



CRN-International: First Scientific Symposium in Geneva, Switzerland on July 3, 2010

In a world where some European and international regulators seem bent on imposing drug-like standards to justify claims for food/dietary/health supplements, leading scientists speaking at the CRN-I scientific forum identified alternative approaches to claim substantiation that are based on scientific evidence, not political protectionism. To help clarify the actual requirements, CRN-I held a scientific symposium titled *Scientific Issues Related to Codex Alimentarius Goals* to summarize and remind delegates from member governments that Codex Alimentarius Commission goals should be supported by appropriate and sufficient scientific evidence. The official goals of the Codex Alimentarius Commission are to protect consumer health through collaborative standard setting and to assure fair practices in international food trade.

For several years, the most active issues related to Codex guidelines and standards have been health claims and safety standards. Codex guidelines have been approved in these areas, but no standards have been established. It is further noteworthy that the World Trade Organization (WTO) has indicated that Codex Alimentarius standards shall be the defining area for consultation in the resolution of trade disputes in foods and related items.

The CRN-I symposium laid out the basic scientific rules within Codex, and provided discussion of examples relevant to health claims and evaluation of the safety of supplements and other food products. For speakers' presentations, abstracts and biographies see the program materials on the CRN-I website: www.crn-i.ch.

The keynote address was given by Professor Arpad Somogyi. It covered a wide range of Codex rules, scientific guidelines and standards, and application of Codex decisions as templates for many member governments and as the basis for decisions by the WTO if official complaints should be filed. He noted that despite much incremental progress over many years, misunderstandings and irregularities that hamper harmonization of food regulations and clearly impede food trade still persist. He emphasized the relationship of the European Union's regulations and Codex guidelines and standards and noted that Europe depends heavily on the precautionary principle in setting its own regulatory framework. He acknowledged the considerable momentum toward application of risk-benefit analysis to foods, but noted that risks and benefits are officially evaluated separately at this time.

Prof. Somogyi stated that risk assessment is a science but risk management under Codex procedures is entitled to consider "other legitimate factors" such as societal values, traditional uses and economic impacts. He acknowledged that there are no exact guidelines on whether the other factors are legitimate.

Session 1 focused on scientific standards for label claims. Professor Hans-Konrad Biesalski concluded that different types of label claims may logically require similar or different types of

CRN-International: First Scientific Symposium in Geneva, Switzerland on July 3, 2010

scientific support. He noted that epidemiological associations are helpful but do not always draw the right conclusions of cause and effect. He emphasized the differences in nutrition and medicine (e.g., disease can be caused by deficiency of a nutrient, but disease is not caused by deficiency of a drug).

Professor Jeffrey Blumberg addressed the needed contrast between evidence-based nutrition and the commonly applied procedures in evidence-based medicine. He emphasized that good comparative evidence shows that high quality observational (epidemiological) data give very similar quantitative answers to those from randomized controlled trials (RCT) across a broad section of interesting subject matters in the categories overseen by Codex.

Dr. Jean-Michel Antoine, of Danone, described the loss of information that occurs when authoritative scientific committees take excessively narrow approaches to decisions by requiring clear demonstration of a cause-and-effect relationship between a food product and a health effect, thereby excluding all evidence except that from RCTs. He recalled many historic examples of correct conclusions having been reached from extremely meager data (e.g., liver to cure night-blindness and limes to prevent or cure scurvy).

Session 2 addressed risk assessment methods that are consistent with Codex Guidelines and WTO agreements. Dr. Wolfgang Gaissmaier stated that public or even professional risk literacy is often low, and risk perception, or commonly mis-perception, may have little relationship to the available evidence. He noted that the search for certainty is illusionary, and excessive adherence to the precautionary principle may create greater risks.

Professor Corrado Galli of the University of Milan described the procedures in risk assessment that are used to provide reasonable evidence of causality and to manage uncertainty. He described causality in both statistical and biological terms. For example, some chemicals have specific effects in only one experimental species or in one sex but not the other, thereby creating considerable uncertainty about a cause-and-effect relationship or tolerable intake for humans.

Mr. Gareth Edwards described the extensive use of the concept and term “history of safe use” without any scientific or regulatory definition or standardized criteria. He listed many factors that must be considered in judging whether a food or ingredient has a history of safe use. He noted that some expert groups and regulatory bodies have published descriptions of the issues in decision-making related to a possible history of safe use for a food, but a definitive answer is not foreseeable.

CRN-I Staff Summary: This first scientific symposium organized by CRN-International described the obligation of Codex to use science as the primary factor in its decisions, and described in detail some of the issues and examples in decisions on health claims and safety evaluations. In addition to this general summary, the speakers have agreed to produce a scientific and referenced manuscript for publication in a peer-reviewed journal with all speakers contributing to the authorship under an initiative by CRN-I.