CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **MAS/37 CRD/21**
ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

Thirty-seventh[th] Session
Budapest, Hungary, 22 – 26 February 2016

(Comments AOAC, IDF)

SUBJECT: PROPOSAL TO ADD LANGUAGE TO THE CODEX PROCEDURAL MANUAL – RE: CRITERIA APPROACH

Need for compliance methods with more strict precision compared to what is required according to the Horwitz/Thompson equation in the "Criteria Approach".

Introduction
At the 26th meeting of International Organizations working in the field of methods of analysis and sampling (Inter-Agency Meeting on February 20, 2015) the use of Standard Method Performance Requirements (SMPR) in AOAC was discussed. From an example it became clear that the allowed precision for a method based on the Codex Criteria approach can be much higher compared to the needed precision to verify certain regulatory requirements.

The basis for the criteria approach in Codex is the Horwitz/Thompson equation, derived from performance characteristics of methods used in the past. These criteria are not suitable for compliance verification of current regulations, particularly at low concentration analytes.
IAM members were invited to work on a revised text of the Procedural Manual to indicate that in some situations it is not appropriate to use the criteria approach to establish suitable precision requirements.

Examples where the Codex Criteria approach based precision cannot be used to verify compliance
Two examples of situations where analytical methods with a low precision are not fit for purpose to verify compliance to regulations are explained below.

1. Many countries have specific regulations including accepted tolerances for label declarations. An example is a minimum tolerance of 20% from the label declaration for low level nutrients in infant formulas.
2. New European draft regulation on specific compositional and information requirements for infant formula and follow-on formula (EU No 609/2013 (June 2015)) stipulates new ranges for fortification of nutrients. The allowed fortification range for e.g. vitamin A is between 70 and 114 µg-RE/100kcal. The relative difference between the levels is 39%.

Assuming a fortification level of 70 µg-RE/100kcal which is equivalent with 0.49 mg vitamin A/kg Ready To Feed (RTF) infant formula. The Codex criteria approach as described in the Procedural Manual, allows a $PRSD_R$ and a maximum RSD_R of 18% and 36% respectively.

It can be concluded that an analytical method with an allowed precision of 36% relatively, cannot be used to verify a minimum tolerance of 20% and a relative fortification range of 39%. The probability to find a value out of range due to analytical variability of the method is high. Consequently, such a method is not suitable for resolving dispute.

New precision data for low level nutrient concentrations and comparison with Horwitz
Recently a new set state of the art methods have been collaboratively validated for nutrients in infant formulas and adult nutritionals. Performance characteristics are summarized in the Table below.

			MLT				SMPR			Horwitz	
Analyte	AOAC Official Method	ISO/IDF Standard	MLT conc low reconstituted prod	MLT conc high reconstituted product	MLT RSDr	MLT RSDR	SMPR conc	SMPR RSDr	SMPR RSDR	max RSDR conc low	max RSDR conc high
			mg/kg	mg/kg			mg/kg	%	%		
Iodine	AOAC 2012.15	ISO 20647|IDF 234:2015	0.0347	0.185	0.8-4.8	5.4-11.5	0.05-10	<8	<15	44.0	41.2
Pantothenic acid	AOAC 2012.16	ISO 20639:2015	2.88	8.97	1.3-2.9	4.1-7.0	0.5-23	<5	<15	27.3	23.0
Chromium	AOAC 2011.19	ISO 20649|IDF 235:2015	0.016	0.14	2.1-7.0	5.8-13.4	0.02-1.6	<5	<15	44.0	43.0
Molybdenum	AOAC 2011.19	ISO 20649|IDF 235:2015	0.018	0.19	1.0-3.3	3.0-7.9	0.02-1	<5	<15	44.0	41.1
Selenium	AOAC 2011.19	ISO 20649|IDF 235:2015	0.023	0.133	2.3-6.4	2.5-9.3	0.01-0.5	<5	<15	44.0	43.3
Vitamin A	AOAC 2012.10	ISO 20633:2015	0.463	0.674	1.1-16.6	6.5-22.6	0.07-3.82	<8	<16	35.9	34.0
Vitamin E (toc ac)	AOAC 2012.10	ISO 20633:2015	13	127	0.6-3.8	4.2-11.3	2-80	<8	<16	21.7	15.4
Vitamin B12	AOAC 2011.10	ISO 20634:2015	0.002	0.015	3.0-9.8	3.5-19.5	0.0001-0.05	<15-<7	<11	44.0	44.0

In this table the Standard Method Performance Requirements (SMPR) summarize the target performance characteristics agreed before a suitable method was identified, looking among other things to regulatory requirements. For comparison, the maximum allowed RSD_R values according to Horwitz based on the levels analyzed are given.

It can be concluded that current methods are able to have a better precision compared to a maximum allowed precision according to Horwitz.

Proposed language to add to the Codex Procedural Manual, Guidelines for establishing numeric values for method criteria.

In certain cases the $PRSD_R$ and RSD_R values based on the Horwitz/Thompson equation, e.g. for low level nutrients, are too high to verify compliance with regulatory requirements. In these cases it should be evaluated what precision is needed versus what is currently feasible from a technical point of view. This should allow defining more strict criteria.

This proposed language is aligned with what was stated by M. Thompson in 2004: “While it is thus widely useful, it would be unreasonable to expect the Horwitz function to cover every contingency. Applications where very high accuracy is required readily spring to mind, and there is evidence that laboratories can fulfill the enhanced requirement” (AMC Technical Brief No. 17, July 2004).