Regulatory Insights on Harmonization of Food Testing Protocols

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Agenda

- Food – A Changing Landscape
- Food Safety Hazards
- Challenges in Food Analysis – India Perspective
- Need for Method Harmonization
- India Section of AOAC INTERNATIONAL
- Vitamin B12 Collaborative Study
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Food – A Changing Landscape

- Food Industry - one of the most powerful industries, worldwide.
- Indian Food Industry plays important role in domestic as well as global economy.
- The food processing industry is one of the largest industries in India and is ranked fifth in terms of production, consumption, export and expected growth.
- Food is grown, processed, & transported in a global manner.
- Advances in food supply chain through increased speed of transport, enhanced food preservation techniques and improved communication and distribution worldwide.
Food – A Changing Landscape

Typical consumer demand trends:
• Safe foods – ingredients not harmful to health
• Healthy foods
• Product sensory quality
• Ease of access
• Take-home meals
• Fresh or minimally processed products
• Lifestyle-complementary foods
• Increased consumption of fruits and vegetables
• Novel food combinations
• One-dish-meal foods
  Fast and impulse-purchase foods
• Foods that help consumers keep in shape
• Foods with high specific cultural value
Food Safety Hazards

- Adulterants / Food Frauds
- Allergens
- Contaminants produced via manufacturing processes - Acrylamide and 3-MCPD
- Counterfeit products - Spurious liquor
- Food Contact Material
- Foreign bodies / filth
- Heavy metals
- Naturally occurring toxins inherently present in Foods
- Pathogenic microorganisms
- Pesticide residue contamination
- Un-permitted Food additives
- Veterinary Drug Residues
Challenges in Food Analysis: India Perspective

• Rapidly changing technologies in food production and processing is adding further complexity and challenge to the already convoluted food matrix. Formulations continue to evolve and further challenge the ability to reliably and accurately test these products.

• Lack of adequate trained manpower.

• Inadequate Infrastructure Facilities – need to bridge the technology gaps in instrumentation.

• Method disparity - need for greater method harmonization among labs and also among specifying agencies.
Need for Method Harmonization

• Old or out of date methods create inaccurate results and false positives.
• Inaccurate results necessitate retesting and confirmatory testing – increasing costs and delays.
• Disputes arise over “fitness for use” with methods.
• Complexity of methods, products and protocols make disputes difficult to resolve.
• Incorrect testing causes loss of confidence and business disruption.
• Need for unambiguous and appropriately validated reference methods suitable for dispute resolution to ensure quality and safety and also for trade purposes.
AOAC INTERNATIONAL is a globally recognized, independent, third party, not-for-profit association and voluntary consensus based standards developing organization founded in 1884.

To attain the vision of “worldwide confidence in analytical results,” AOAC serves its stakeholders by providing the tools and processes necessary to collaborate and through voluntary consensus building, develop fit-for-purpose methods and services for ensuring quality measurements.

Since its inception in 2011 India Section of AOAC INTERNATIONAL has been a conduit between AOAC INTERNATIONAL and the Indian Analytical Community.
Mission: India Section of AOAC INTERNATIONAL

- Understanding the Indian analytical needs and challenges and working towards their upgradation.

- Providing the analytical fraternity with increased knowledge on current topics of development and technical skill enhancement through seminars, forums and workshops.

- To provide a platform to network with the analytically inclined and bring together people who work behind the scenes to enhance quality in manufacturing units and those who are involved in R&D to bring about new products in the country.
Mission: India Section of AOAC INTERNATIONAL

- Developing corporative relationships and professional networking with
  - food testing laboratories
  - educational institutes
  - government bodies
  - industries

and encourage their participation in the India Section of AOAC International for analytical method development/validation and skill enhancement.

- Upgrading India’s analytical abilities will help us put Indian laboratories on the global map for technical expertise. It will also help in identifying gaps and plan steps for upgradation.
Collaborative Study in Infant Formula and Adult Nutritionals

• Before a given method can be approved as an AOAC official method, it is generally tested in 8-10 laboratories, which is known as "Collaborative Study“

• Imparts confidence on test results

• Improves international acceptability of test results

• One of the prime objective of India Section of AOAC International is to apply the global methods (e.g. AOAC methods) for priority nutrients to Indian foods/food product matrices of Infant Formula and Adult Nutritionals.

• Purpose is to build a scientific justification to persuade FSSAI/BIS and other national regulatory bodies to replace the current conventional methodologies with these highly accurate ones as Dispute Resolution Methods.
Vitamin B12 – Collaborative Study

Why Single Lab Validation?

- Since the Indian foods/food product matrices of Infant Formula and Adult Nutritionals does not fall under the scope of current AOAC 2011.10, Single Lab Validation (SLV) is needed prior to Multi-Laboratory Testing (MLT).

Why Vitamin B12

- Traditional microbiological methods for vitamin B12 are not precise and accurate enough to meet the nutrient specification/claim requirements of infant, pediatric, and adult nutritionals.

Vitamin B12 – Collaborative Study

International Methods

- AOAC 952.20 Vitamin B12 in vitamin preparations - Microbiological assay
- AOAC 986.23 Vitamin B12 in milk-based infant formula - Microbiological assay
- AOAC 2011.08 and 2011.09- HPLC with immunoaffinity extraction (1st action)
- AOAC 2011.16 Determination of vitamin B12 in infant formula and adult nutritionals by surface plasmon resonance: (test kit method) – Biacore technology (1st action)
Vitamin B12 – Collaborative Study

International Methods

• AOAC 2011.10 Determination of vitamin B12 in infant formula and adult nutritionals by HPLC: (Final Action) – HPLC with SPE clean-up (column switching).

• ISO 20634:2015 - Infant formula and adult nutritionals - Determination of vitamin B12 by reversed phase high performance liquid chromatography (RP-HPLC) [is equivalent to the AOAC Official Method 2011.10].
Collaborative Studies - Roadmap

Next One Year:

- Pantothenic Acid (LC-MS/MS)
- Fatty Acids (GC)

Down the Road (order of priority to be finalized):

- Inositol
- Iodine
- Vitamin A
- Vitamin E
- Nucleotides
- Ultra Trace Minerals
Summary

• Food safety scientists and industry stakeholders face a mounting challenge to keep up with the scale and scope of the quality requirements

• Stakeholders should understand the viewpoints and constraints of each other in the food system

• It is important to integrate the ability of Academia, Government and Industry to work together to improve food safety

• Food safety standards are not harmonized

• In the absence of harmonization, better national & international collaborations are needed to achieve the desired goal.
Way Forward

- Adoption of internationally accepted analytical methods (directly or through ISO or Codex)
- Standardization bodies need to collaborate to enhance harmonization and avoiding duplication of work.
- Promote public-private sector collaborations
- Upgrade laboratory infrastructure
  - Modernize Laboratories
  - Set-up/increase network of Referral Labs.
  - Training of Food Inspectors and Lab. Analysts
Thank You

COMING TOGETHER IS A BEGINNING; KEEPING TOGETHER IS PROGRESS; WORKING TOGETHER IS SUCCESS.
HENRY FORD