ODS Update: Use of Reference Materials in Dietary Supplement Research

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Strengthening Knowledge and Understanding of Dietary Supplements

March 19, 2024

Recent Developments in Dietary Supplement Science



A critical step in evaluating the safety and efficacy of dietary supplements is their thorough characterization using valid analytical methods. In this issue of *ODS Update: Recent Developments in Dietary Supplement Science*, we highlight three recent publications that demonstrate the use of reference materials (RMs) as important tools in the field of dietary supplement research.

The publications include a review of vitamin D RMs co-authored by Adam Kuszak, Ph.D., Director of the ODS Analytical Methods and Reference Materials Program, and Stephen Wise, Ph.D., an ICF scientific consultant who supports ODS.

Black Cohosh: The chemical composition of plant-based dietary supplement ingredients, such as black cohosh (*Actaea racemosa*), can vary considerably due to differences in plant genetics, growing environment, harvest conditions, and processing. This inherent variability might affect biological activity and also means that any one botanical RM does not represent the full spectrum of chemical compositions that may be observed for that species. A March 2024 publication by Harnly and Upton in the *Journal of AOAC*International used non-targeted analytical methods to examine the chemical profile of dozens of botanical RMs representing seven different *Actaea* species as well as commercial black cohosh roots and dietary supplements. RMs for black cohosh from the National Institute of Standards and Technology (NIST) and samples of *Panax* and *Echinacea* species were also analyzed. Statistical modeling of chemical composition discriminated between genera and between *Actaea* species. Chemical variation among the authentic *Actaea racemosa* samples was demonstrated, and a distinct group of highly conserved chemical variables was identified. In addition, the study found technical factors that can affect non-targeted chemical analyses, such as data processing approaches and unexpected differences between technical repeats. This study highlights the importance of understanding the chemical complexity of botanicals in assessments of authenticity and their potential effects on health.

Folic Acid: Analytical chemistry methods intended to characterize the identity, content, and purity of dietary supplement ingredients need to be accurate and reliable. This is particularly important when measuring vitamins or minerals with known health benefits such as folic acid. Certified reference materials (CRMs) with precisely known amounts of specific nutrients are used as controls to validate method performance. In the March 2024 issue of the *Journal of AOAC International*, Lusi and colleagues describe a validation of a novel method for measuring folic acid in capsule, tablet, powdered, chewable gel, and gummy dietary supplements. Using a NIST multivitamin tablet CRM with known folic acid content as a control, the researchers demonstrated the high accuracy of the method across this wide range of supplement formulations.

This method expands the capability of researchers to reliably measure and compare folic acid content in all of the most commonly consumed dietary supplement formulations.

Vitamin D: Different analytical chemistry methods can be employed by clinical laboratories to assess nutrient status. For example, ligand binding immunoassays or liquid chromatography with tandem mass spectrometry methods are commonly used to measure vitamin D status. These methods can have differing selectivity for measuring the distinct metabolites of vitamin D. A January 2024 review by Wise and colleagues published in *Analytical and Bioanalytical Chemistry* describes ODS and NIST efforts to develop clinical CRMs for vitamin D metabolites and their effects on the accuracy and comparability of vitamin D status measurements. Seven serum matrix CRMs and three calibration solution CRMs currently available from NIST provide control values for four major vitamin D metabolites. The authors describe how the use of vitamin D metabolite CRMs for method validation and measurement performance assessments, as reported in over 90 publications, has improved clinical measurements to assess vitamin D status over the past 15 years. These CRMs also contributed to efforts to retrospectively standardize serum vitamin D measurements from national and international population surveys. The authors conclude by considering measurement needs for the next generation of vitamin D CRMs, such as whether clinically relevant concentrations of the 3-epi-25(OH)D3 or 24,25(OH)2D3 metabolites are adequately represented, or whether future CRMs should be developed as a suite spanning a range of vitamin D concentrations.

Upcoming ODS Seminars (virtual meetings)



Wednesday, April 10, 2024, 11:00 a.m. (ET)

Vitamin D, the Microbiota and Immune Regulation

Margherita T. Cantorna, Ph.D.—Pennsylvania State College of Agricultural Sciences,
University Park, PA

Wednesday, May 22, 2024, 11:00 a.m. (ET)

Effects of Soluble Corn Fiber on Bone Metabolism in Children

Cristina Palacios, M.S., Ph.D.—Florida International University, Miami, FL







About ODS

The Office of Dietary Supplements (ODS) is part of the National Institutes of Health (NIH), the nation's medical research agency—supporting scientific studies that turn discovery into health.

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