

**INC Response to CCNSFDU37 Agenda Item 11(a)  
Methods of analysis in the *Standard for Infant Formula and  
Formulas for Special Medical Purposes Intended for Infants*  
(CODEX STAN 72-1981)**

20 October 2015

**SUMMARY**

INC is generally supportive of the eight proposed methods of analysis and of their recommendation to CCMAS for inclusion in CODEX STAN 234-1999. However, INC is concerned that the validation of these methods may not have sufficiently investigated their suitability for milk based formula made from non-bovine milk sources. The micronutrients naturally present in milks sourced from different species can vary with respect to both overall levels present as well as the relative proportions of different forms present.

INC therefore recommends the addition of a note to the appropriate section in CODEX STAN 234-1999 which states that while the proposed methods have been validated for infant formula, their suitability for use for milk formulas based on non-bovine milk should be assessed and confirmed.

INC supports the proposal in the Agenda Item 11a) paper at paragraphs 4 and 5 that the list of methods are submitted to CCMAS for review and approval to replace current Type II reference methods in infant formulas and formulas for special medical purposes for infants and that they be recommended for inclusion in CODEX STAN 234-1999 to replace current methods in that standard.

**Proposal**

CCNSFDU is requested in a paper prepared by the United States to consider submitting the following eight methods of analysis for nutrients in infant formula to CCMAS for technical review, typing, endorsement, and inclusion in Part A, Section Foods for Special Dietary Uses, with the description “Infant Formula” in the *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999):

- Vitamin B12 – AOAC 2011.10, ISO/DIS 20634
- Myo-Inositol – AOAC 2011.18, ISO/DIS 20637
- Chromium – AOAC 2011.19, ISO/DIS 20649, IDF 235
- Selenium AOAC 2011.19, ISO/DIS 20649, IDF 235
- Molybdenum – AOAC 2011.19, ISO/DIS 20649, IDF 235
- 5’Mononucleotides – AOAC 2011.20, ISO/DIS 20638
- Vitamins A and E – AOAC 2012.10, ISO/DIS 20633
- Total fatty acid profile – AOAC 2012.13, ISO/DIS 16958, IDF 231
- Iodine – AOAC 2012.15, ISO/DIS 20647, IDF 234
- Pantothenic acid – AOAC 2012.16, ISO/DIS 20639

The paper states that these methods reflect the most recent scientific methods of analysis for nutrients in infant formula and have been validated in infant formula.

## **INC Response**

INC is generally supportive of these methods of analysis and recognises the importance of maintaining the current Codex Standards by updating them to reflect advances in scientific analysis and evidence.

INC notes that these methods have been validated across a wide range of infant formula matrices. However, their suitability to formula made from non-bovine milk sources has not been specifically verified. It is recognised that the micronutrients naturally present in milks sourced from different species can vary with respect to both overall levels present as well as the relative proportions of different forms present.

It is important that where assays are applied they capture the full natural content as well as added levels. For micronutrients that are not present in cows' milk, or present in cows' milk at levels considered to be negligible, assay development tends to focus primarily on quantification of added forms. Application of such assay methods to formulas based on alternative milk sources containing significant natural levels of the micronutrient concerned can result in a significant underestimation of the levels delivered by the product. The nucleotides naturally present in goats' milk is an example. Similarly, it is not possible to validate methods for future novel approaches applied to the formulation and manufacture of infant formula products.

INC therefore recommends the addition of a note to *Recommended Methods of Analysis and Sampling* (CODEX STAN 234-1999) Part A, section "Foods for Special Dietary Uses", with the description "Infant Formula". The note is proposed to state:

"While these methods have been validated for infant formula across a wide range of matrices, their suitability for use for milk formulas based on non-bovine milk and formulas produced using novel approaches should be assessed and confirmed."

With the addition of the above note, INC supports the proposal in the Agenda Item 11a) paper at paragraphs 4 and 5 that:

- the list of methods are submitted to CCMAS for review and approval to replace current Type II reference methods in infant formulas and formulas for special medical purposes for infants;
- the list of methods are included further in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) in Part A, (section "Foods for Special Dietary Uses", with the description "Infant Formula"); and
- a recommendation is made to CCMAS that current methods in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) are removed or reclassified because they are not validated for infant formula.