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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECCIAL DIETARY USES

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METHODS OF ANALYSIS FOR PROVISIONS IN THE STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS

PWG Side Session report: recommendations to the Committee

Prepared by the United States of America

An in-session physical working group (PWG) was held on the 6th of December 2016 during the CCNFSDU meeting. The focus of the working group was to provide recommendations to the Committee on the Matters Referred from CCMAS regarding the *Methods of analysis for provisions in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*. The working group reviewed the CCMAS requests in para 20 of the Agenda paper (16/38/2). A summary of the discussions and the conclusions of the physical working group are outlined below.

Methods for Chromium, selenium and molybdenum (AOAC 2011.19 ISO/DIS 20649 | IDF 235):

CCMAS requested the Committee review the proposed numeric values for method criteria.

The pWG discussed that CCMAS has requested that the Committee review the proposed numeric values (the minimum levels (ML) from CODEX STAN 72-1981 for Cr, Se, and Mo). However, the pWG noted that CCMAS also determined that none of the current methods in CODEX STAN 234-1999, nor the newer methods (AOAC 2011.19 ISO/DIS 20649 | IDF 235) meet the criteria or in other words, measure the ML for these nutrients (REP16/MAS para 30).

The pWG acknowledged that AOAC International (CRD4) has recently published additional validation data showing that the newer method (AOAC 2011.19 ISO/DIS 20649 | IDF 235) measures the minimum levels specified in CODEX STAN 72-1981.[1] In light of published validation data, the pWG concluded that the 'method criteria' approach is inappropriate in this case because the goal of this approach is to allow flexibility in choosing a method, but at the time CCMAS reviewed newer and existing methods, there were no available methods that measured the MLs specified in CODEX STAN 72-1981. As current methods cannot measure the specified MLs, the pWG was concerned that using a criteria approach in this case could lead to questioning the MLs in CODEX STAN 72-1981 and agreed that it is inappropriate to set MLs for infant formula based on the detection level of an analytical method as infant formula provides sole nutrition for infants and levels for nutrients should be based on requirements for growth and development.

As the newer method (AOAC 2011.19 ISO/DIS 20649 | IDF 235) is the only method that has been validated in infant formula to show it measures the ML in CODEX STAN 72-1981, the pWG was in general agreement that the method should be referred to CCMAS for review and typing as a conflict resolution method (Type II). The pWG acknowledged concerns that this method use more expensive instrumentation and noted that if parties have a dispute about an analytical result, then the parties can agree on *any* validated method to test the product. The selected method does not have to be the Type II method. The Type II method or the default conflict resolution method is used *only if* the parties cannot agree on a method.

[1] Thompson and Pacquette. Characterization of AOAC Final Action Official Method 2011.19 and AOAC First Action Official Method 2015.06 Performance at Analyte Levels Corresponding to CODEX STAN 72-1981 Minimum Levels. JAOAC INTERNTIONAL. Published online November 2016. http://ingentaconnect.com/content/aoac/jaoac/pre-prints/content-160325

Recommendation for Chromium, selenium and molybdenum:

That CCNFSDU reply to CCMAS that:

- **CCNFSDU does not support using the criteria approach because:**

  (1) A general or single conversion factor to convert ug/100 kcal to ug/g should not be used as the energy density of infant formula varies across products and;

  (2) None of the current methods in CODEX STAN 234-1999, nor the newer proposed methods (AOAC 2011.19 ISO/DIS 20649 | IDF 235) meet the criteria (REP16|MAS, para 31).

- **In light of published validation data measuring the minimum level for Chromium, Selenium and Molybdenum in CODEX STAN 72-1981, CCNFSDU requests that CCMAS reconsider the method for Chromium, Selenium and Molybdenum AOAC 2011.19 | ISO 20649 | IDF 235 for review, typing as Type II, endorsement, and inclusion in Codex Stan 234-1999 in Part A, section "Foods for Special Dietary Uses," with the description "Infant Formula"**

- **Reply that methods for Chromium, Selenium, and Molybdenum other than AOAC 2011.19 ISO/DIS 20649 | IDF 235 are still fit for purpose.**

Methods for Vitamin B12 and Total Fatty Acid profile*:*

- **CCMAS asked whether the existing methods in CODEX STAN 234-1999 for Vitamin B12 and Total Fatty Acid profile are 'fit for purpose' or in other words still used in countries. If the methods are fit for purpose, then these methods will be sent to CAC for adoption.**
- **The pWG noted the discussion of method for Total Fatty Acid profile in REP16\MAS para 38 and its omission in CX/NFSDU 16/38/2.**

The pWG confirmed that these methods are still used in countries and was in agreement that the methods for B12 and Total Fatty Acid Profile are fit for purpose. The pWG noted that with CCNFSDU's reply that the methods are fit for purpose; the methods would proceed directly to CAC for adoption.

- **CCMAS recommended changing the wording of the provision "Total Fatty Acid Profile" to "Fatty Acids including trans fats"**

The pWG discussed the CCMAS recommendation to change the title of the method for Total Fatty Acids to Fatty Acids including trans fats. While the pWG agreed with the change, the pWG chair proposes that CCNFSDU retain the provision 'Total Fatty Acids' profile in light of the efforts of CCNFSDU to maintain consistency with the reference to Total fatty acids in CODEX STAN 72-1981 and CODEX STAN 156-1987.

Recommendation for Vitamin B12:

That CCNFSDU reply to CCMAS that:

- **The existing method (AOAC 986.23) is fit for purpose. This means that AOAC 986.23 would become type III and be sent to CAC for adoption (REP16\MAS para 33).**
- **Send the method AOAC 2011.10 | ISO 20634 endorsed by CCMAS to CAC for adoption.**

Recommendation for Total Fatty Acid profile: (AOAC 2012.13 | ISO 16958 | IDF 231)

That CCNFSDU reply to CCMAS that

- **The current method (AOAC 996.06) is fit for purpose .**
- **CCNFSDU agrees with the CCMAS recommendation to designate (AOAC 996.06) as Type III (REP16/MAS para 38).**
- **Retain the provision "Total Fatty acid" profile to maintain consistency with the terms used in CCNFSDU texts (e.g. CODEX STAN 72-1981, CODEX STAN 156-1987).**

Methods for Myo-inositol and Vitamin E*:*

- **CCMAS asked if the provision in CODEX STAN 72-1981 for these nutrients and scope of the methods harmonize.**

- **If the provision and scope of the methods do harmonize, then these methods will be sent to the CAC for adoption (REP16\MAS para 35 and 37).**

The pWG discussed that the evidence used to set the myo-inositol levels in the Infant formula standard included both free and bound[2] forms and noted that AOAC 2011.18/IDF 20637 determines both free and bound myo-inositol. Thus, the pWG agreed that the provision for myo-inositol in CODEX STAN 72-1981 and the scope of the endorsed method AOAC 2011.18/IDF 20637 harmonize and should be sent to the CAC for approval.

Recommendation for Myo-inositol:

That CCNFSDU reply to CCMAS that:

The definition and the scope of the methods harmonize. Therefore, the method AOAC 2011.18 ISO 20637 endorsed by CCMAS should be sent to CAC for adoption.

Method for Vitamin E (AOAC 2012.10 ISO 20633):

The pWG discussed that the method endorsed by CCMAS measures the same forms of vitamin E (d and dl alpha-tocopherol) that the existing Codex methods measure[3]. The pWG noted that CODEX STAN 72-1981 refers to d-alpha tocopherol for ease in reporting and that the activity of other forms of alpha tocopherol measured are corrected to reflect d-alpha-tocopherol. The pWG also noted that other allowed vitamin E sources (CAC/GL10-1979are corrected for their biological activity with the appropriate conversion factor. In summary, the pWG agreed that the provision for vitamin E in CODEX STAN 72-1981 harmonizes with the scope of the endorsed method for Vitamin E (AOAC 2012.10 ISO 20633).

Recommendation for Vitamin E:

That CCNFSDU reply to CCMAS that

The definition and the scope of the methods harmonize. Therefore, the method AOAC 2012.10 | ISO 20633 endorsed by CCMAS should be sent to CAC for adoption.

Other general considerations

CCMAS asked CCNFSDU to consider including a formula for conversion of units in the CODEX STAN 72-1981.

The pWG discussed that the energy density of infant formula (CODEX STAN 71-1981) ranges from 60 – 70 kcal/100 ml; therefore, a general or single conversion factor cannot be used. Therefore, the pWG agreed to not to recommend a formula for conversion of units in the Standard.

Recommendation for a formula for the conversion of units:

That CCNFSDU reply to CCMAS that the Committee does not recommend a conversion of units in CODEX STAN 72-1981.

Proposed Method for Vitamin C (AOAC 2012.22 |ISO/DIS 20635)

The pWG discussed and agreed that that the proposed method reflects the most recent scientific method of analysis for Vitamin C in infant formula and has been validated in infant formula.

[2] Joint FAO/WHO Food Standards Programme. Codex Committee on Nutrition and Foods for Special Dietary Uses, 30th Session, Cape Town, Africa. Report of the Electronic Working Group on Methods of Analysis for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981). September 2008. ftp://ftp.fao.org/codex/Meetings/CCNFSDU/ccnfsdu30/nf3002ae.pdf

[3] RECOMMENDED METHODS OF ANALYSIS AND SAMPLING CODEX STAN 234-1999

Recommendation for Vitamin C:

That CCNFSDU

- **Refer to CCMAS the method of analysis for vitamin C AOAC 2012.22 | ISO/DIS 20635 for review, typing as Type II, endorsement, and inclusion in Codex Stan 234-1999 in Part A, section "Foods for Special Dietary Uses," with the description "Infant Formula."**
- **Request that CCMAS remove or reclassify methods that are not validated for infant formula in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) that may be replaced by the proposed method for vitamin C AOAC 2012.22 | ISO/DIS.**