkers: Panel Discussion – Part II** (Dr. Juliane Kleiner, European Food Safety Authority; Dr. Paula Trumbo, U.S. Food and Drug Administration; and Ms. Lydia Dumais, Food Directorate, Health Canada)
For disease risk reduction claims, the regulatory authorities will discuss biomarkers that are currently considered acceptable, as well as the potential for drawing on emerging surrogate measures of disease risk.
- 4:15 – 4:30 pm** **Concluding Remarks** (Dr. Andrea Wong)
- 4:30 – 5:30 pm** **Closing Reception**

Registration Fee

The cost of our workshop is \$975.00 US (approx. 650.00 EUR) The registration fee for this workshop includes applicable taxes and workshop materials. Advance reservations will be accepted by facsimile; full payment is required in advance.**

**Cancellations received in writing on or before February 9, 2010 will be eligible for a full refund minus a \$50.00 administration fee.

No refunds will be made available after this time.

