Food labs in a crystal ball
Industry and an SDO’s perspective

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President AOAC INTRNATIONAL

2015-05-21

Nestlé Research
Good Food, Good Life
• Nestlé at a glance

• Food Labs in a crystal ball, industry perspective
  – Role of physico-chemical alternative methods in quality and safety testing
  – Need for harmonized international guidelines for the calibration, validation, and monitoring of all types of alternative methods

• Food Labs in a crystal ball, SDO’s perspective
  – Need for globally harmonized reference standards for (official) control purposes
  – Stakeholders including SDO’s collaborate. AOAC SPIFAN as example.
  – Opportunities for AOAC Europe section
Nestlé at a glance

CHF 91.6 billion in sales in 2014

339,000 employees in over 150 countries

447 factories in 86 countries

Over 2,000 brands

1 billion Nestlé products sold every day
Nestlé in Figures

**Turnover 2014:** CHF 91.6 billion

- >330,000 employees in 150 countries
- >440 factories in 86 countries
- >2,000 brands

**Nutrition & Healthcare** 11%

**Pet Care** 12%

**Confectionery** 11%

**Nestlé Waters** 8%

**Milk Products & Ice Cream** 20%

**Prep. Dishes & Cooking aids** 16%

**Powdered & Liquid Beverages** 22%

OVER 1 BILLION PRODUCTS SOLD EVERY DAY
To ensure full product safety & quality for consumers, Nestlé generates millions of analytical data along the year.

Most of these analyses are performed at factory level using frequently alternative analytical methods.
What is an Alternative Method?

**Definition:** Physico-chemical quantitative alternative method is defined as an indirect method that replaces an established reference method, against which it is calibrated, validated and monitored.

Alternative Method

Reference Methods

- **Moisture:** Karl Fisher; Oven method
- **Fat:** Mojonnier - Röse-Gottlieb
- **Protein:** Total Nitrogen by Kjeldahl

Near Infrared spectroscopy FT-IR
Alternative methods are used in routine along the food production process stream.

Four types of Alternative Method are identified:

<table>
<thead>
<tr>
<th>Alternative method type</th>
<th>Time (mins)</th>
<th>Operator</th>
<th>In factory process area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off line</td>
<td>&gt; 60</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>At line</td>
<td>~15-30</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>On line</td>
<td>~ 5</td>
<td>✗</td>
<td>✓</td>
</tr>
<tr>
<td>In line</td>
<td>Real time</td>
<td>✗</td>
<td>✓</td>
</tr>
</tbody>
</table>
Alternative methods should be fast and cost-effective involving analytical instruments able to analyse samples from raw material to finished product.

The use of Alternative Methods offers to the factories many advantages:

- Reduce measurement time
- Reduce use/cost of chemicals
- Be more simple and require less training
- Be used close to the production line or on-line (towards a real-time analysis)
- Require simple and fast sample preparation
- Reduce time of product release
- Reduce warehouse cost

Hundreds of instruments are currently implemented in the 447 Nestlé factories
<table>
<thead>
<tr>
<th>Technology</th>
<th>Analyte</th>
<th>Off-line/At-line</th>
<th>On-line/In-line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near Infrared spectroscopy (NIR/FT-IR)</td>
<td>Moisture, fat/oil, proteins, carbohydrates, vitamins, identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-Ray Fluorescence spectroscopy (XRF)</td>
<td>Minerals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuclear Magnetic Resonance spectroscopy (NMR)</td>
<td>Fat, solid fat content</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refractometry</td>
<td>Solid none fat, sugar, dry matter, cocoa butter, total solids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermo-balance halogen/infrared</td>
<td>Moisture, dry matter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capacitance Microwave Resonance</td>
<td>Moisture</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Along the production line Alternative Analytical Methods can monitor step by step the production until the release of finished product.

→ It contributes to:

- Check quickly the composition of raw material
- Master the quality of product along the production line
- Achieve consistency of finished products
- Release rapidly finished products based on demanding quality and safety criteria
- Reduce wasting time and the amount of non-compliant products
The use of Alternative Methods highly contributes to ensure the high quality level of finished products proposed to consumers by the food industry.

Achieving product Safety, Consistency and Compliance lead to consumer satisfaction.
How to validate and use Alternative Methods correctly?

Is there an international harmonized guideline?
Currently there are numerous official documents dedicated to the specific aspects / matrices / technologies of Alternative Method management. The ideal situation would be to have an official and internationally recognized harmonized guideline for the calibration, validation and monitoring of all types of alternative methods.
For Nestlé, an internal guideline for the implementation, validation and use of Alternative Methods ensures the delivery of reliable analytical results over the time.
Based on the Good Laboratory Practices (ISO 17025) and several key reference standards and guidelines, the Nestlé internal guideline includes 4 key steps of achievement:

- **Requirements**
  - Scope & Target Performance of the method (precision, LOQ)
  - Instrument qualification (Design, installation, operational, performance)
  - Reference method(s)
  - Sampling & samples handling

- **Calibration**
  - Model building (mainly linear regression)
  - Model acceptance

- **Validation**
  - Trueness analysis
  - Precision analysis
  - Measurement uncertainty & Fitness-for-purpose vs target performance

- **ICP Monitoring**
  - Internal control plan
  - Monitoring of the instrument and the calibration model

Against a Reference Method established beforehand
What is expected for promoting and acceptance of the use of alternative methods?

- **Enhance and harmonize the use of at-line alternative methods in routine for checking the raw material and release the finished products**
- **Promote the implementation of on-line/in-line methods to monitor the key process parameters in real time (Process Analytical Technology)**
- **Validate the implementation of emerging new technologies applied as alternative analytical methods (i.e. RF, MW, Terahertz, etc.)**
- **Develop an international official guideline for the use of all types of alternative methods**
- **Engage the Authorities to accept alternative methods for the release of products**
Food labs in a crystal ball

SDO’s perspective

2015-05-21
AOAC Europe section meeting, May 21-22, Stockholm, Sweden
Needs in global trade

• With globalization need for harmonized standards to meet demands of international trade, ensuring safety, quality and fair trade

• Harmonized standards
  – Validation protocols
Third Party validation schemes for microbiology

• No globally harmonized validation protocol

• In Europe, according to regulation 2073/2005, ISO 16140 approach is cited and validation against ISO reference methods is mandatory.

• Each of these protocols and organizations are validating alternative methods against different reference methods (AOAC, ISO or NMKL methods).
Needs in global trade

• With globalization need for harmonized standards to meet demands of international trade, ensuring safety, quality and fair trade
• Harmonized standards
  – Validation protocols
  – Methods used for Official control purposes
• Collaboration between regulatory bodies, standard development organizations, industry, and reference/commercial laboratories
• AOAC acts as an independent third party between private and public stakeholders
• Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) example how AOAC removes barriers to collaborate
ISO and AOAC Sign Cooperation Agreement for Joint Development and Approval of Common Standards

FOR IMMEDIATE RELEASE

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ISO and AOAC Sign Cooperation Agreement for Joint Development and Approval of Common Standards

Both AOAC and ISO are already internationally recognized and respected, and the collaboration will reinforce the global reputation of both organizations. Under the new agreement, ISO and AOAC can participate in each other's work to jointly develop and approve standards. Initial priorities will focus on nutritionals for the benefit of all stakeholders, including consumers.
SPIFAN is a project governed by AOAC INTERNATIONAL and supported by Infant Formula Industry aiming to establish recognized International Reference Standards for infant and adult nutritionals.
Communicates on behalf of all manufacturers with AOAC

Governance
Manufacturers
Authorities, technology providers, private laboratories, associations, academia

Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN)
Joint development of Standards
Why is there a need for new Standards for analytical methods?

- Heavily regulated
- Official Methods for limited number of parameters, stakeholders using their ‘own’ methods
- Modern products with analytical challenges
- Existing Standards mostly not validated for IF, HCN and more complex modern products
AOAC Standards Development to Final Action Status

Advisory Panel

Stakeholder Panel

Established SMPRs

Call for Methods Call for Experts (if needed)

ERP Review of Methods and First Action status

ERP Review of First Action Methods & any recommendations for Final Action Status/Repeal/etc...

OMB review & rendered decisions on Final Action status/Repeal

Working Groups

*SMPR= Standard Method Performance Requirements
Standard Development process

- Stakeholder Panel.
- Standard Method Performance Requirements.
- Call for methods.
- AOAC First/Final action Official Method designation by Expert Review Panel.
Process for Acceptance and Adoption of SPIFAN/AOAC OMs by CODEX Alimentarius

AOAC Official Methods → ISO-IDF Standards → Submission to CCNFSDU → Endorsement by CCMAS → Endorsement by CODEX

Timeline
5 years

CCNFSDU: Codex Committee on Nutrition and Foods for Special Dietary Uses
CCMAS: Codex Committee on Methods of Analysis and Sampling
## Methods for joint submission to CODEX

<table>
<thead>
<tr>
<th>AOAC OM</th>
<th>Nutrient(s)</th>
<th>ISO committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012.10</td>
<td>Vitamin A and E</td>
<td>ISO/TC 34/WG 14</td>
</tr>
<tr>
<td>2011.10</td>
<td>Vitamin B&lt;sub&gt;12&lt;/sub&gt;</td>
<td>ISO/TC 34/WG 14</td>
</tr>
<tr>
<td>2011.20</td>
<td>Nucleotides</td>
<td>ISO/TC 34/WG 14</td>
</tr>
<tr>
<td>2011.18</td>
<td>Inositol</td>
<td>ISO/TC 34/WG 14</td>
</tr>
<tr>
<td>2012.16</td>
<td>Pantothenic acid</td>
<td>ISO/TC 34/WG 14</td>
</tr>
<tr>
<td>2011.19</td>
<td>Ultra trace minerals (Cr, Mo, Se)</td>
<td>ISO/TC 34/SC 5</td>
</tr>
<tr>
<td>2012.13</td>
<td>Fatty acids</td>
<td>ISO/TC 34/SC 5</td>
</tr>
<tr>
<td>2012.15</td>
<td>Iodine</td>
<td>ISO/TC 34/SC 5</td>
</tr>
</tbody>
</table>
AOAC INTERNATIONAL Stakeholder Panels

- SPIFAN Stakeholder Panel on Infant Formula and Adult Nutritionals.
- SPSFAM Stakeholder Panel on Strategic Food Analytical Methods.
- SPDS Stakeholder Panel on Dietary Supplements.
- SPADA Stakeholder Panel on Agent Detection Assays.
Formation of a Stakeholder Panel dedicated to developing consensus Standard Method Performance Requirements (SMPRs) for contaminants, adulterants, and impurities of concern in raw ingredients (e.g. dairy, oils, carbohydrates)

Objective:
• Harmonize analytical methods for testing
• Define a rational and cost effective testing framework for ingredient suppliers and other stakeholders
Working Group (WG) Initiative

- December 2014, AOAC Board of Directors initiates WG Initiative
  - as a mechanism for AOAC Organizational Affiliate members to initiate relevant standard development projects using existing AOAC stakeholder panels
    - Expressed a need for a consensus standards and scientifically valid fit for purpose consensus methodology
    - WG supported through AOAC Organizational Affiliates funded and formed through AOAC staff
    - AOAC works with Organizational Affiliates to find additional Organizational Affiliates with the same need for scientifically valid fit for purpose methodology
  - WG will develop SMPR to present to an existing stakeholder panels for review
Why the new WG Initiative?

• Offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels
  – Advisory Panel participation and discussion

• WG’s funded by current OA’s and new companies interested in addressing immediate needs
  – for analytical standards/standard method performance requirements; and
  – scientifically valid fit for purpose methodology.
'Eco-terrorism' threat to poison infant formula in New Zealand

By Tim Hume, CNN

Updated 1455 GMT (2255 HKT) March 10, 2015

Police reveal threat to poison baby milk formula 02:39
AOAC able to act quickly!

• March 10, need method identified.

• March 16 and 17: Stakeholders convene.

• March 17: Stakeholders agreed on SMPR.

• March 17: Expert Review Panel designated 3 methods as AOAC Official Method first action.
Opportunities for AOAC Europe section

• Provide regional input in AOAC INTERNATIONAL Standard Development Process (technical/stakeholders).

• Harmonization of standards to facilitate global trade.

• Intensify collaboration between AOAC INTERNATIONAL and AOAC Europe section.
Summary

- Increased use of alternative methods in quality and safety testing.
- Need for harmonized international guidelines for the calibration, validation, and monitoring of all types of alternative methods.
- Acceptance of alternative methods in product release by authorities.

- With globalization need for harmonized standards to meet demands of international trade, ensuring safety, quality and fair trade
  - Validation protocols
  - Methods used for Official control purposes
- Increase collaboration between regulatory bodies, standard development organizations, industry, and reference/commercial laboratories.
- Opportunities for AOAC Europe to intensify collaboration with AOAC INTERNATIONAL on Standard Development to facilitate global trade.