

Industry Perspective on Method Harmonization

Modernization of Global Standards for Methods of Analysis Intended for Infant Formula

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Infant formula, one of the most regulated foods in the world, has advanced in complexity over the years, due to numerous innovation driven advancements. To keep pace, and ensure product safety and quality, analytical technologies have advanced as well. Given the rigorous performance demands expected of these methods, and the ever-growing array of complex matrices, there are many potential gaps that exist in current *Official Methods*SM and other recognized international methods for infant and adult nutritionals. Food safety concerns, particularly for infants, have driven extensive testing by both manufacturers and regulators, with the potential to result in time- and resource-consuming regulatory disputes. To mitigate these risks, AOAC INTERNATIONAL, under the direction of the Infant Nutrition Council of America (INCA), a trade association of manufacturers and marketers of formulated nutritional products, agreed to establish voluntary consensus standard method performance requirements (SMPRs) through the Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN). The goal being, to identify and publish globally recognized, fit-for-purpose standard methods. Prior to publication, these methods are subjected to rigorous scientific scrutiny by global experts and stakeholders, providing the highest confidence in results, and offering a means for rapid resolution of method disputes and helping to ensure fair trade. In this presentation, you will be given an overview of Abbott Nutrition, who we are, what we manufacture, and why fit-for-purpose, globally harmonized standard methods are so important, not only for our industry, but government regulatory bodies and consumers across the globe. The role of standard setting Organizations like AOAC INTERNATIONAL and their importance will be addressed, along with other public-private partnerships as they relate to the overall process.