



The Academy of Toxicological Sciences

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May 8, 2015

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue.SW
Washington, DC 20201

The Honorable Thomas J. Vilsack
Secretary of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

The Academy of Toxicological Sciences (ATS) is a non-profit professional organization recognized as the leading international organization that certifies toxicologists by peer review of education, professional experience, leadership, demonstrated achievement and scientific expertise. In addition to certifying toxicologists, the Academy also imposes a code of ethics that assures that ATS Fellows who participate in research, testing, or determinations of safety, risk and risk-benefit assessments, and who make regulatory decisions that impact public health and the environment, exercise sound scientific judgment that is free of bias and based exclusively on the scientific evidence. Fellows of the Academy are generally engaged in research leading to an understanding of the processes involved in biological responses occurring from exposure to chemical, biological, or physical agents, and the evaluation and integrated interpretation of the human health implications of data describing toxic effects occurring in humans or experimental animals. The research conducted by Fellows of the ATS generally culminates in the application of toxicological data to the development of health and environmental safety standards protective of human health. The Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC) has been brought to the attention of the ATS Board of Directors for discussion, and it is within this context that we raise concerns with the report with particular reference to Chapter 5, Food Sustainability and Safety, and questions 5-7 on pages 5 & 6.

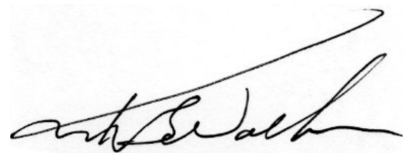
As stated in the letter of submission to the report, the charge to the DGAC was to examine “where sufficient new scientific evidence is likely to be available that may inform revisions to current guidance or suggest new guidance”. As toxicologists, we interpret this charge to include the totality of scientific evidence including human, non-human experimental animal, *in vitro*, and *in silico* scientific evidence. We object to the fact that in their assessment of food safety, the 2015 DGAC explicitly reviewed only human epidemiology studies and ignored the wealth of new scientific evidence from experimental sources in their safety assessment determinations. A robust assessment of safety includes consideration of all available evidence in order to not only establish exposure:human health effect associations, but to also document the strength and consistency of the evidence and to demonstrate exposure-response gradients, consistence in temporality, biological plausibility, and coherence between epidemiological and experimental observations. According to these Bradford Hill criteria, conclusion of causation cannot be established without considering all of the available evidence, including non-human, *in vitro* and *in silico*. Thus, although epidemiological studies are highly valuable in demonstrating associations and concordance with regard to food safety determinations, by themselves they are not sufficient to establish evidence-based public policy, especially in cases where abundant non-human data are available. This point of concern cannot be overstated, especially in light of the following foundational statements by the 2015 DGAC:

- “the importance and key function of the U.S. dietary Guidelines in forming the basis of Federal nutrition policy and programs and in providing a critical framework for local, state, and national health promotion and disease prevention strategies”
- “the influence of the Guidelines in shaping public policies, standards, and initiatives across the public and private sectors, including public health and health care, education, business, and the food industry and retailers.”

Moreover, the approach taken by the DGAC – e.g., reviewing only human epidemiology studies – limits their evaluation of the components of our nation’s food supply to those with existing human epidemiology studies. The public confidence in the safety of our food supply warrants a consideration of all components – to the extent possible – which can only be accomplished by considering the weight of all the scientific evidence.

In conclusion, a review of new scientific evidence needed to gain a robust, comprehensive, and biologically-based opinion to inform revisions to current guidance or suggest new guidance necessarily requires consideration of the totality of evidence, including both human and non-human experimental data. To exclude one or more sources of evidence falls vastly short of a sound scientific approach. As an international organization of professional toxicologists recognized for their distinction in the discipline, the ATS is a resource for the departments of Health and Human Services and Agriculture. We believe that within the ATS, you will find the professional expertise needed to accomplish this broad advisory committee charge to evaluate and integrate the totality of scientific evidence impacting human food safety. As the current leaders of the ATS, we offer our support in identifying highly qualified toxicologists who have the expertise to assist in achieving this charge, and who would be happy to assist advisory committees such as the DGAC.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kendall B. Wallace". The signature is fluid and cursive, with a prominent initial "K" and "W".

Kendall B. Wallace, Ph.D., DABT, ATS
President

A handwritten signature in black ink, appearing to read "Michael P. Holsapple". The signature is cursive and clearly legible.

Michael P. Holsapple, Ph.D., ATS
Vice- President