

# Establishing Standard Method Performance Requirements for Infant and Adult Nutritionals

Infant formulas—one of the most regulated foods in the world—has advanced enormously over the years as a result of numerous nutritional developments.

Since the 1970s and 1980s, analytical technologies have also advanced. Given the rigorous performance demands expected of these methods and an ever-burgeoning array of complex matrices, there are many gaps with the current *Official Methods<sup>SM</sup>* and other recognized international methods for infant and adult nutritionals. Exacerbating matters, recent changes to prominent regulations and standards for infant formula, particularly in the European Union and Codex Alimentarius, have stipulated tighter ranges for most nutrients. Because of the vulnerable populations these products serve, they are extensively tested by both manufacturers and regulators to ensure safety and compliance, which at times has resulted in time- and resource-consuming regulatory disputes. ►



To help solve these pressing issues with science-based solutions through consensus of international experts, AOAC on April 26, 2010, successfully reached agreement on a contract with the International Formula Council (IFC), an association of manufacturers and marketers of formulated nutrition products (e.g., infant formulas and adult nutritionals), to establish voluntary consensus standard method performance requirements (SMPRs) for infant and adult nutritionals.

"There is a strong need to update official analytical standards to verify compliance of infant/adult nutritionals," said **Erik Konings** of Nestlé. "It is of utmost importance that these standards are accepted and applied worldwide to ensure fair trade. AOAC INTERNATIONAL can provide the scientific tools to accomplish this and offers a forum to bring together all interested stakeholders worldwide to reach consensus on the requirements of these future standards."

The contract is based on support IFC has received from various leading manufacturers and which now constitute funding partners.

"We're very pleased that Abbott Nutrition, Fonterra, Mead Johnson Nutrition, Nestlé, and Danone have committed to funding this important project," said **Mardi Mountford**, executive vice president of IFC.

"We're now looking to AOAC to draw on international experts to develop SMPRs for key nutrients in infant and adult nutritionals."



*Executive Director James Bradford, with Anita Mishra (executive for scientific business development), makes it official with the signing of the International Formula Council contract on April 26, 2010.*

The high-profile initiative could impact import/export and international regulations. "This is a big deal and calls for full engagement of governments, industry, and AOAC and its members to evaluate and validate new and modern methods to analyze the formulations," said **James Bradford**, AOAC executive director. "Just as importantly, we want to engage key international stakeholders, including governments and major laboratories, so these new methods become the consensus reference methods for the entire industry around the world. It truly will be a global project."

#### **Harmonized Methods Needed for Dispute Resolution**

Currently, a variety of sources of methodology may be used for the analysis of nutrients in infant formula and adult nutritionals, ranging from different sets of compendial methods (e.g., AOAC, CEN, GB, BIS, ISO, etc.) to proprietary methods. Very few of these have been validated and collaboratively studied across the broad range of

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*"This is a high-profile initiative with great impact that calls for full engagement of AOAC, its members, and international stakeholders," said James Bradford, with AOAC staff (front l to r: Joyce Shumacher, James Bradford, and Anita Mishra; back l to r: Krystyna McIver, Bob Rathbone, May Jones, Alicia Meiklejohn, Delia Boyd, Deborah McKenzie, Tien Milor, Saliha Argubie, and Angelita Lotinsky).*

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matrices found in the market. The biggest challenge is when disputes arise about methods. Global recognition and acceptance of methods is urgently needed to resolve these disputes.

Disputes involving methodology have been commonplace in the industry, declared **Dan Schmitz** of Abbott Nutrition, a Division of Abbott Laboratories, a global, health-care company which manufactures nutritional as well as pharmaceutical products.

Schmitz explained that the accuracy and precision of these methods should be paramount. These are the methods that would be used for resolving trade and regulatory updates as well as validating other routine methods. Schmitz added that these “dispute resolution standards” are urgently needed.

There is not currently a rigorous set of definitive reference methods that have been specifically validated and collaboratively studied against all these product types and which could be invoked to quickly resolve disputes. Both AOAC and CEN have compendial methods for infant formula. In fact, Codex has recently drawn from both standards bodies to compile a collection of Type II methods (indicated for dispute resolution) for analysis of infant formula. Unfortunately, there are a number of deficiencies with many of these recommended methods that would likely

further complicate dispute resolution.

Because of the wide variety of methodologies being used around the world for these types of products, industry is realizing that all stakeholders, public and private, would benefit if robust international consensus methods for purposes of dispute resolution would be collectively established. If this project were to enlist all key stakeholders from major private and public enterprises (including major manufacturers and government representatives from the United States, Canada, European Union, Middle East, South America, Australia, Asia, and Africa), recognition as international consensus standards and adoption by Codex could be attainable.

## A Global Initiative in the Making

Previously, some 50 key stakeholders from government and industry met at AOAC's Annual Meeting in September 2008 in Dallas, Texas, USA, to discuss the need for new and modernized methods for infant and adult nutritionals. Stakeholders from the infant formula community recommended several working groups to cover nutrient classes for which analytical methods are needed.

The effort continued on June 26, 2009, when AOAC INTERNATIONAL held a session on infant formula as part of the President's Technology

Conference. Stakeholders recommended criteria for ingredient ranking, matrices, and nutrients. In addition, recommendations for topic-specific working groups were proposed.

## SMPRs to Address Critical Needs Through Consensus

Analysis of nutrients in complex matrices like infant formula and adult nutritionals presents significant analytical challenges, particularly since many of the micronutrients reside in the low part-per-billion to part-per-million levels.

With the agreement now signed, AOAC will identify 40–50 key international stakeholders, including AOAC experts, with 12–15 as voting members, who will first review the criteria for ranking nutrients earlier identified at the June 2009 meeting, review and update, if needed, the list of priority nutrients generated at that meeting, agree on fitness-for-purpose statements [overall goal/objective of method(s)], and consider the recommendation in forming working groups, their membership, and, of utmost importance, obtain global buy-in from the broader community.

At the June 2009 meeting, participants recommended the formation of five topic-specific working groups consisting of water-soluble vitamins, fat-soluble vitamins, minerals (elements), proximates and related analytes (protein, fat, carbohydrates, amino acids, fiber), and other nutrients (nucleotides, inositol, choline, etc.). Because of the certainty that multiple nutrients and product matrices will be covered within one working group, it is anticipated that each working group may recommend multiple SMPRs. Their goal will be to define SMPRs based on the fitness-for-purpose statement articulated by the larger stakeholders group.

For each SMPR, working groups will compare available methods pertaining to the nutrient(s) with respect to detected analytes, quantitated analytes, analytical range, accuracy, precision,

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LODs, instrument requirements, sample preparation, sample and solution stability, reference materials, and potential interferences, e.g., contaminants.

The SMPRs will also include applicable matrices, including liquid and powder finished products, representing infant and adult nutritionals (milk-based, whey dominant, soy-based), as well as selected macro-ingredient sample matrices which may contribute to finished product label claim targets (skim milk powder, whey protein, etc.).

Integral to the program will also be a suitable standard reference material and a proficiency and training program to eventually support all the new standards.

After SMPRs are recommended by working groups and approved by the larger stakeholder panel, an expert review panel (ERP) will review available methods and recommend an analytical method(s) to be considered for a Phase II single-laboratory validation (SLV) study. The candidate method(s) may be, but is not limited to, one of the following: (1) Codex Type II, (2) compendial, (3) infant formula manufacturer, or (4) a new procedure that incorporates best aspects of existing methods. It is understood that some form of method

optimization may be needed for the latter case prior to a Phase II SLV study.

The deliverables of this program are to specifically develop SMPRs for at least 20 nutrients in infant formula and adult nutritionals deemed to be the most important by manufacturers and regulators ("priority nutrients"). This part of the process is referred to as the 'standards development' phase by AOAC and represents Phase I of the collaborative effort. In addition to the SMPRs, Phase I will provide recommendations for methods to proceed into Phase II of this multi-year program. The ultimate goal is to translate these SMPRs into consensus reference methods that would address deficiencies within the current Codex Type II methods and could be used by industry in cases of dispute resolution for infant and adult nutritionals testing. This part of the process is referred to

as the 'conformity assessment' phase in AOAC's *Official Methods*<sup>SM</sup> Program and represents Phase II, a separately funded portion of the collaborative effort. These internationally developed consensus methods would then be positioned to be adopted as the new Codex Type II dispute resolution methods.

### Conclusion

Industry needs rigorous, international, consensus, reference methods to resolve disputes. Mechanisms must be put in place so that methods meeting SMPRs are adopted for dispute resolution by the international community. Participation of international stakeholders will ensure that new methods become the consensus reference methods for industry worldwide.

This is not a small endeavor: infant formula nutrition and methodology have advanced, formulas change, and new formulas enter the market. Adult nutritional preparations further compound the demands placed upon these methods. Planning for a stakeholders meeting is underway.

"This is not a project a single company could do alone; many working together, with AOAC, can achieve it," Bradford said.

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