CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES 30th SESSION

U.S. DRAFT POSITIONS

As of
September 19, 2008

Notice to U.S. Interested Parties in the Activities of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

The next (30th) session of this Codex committee will be held from November 3 to 7, 2008 in Cape Town, South Africa. An *ad hoc* working group will meet on November 1 to discuss Health Claims, Nutrient Reference Values for food labeling purposes, and matters related to consideration of the World Health Organization's Global Strategy on Diet, Physical Activity and Health. Dr. Barbara Schneeman will head the U.S. Delegation; Dr. Allison Yates is the alternate U.S. Delegate.

This document identifies U.S. preliminary draft positions as of September 19, 2008 on agenda items for the next session. The agenda is posted at the following web address, along with reference documents on each agenda item as they become available.

http://www.codexalimentarius.net/web/current.jsp?lang=en

As identified in the U.S. Delegate's August 8, 2008 communication to U.S. interested parties in the activities of this Codex Committee, a public meeting will be held on September 24, 2008 from 1:00 p.m. to 4:00 p.m. in College Park, Maryland. The purpose is to provide information and receive public comments on the agenda items that will be discussed at the next CCNFSDU session and on U.S. draft positions. The meeting will be in the FDA Auditorium (1A003), Harvey Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740. Parking is adjacent to the building and will be available at no charge to attendees who pre-registered by September 17.

Note: If you plan to attend this public meeting, you may wish to download from the above web site the CCNFSDU documents for reference.

We also invite you to submit written comments by October 6, 2008. Please direct these to: CCNFSDU@fda.hhs.gov . We request comments by this date to facilitate their consideration in preparing final draft U.S. positions for the next CCNFSDU session.

MATTERS REFERRED BY
THE CODEX ALIMENTARIUS COMMISSION
AND/OR OTHER CODEX COMMITTEES

AGENDA ITEM No. 2

BACKGROUND

Reference:

- CX/NFSDU 08/30/2-REV (September 2008)
- Infant formula method references from 29th CCNFSDU Session: (ALINORM 08/31/26 para 149-159, CRD 10, CRD 15)

One of the topics in the Matters Referred document is methods of analysis for infant formula. At the 29th Session of the CCNFSDU, an Electronic Working Group (eWG) was established to prepare a list of methods of analysis for infant formulas to be considered at the 30th Session of the Committee. The eWG was given the following terms of reference:

- Review methods of analysis for provisions listed in Section 3.1 of the Codex Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants;
- Follow the Principles for Establishment of Codex Methods of Analysis in the Codex Procedural Manual, including the General Criteria for the Selection of Methods of Analysis;
- The eWG, chaired by New Zealand would be open to all members and observers, and would work in English.

Please refer to the above documents for additional background.

DRAFT POSITION- Infant formula methods

I. GENERAL COMMENTS

The United States would like to express its appreciation to the Delegation of New Zealand for its efforts to develop a report that clearly describes the review process and the rationale and criteria used by the eWG to recommend analytical methods for consideration by the CCNFSDU. We have provided comments on application of the General Criteria for the Selection of Methods of Analysis and the process for completion of the review by the eWG. The United States has also submitted analytical methods, references for each method and supporting materials, and brief comments about validation of each method for consideration by the eWG participants. The table appended at the end of this document provides details about the analytical methods submitted by the United States to the eWG in March. Additional comments and information subsequently provided by the United States are detailed in the specific comments below.

The United States recently received the analytical methods proposed by the Chair of the eWG and is currently reviewing those methods for analysis of infant formula. We anticipate development of additional comments for the upcoming CCNFSDU session.

II. SPECIFIC COMMENTS

Supporting Criteria to Recommend Methods

As detailed in the terms of reference in para 153 of ALINORM 08/31/26, the eWG is to "follow the Principles for the Establishment of Codex Methods of Analysis in the Codex Procedural Manual, including the General Criteria for the Selection of Methods of Analysis." In this context, it is important for members of the eWG to have access to information submitted in order to assess the proposed methods. The Codex Procedural Manual (16th edition) lists the criteria shown in italics on pages 74 and 75.

(a) *Official methods of analysis elaborated by international organizations occupying themselves with a food group or group of foods should be preferred*.

Comment: Methods meeting criterion (a) have been submitted for most provisions listed in Section 3.1. Methods meeting this criterion should be considered for classification as Type I, II, or III. CCNFSDU will need adequate information on each method proposed to determine if the criteria have been met.

If two (or more) methods are equivalent, this should be recognized and both (all) should be listed as the same type of method (e.g., listing of AOAC 991.20 and ISO 8968-1/2 | IDF 20-1/2: 2001 as type I or type II method for crude protein). If no method meeting criterion (a) is submitted for a provision, then any methods submitted for the provision can only be considered for inclusion as Type IV methods. Methods described as "in press" should not be considered by the eWG.

(b) Preference should be given to methods of analysis, the reliability of which have been established in respect of the following criteria, selected as appropriate:
- *(i) specificity*
- *(ii) accuracy*
- *(iii) precision: repeatability, intra-laboratory (within laboratory) reproducibility, and inter-laboratory (between laboratories) reproducibility*
- *(iv) limit of detection*
- *(v) sensitivity*
- *(vi) practicability and applicability under normal laboratory conditions*
- *(vii) other criteria which may be selected as required.*

Comment: When one or more methods meeting criterion (a) have been submitted, each method and the supporting documentation on its reliability should be distributed to the eWG in order to evaluate the information. If the method and reliability information are not provided for a method, it should not be considered for recommendation as a Type II or Type III method by the eWG.

(c) The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use.

Comment: The methods recommended as Type II methods by the eWG should be practical, applicable for routine use, and publicly accessible, preferably without cost to users. In some cases, this may result in selection of a Type II method that is not "cutting edge" technologically; however, setting "cutting edge" as a criterion for Type II methods places a burden on countries and CCNFSDU to update and change methods frequently, often at significant cost but not necessarily with gains in analytical precision and reliability.

We believe selection of methods that meet criterion (c) as Type II methods is likely to result in wider access for use of the Type II methods. Use of methods that can be routinely applied in various settings and in different countries should improve the ability to compare results, which would be consistent with the Codex goal of facilitating fair international trade.

(d) *All proposed methods of analysis must have direct pertinence to the Codex Standard for which they are directed.*

Comment: Codex Standard 72—1981 Rev. 2007 (Section 3.1) lists the nutrients of essential composition for infant formulas and this is the list for which methods should be proposed by the eWG. Recommendations by the eWG for revisions to Codex Standard 234 apply only to infant formula. A footnote should be added following the title of the "Foods for Special Dietary Use" category in Codex Standard 234 to indicate that the analytical methods listed specifically for infant formulas should be used for those products.

The methods most directly pertinent to infant formula are those that have been validated for infant formula. Methods that have been evaluated in infant formula and found appropriate for analyses of infant formula matrices should be recommended as Type II methods whenever possible.

(e) *Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.*

Comment: We agree with use of broadly applicable methods in cases in which infant formula has been specifically studied as a part of the applicability of the method for various groups of commodities. However, we consider that much more information is needed before we can agree that to the application of criterion (e) in cases where the method has not been validated for analysis of infant formula. We do not think it is the intent of criterion (e) to use general methods validated in a variety of commodities, not including infant formula, to displace methods that have been specifically validated for infant formula. Because infant formula is used as the sole source of nutrition for a vulnerable population, there is no room for error in its composition. Likewise, there is no room for error in the analysis of its composition.

The applicability of analytical methods to infant formula is a function of the nature of the analyte and the nature of the matrix. For example, methods validated for other foods, including a similar food such as milk powder, may be generally appropriate for analysis of minerals, but not for vitamins, in infant formulas. Methods that have been validated for use in infant formula should be given preference as Type II methods over analytical methods that have been shown to be useful for analysis of similar foods but have not been studied in infant formula.

Process for Completion of Review

We believe it is necessary that the eWG have a clear rationale for application of the General Criteria for the Selection of Methods of Analysis before proceeding with selection of methods and assignment of method types for recommendation to CCNFSDU. With an agreed upon rationale, the eWG can examine the methods and the information that documents the validation of methods and then provide comment relating to the selection of methods and assignment of type.

Ultimately, the CCNFSDU will have a better basis to accept the eWG recommendations if 1) the review is done in a transparent and comprehensible manner and 2) the eWG report to CCNFSDU includes a clear description of the review process and the rationale and criteria used by the eWG to recommend the analytical methods.

Inclusion of an Analytical Method for Dietary Fiber

In response to the CCMAS request to reconsider inclusion of methods for dietary fiber, the U.S. notes that ingredients used to make infant formulas do not contain dietary fiber. Therefore, it should not be necessary to apply a correction factor for dietary fiber and an analytical method for dietary fiber would not be needed to calculate total energy.

GUIDELINES FOR THE USE OF NUTRITION CLAIMS:
DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS
(PART B CONTAINING PROVISIONS ON DIETARY FIBRE)
AT STEP 6

AGENDA ITEM No. 3

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, Appendix II and paras 22-41)
- CL 2007/43-NFSDU; Comments at Step 6 (CX/NFSDU 08/30/3)

Codex: Nutrition Labeling and Content Claims. The Codex *Guidelines on Nutrition Labelling (CAC/GL 2-1985)* currently define dietary fiber as:

> "Dietary Fibre means edible plant and animal material not hydrolysed by the endogenous enzymes of the human digestive tract as determined by the agreed upon method."

Since 1992, the Committee has discussed conditions for (dietary) fibre content claims (ALINORM 93/26, Appendix III). Early in these deliberations, it noted the difficulties associated with the definition of (dietary) fibre and the methods of analysis for its determination (ALINORM 95/26, para 9). In recent years, the Committee has discussed a draft revised definition of dietary fiber for purposes of nutrition labeling and nutrient content claims. Among other things, the latest version of the draft definition would include synthetic carbohydrate polymers with a degree of polymerization ≥ 3 which are neither digested nor absorbed in the small intestine provided they have a physiological effect. The physiological effects and how they are measured would be determined at the national level (ALINORM 08/31/26, Appendix II).

In contrast, an alternative definition, (i.e.,"intrinsic plant cell wall polysaccharides") offered at the 28th CCNFSDU Session based on a Joint FAO/WHO Scientific Update on Carbohydrates in Human Nutrition proposed to exclude resistant starch and oligosaccharides or isolated components of whole-grains, fruits, vegetables and legumes, and instead suggested that the physiological effects of these components were more appropriately considered in the province of health claims (ALINORM 08/31/26, para 22-34).

To date, the Committee has had little discussion about the methods proposed for each of the definitions. The U.S. noted in written comments at the last session, however, that there is no single AOAC method to measure total fiber content based on the proposed definitions, and no validated procedure to combine methods to estimate total fiber that would be consistent with the draft Codex definition (CX/NFSDU 07/29/3, 2007).

At the last session, the Committee agreed it was not possible to progress further on this document and that it was preferable to allow more time at the national level to consider the papers of the FAO/WHO Scientific Update on Carbohydrates in Human Nutrition, and how this

update applied to Codex provisions for dietary fibre content claims and the definition of dietary fiber.

Codex: Health Claims.
For additional perspective, the Codex *Guidelines for Use of Nutrition and Health Claims* defines a health claim as "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health", and specifies three types of claims: "nutrient function claims", "other function claims", and "reduction of disease risk claims." Unlike nutrient content claims and the listing of nutrient amounts in nutrition labeling, the labeling of food components that meet the Codex provisions for health claims would identify the specific physiological function, health-related condition, or disease that is the subject of the health claim.

United States: Nutrition Labeling and Content Claims. For purposes of declaring a food's dietary fiber content for nutrition labeling and for nutrient content claims (e.g., "good source" of dietary fiber), the U.S. Food and Drug Administration (FDA) uses an analytical definition for dietary fiber based on the material isolated using AOAC INTERNATIONAL Enzymatic-Gravimetric Method 985.29 or using related methods that isolate the same components (21 Code of Federal Regulations (CFR § 101.9(g)(2)). In 2001, an Institute of Medicine panel responded to FDA's request to provide definitions for dietary fiber based on its role in human physiology and health--and the following definitions for "dietary fiber", "functional fiber", and "total fiber" were proposed in a 2002 report on macronutrient dietary reference intakes:

> Dietary Fiber consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants.
> Functional Fiber consists of isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.
> Total Fiber is the sum of dietary fiber and functional fiber.

The FDA is considering whether to revise its regulatory provisions for declaring dietary fiber content. This is part of an Advance Notice of Proposed Rulemaking published in November of 2007 which requested comment on the need to update U.S. food label nutrient reference values. Some questions asked in this notice are:

- Should FDA continue to use the AOAC INTERNATIONAL methods to determine dietary fiber? If not, what other or additional methods should be used?
- Should the IOM dietary fiber and/or functional fiber definitions replace the current FDA definition for dietary fiber? Explain why or why not.
- Do you recommend another name for functional fiber? If so, what do you recommend and why?
- Until FDA identifies functional fibers and analytical methods are established for distinguishing functional fiber from dietary fiber, should total fiber be used on the label to represent dietary fiber? Explain why or why not.
- If FDA includes functional fiber in the Nutrition Facts labels, should FDA develop criteria for identifying fibers that meet the definition of functional fiber (i.e., demonstrates a physiological benefit)? If so, what should those criteria be?

United States: Health Claims. For purposes of making certain claims about reduction of disease risk, the FDA uses requirements that pertain to specific types of dietary fiber with documented

physiological effects (e.g., beta glucan soluble fiber from whole oat sources and psyllium husk soluble fiber are eligible fibers for health claims relating soluble fiber from certain foods and reduced risk of heart disease.)

DRAFT POSITION

Definition of Dietary Fiber

With regard to the Committee's current work to consider revisions to the existing Codex definition of dietary fiber, the United States has the following questions:

- Is there sufficient scientific evidence to indicate that a revised Codex dietary fiber definition is needed to improve public health?
- Is there international scientific consensus on the term(s) to be defined (e.g.,"dietary fibre", "fibre", "total fibre", "synthetic/isolated fibre", "(beneficial) physiological effect" and on the definition(s)?
- For the definition proposed in ALINORM 08/31/26, Appendix II, what are the implications of having a definition in which evaluation of physiological effects would be required but without established methods for testing all the physiological effects?
- Is there a validated method to measure total fiber content based on the proposed definitions in various food matrices?

The U.S. looks forward to further discussion of the definition at the next session, including unresolved scientific and methodological issues.

Draft Table of Conditions for Dietary Fibre Content Claims

Basis for Dietary Fiber Content Claims

The United States continues to support inclusion of serving size as a basis for expressing dietary fiber content claims, and emphasizes the importance that the criteria be based on scientific recommendations for daily dietary fiber intake.

Accordingly, we propose that the Committee consider expressing conditions for dietary fiber claims in a similar manner as the 2001 amendments to the Table of Conditions of Nutrient Contents in the *Guidelines for Use of Nutrition and Health Claims* which specifies conditions for "source" and "high" claims for protein, vitamins and minerals as a percentage of a daily reference value for food labelling purposes (CAC/GL 23-1997, Rev. 2-2004). Specifically, these guidelines express the conditions as a specified percentage of the Nutrient Reference Value (NRV) per 100 g, per 100 ml, per 100 kcal, or per serving. This would not only promote consistency with recent approaches, but might also promote transparency in identifying the relationship between the criteria and recommendations for daily dietary fiber intake. In addition, it should obviate the need to update this table if a Nutrient Reference Value for dietary fiber is established or subsequently updated.

Accordingly, we propose that the Committee consider the option of revising the table in Appendix III as follows:

COMPONENT	**CLAIM**	**CONDITIONS**
B.		**NOT LESS THAN**
Dietary Fibre	Source	[__% of daily reference value[1] per 100 g (solids) ___% of daily reference value per 100 ml (liquids) or ___% of daily reference value per 100 kcal or 10% of daily reference value per serving[2]]
	High	2 times the value for "source"

[1] A daily reference value may be either a Codex Nutrient Reference Value for food labelling purposes (to be determined) or a labelling reference value determined at the national level based on science-based recommended daily intakes taking into account additional factors specific to a country or region.

[2] Serving size to be determined at the national level.

DRAFT ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN: Part D Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic (Gum Acacia) At Step 6

Agenda Item No. 4

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, paras 75-78, Appendix V)
- Comments at Step 6 CX/NFSDU 08/30/4

At the last meeting, the Committee agreed to advance the draft Advisory List to Step 8 for adoption by the 31st Session of the Codex Alimentarius Commission, with the exception of the level of gum Arabic (gum acacia) in Part D, which was returned to Step 6 for further comment and consideration.

Please refer to the above documents for additional information.

DRAFT POSITION

The comments submitted by the International Association for the Development of Natural Gums (AIDGUM) clarify that the bracketed level of gum arabic/gum acacia of 100 mg/kg in Appendix V, ALINORM 08/31/26 refers to the amount used for a food ingredient as a coating agent to prevent oxidation or other deterioration of "vitamins or other minor ingredients" and state that the level of gum arabic/gum acacia in the finished product will be "well below 10 mg/kg." The United States notes that the Part D table in Appendix V lists levels for the food additives in terms of maximum levels in ready-to-use food for infants and young children (mg/kg). The United States believes that the maximum level of gum arabic/gum acacia should also be expressed as amounts in the ready-to-use food, and thus tentatively supports a 10 mg/kg level based on the information submitted by AIDGUM.

If it would help provide clarification, the Committee report could include language to indicate that the Advisory List specifies levels of food additives in ready-to-use food and that levels of a food additive in individual ingredients may be higher so long as the total level of the food additive in the ready-to-use food does not exceed the level listed in the table in Part D: Advisory List of Food Additives for Special Nutrient Forms. As with food additives used for all purposes, the lowest level needed to achieve the technical effect under good manufacturing practice should be used.

DRAFT NUTRITIONAL RISK ANALYSIS PRINCIPLES AND GUIDELINES FOR APPLICATION TO THE COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES AT STEP 5

AGENDA ITEM No. 5

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, para 98-121)
- Comments in response to CL 2008/21-NFSDU *not yet available*

At the last session, the Committee reviewed the draft document section by section, and reached agreement on the majority of the provisions. While certain text was left in square brackets, the Committee agreed to advance the document to Step 5 for adoption by the 31st Session of the Codex Alimentarius Commission.

DRAFT POSITION

I. GENERAL COMMENTS

The United States notes the substantial progress made on this Codex text. Our comments mainly focus on bracketed text. We also offer a few other comments intended for clarification.

II. SPECIFIC COMMENTS

SECTION 2--INTRODUCTION

3. Codex nutritional risk analysis addresses nutrients[1] and related substances[2] and the risk to health from their inadequate and/or excessive intake. Nutritional risk analysis applies the same general approach as traditional food safety risk analysis to consideration of excessive intakes of nutrients and related substances. However, unlike many constituents of food that are the subject of traditional food safety risk analysis such as food additives, chemical (pesticide and veterinary drug) residues**, microbiological pathogens, contaminants and** inherent constituents such as allergens**,;** nutrients and related substances are inherent constituents that are biologically essential (in the case of essential nutrients) or in other ways potentially favourable to health. Nutritional risk analysis therefore adds a new dimension to traditional risk analysis by also considering risks directly posed by inadequate intakes.~~, microbiological pathogens, contaminants and~~

> Comment: The United States agrees with comments from the Australian delegation that certain text in para 3 appears to have been corrupted. The repositioning of the text "microbiological pathogens, contaminants and" is proposed to restore text to that shown in CX/NFSDU 07/29/7, which was agreed upon at the last session.

In addition, in the third sentence we suggest that a semi-colon be placed after "allergens" (instead of a comma) to separate independent clauses.

Footnote 2. [A related substance is an inherent constituent of food (other than a nutrient) that has a ~~[~~potential~~]~~ ~~nutritional or~~ **favourable** physiological effect.]

Comment: The United States proposes the above edits to footnote 2 to define a related substance as having a "potential favourable physiological effect", which is consistent with text agreed upon in para 3, line 3 (i.e., "potentially favourable to health"). The U.S. believes it would be confusing to refer to related substances that are not nutrients as having "nutritional effects".

4. The ~~[~~*Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses*~~]~~ presented in this document (hereafter cited as "Nutritional Risk Analysis Principles") are subsidiary to and should be read in conjunction with the Working Principles.

Comment: The United States supports the deletion of brackets in the above text, given that this title was agreed upon at the last session (ALINORM 08/31/26, para 105).

These Nutritional Risk Analysis Principles are framed within the three-component structure of the Working Principles, but with an added initial step to formally recognize Problem Formulation as an important preliminary risk management activity.

Comment: The United States believes that this should be a separately numbered paragraph as is shown in CX/NFSDU 07/29/7, August 2007.

5. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO and their joint expert consultations ~~[and expert bodies]~~ are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This role however, does not preclude the choice of other sources of scientific advice such as appropriate international expert groups or organizations if and when justified.

Comment: The first sentence identifies <u>primary</u> source(s) of nutritional risk assessment advice to Codex. The United States recommends deleting the reference to "expert bodies." Presently there is no FAO/WHO expert body that serves as a <u>primary</u> source of scientific advice on nutritional risk assessment to Codex or that has nutritional risk assessment in its terms of reference. While the Joint Expert Committee on Food Additives (JECFA) has established Acceptable Daily Intakes (ADIs) for certain nutrient compounds that have food additive functional effects, there are differences in the objectives and process for establishing food additive ADIs compared to those for establishing levels of upper intake for nutrients.

If in the future FAO/WHO establishes an expert body with terms of reference to conduct nutritional risk assessment, the Committee could consider amending this Codex text to add "expert bodies" then.

SECTION 3-- SCOPE AND APPLICATION

6. ~~[~~The Nutritional Risk Analysis Principles are established to guide the Codex Alimentarius Commission and its subsidiary bodies - primarily but not exclusively the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) - in applying nutritional risk analysis to their work. This guidance potentially extends beyond CCNFSDU since the Committee is also mandated, in accordance with its 4th term of reference, "to consider, amend if necessary, and endorse provisions on nutritional aspects" of foods including those resulting from application of nutritional risk analysis that are developed by other Codex subsidiary bodies. ~~]~~

> Comment: The United States supports retention of this text and deletion of the square brackets in order to clarify that this guidance may extend to the work of other Codex committees as reflected in CCNFSDU's fourth term of reference. As a recent example, the Committee endorsed at its last session the Annex on *Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits.*

7. Nutritional risk analysis considers the risk of adverse health effects from inadequate and/or excessive intakes of nutrients and related substances, and the predicted reduction in risk from proposed management strategies. ~~In situations that address inadequate intakes,~~ **S**uch a reduction in risk might **also** be referred to as ~~[one form of]~~ a nutritional benefit.

> Comment:
> The United States offers the above edits for the Committee's consideration, which may more clearly express the intent.

8. The food constituents ~~of primary interest~~ in nutritional risk analysis are inherent components of food and/or intentionally added to food ~~[~~and are identified as:

> • nutrients **of primary interest** that may reduce the risk of inadequacy and those that may increase the risk of adverse health effects; or
>
> • related substances[2] **of primary interest** that may increase the risk of adverse health effects at excessive intake and may also reduce the risk of other adverse health effects at lower intake; **or**
>
> • ~~[~~**other** nutrients that increase the risk of adverse health effects ~~that exist~~ **when also present** in a food matrix with a nutrient(s) or related substance(s) **of primary interest** ~~associated with reduction of the risk of inadequacy or adverse health effects at lower intake];]~~.
>
> > Comment: The United States supports the above edits which were proposed by the Australian delegation, with the subsequent deletion of both sets of square brackets.

SECTION 4--DEFINITIONS

Highest observed intake[4] – **The highest observed intake is derived only when no adverse health effects have been identified. It is** the highest level of intake observed or administered as reported within a stud**y**(ies) of acceptable quality. ~~It is derived only when no adverse health effects have been identified.~~

> Comment: As noted above, the Committee may wish to reverse the order of these sentences to be consistent with the text in p. 85 of the footnote 4 reference (i.e., the report of a 2005 joint FAO/WHO technical workshop on nutrient risk assessment) and to place emphasis in the first sentence on appropriate circumstances in which a "highest observed intake" may be considered.

SECTION 5- PRINCIPLES FOR NUTRITIONAL RISK ANALYSIS

27. Nutrient-related intake assessment and risk characterization should be applied within a total diet context. Where feasible, it would typically involve the evaluation of the distribution of habitual total daily intakes for the target population(s). This approach recognizes that nutrient-related risks are often associated with total intakes from multiple dietary sources, including fortified foods, food supplements[1], and in the case of certain minerals, water. ~~[~~It may also take into account the bioavailability and stability of nutrients and related substances in the foods consumed.~~]~~

> Comment: The United States supports retaining the last sentence and deletion of the brackets.

29. Nutritional risk management can be effected through quantitative measures or qualitative guidance elaborated in Codex texts. Such risk management could involve decisions about nutrient composition, consideration of the suitability of foods ~~containing risk-increasing nutrients~~ **for meeting nutritional needs** for certain purposes or (sub)populations, labelling advice intended to mitigate nutritional risks to public health, and formulation of relevant general principles.

~~[Nutritional risk management decisions should take into account, the actual, or likely, impact on consumers' behaviour, such as dietary patterns and preparation practices, which are cultural habits, in order to anticipate possible product substitutions and to ensure an overall risk reduction.]~~

> Comment: The United States suggests the above edits to the first paragraph in lieu of retaining the second paragraph. This document is intended to provide general principles for the work of CCNFSDU rather than specific guidance to governments in the conduct of their own nutritional risk analyses. In the latter case, additional factors may be considered, and the assessment of impacts on behaviors and/or dietary patterns at the national or regional level may be more feasible—although still challenging.

SECTION 6 – SELECTION OF RISK ASSESSOR BY CCNFSDU

32. Consistent with their important role in providing scientific advice to Codex Alimentarius and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. However, this role does not preclude the choice of other sources of advice such as appropriate international expert groups or organizations ~~[~~as well as national relevant expertise~~,~~] if and when justified.

> Comment: With the qualifying text of "if and when justified", the United States supports retaining the bracketed text and removal of the brackets.

SECTION 7 – REVIEW PROCESS

34. These Nutritional Risk Analysis Principles should be reviewed by CCNFSDU at appropriate intervals after implementation to ensure currency and consistency with ~~[good regulatory practice]~~ **advances in nutritional risk assessment** and ~~subsequent to~~ any future amendments to the Codex Working Principles.

> Comment: The United States offers the above edits for the Committee's consideration, consistent with the reference in paragraph 22 to recognizing scientific advances in nutritional risk assessment.

PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 4

AGENDA ITEM NO. 6

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, paras 79-97)
- Proposed Draft Recommendations (CX/NFSDU 08/30/6, September 2008)
- Comments at Step 3 (CX/NFSDU 08/30/6-Add.1) *not yet available*

At the last meeting, the Committee agreed that these draft recommendations, when finalized, would be included as an Annex in the Codex *Guidelines for Use of Nutrition and Health Claims*. The Committee discussed the organization of the document and the sections on scope, definitions, and evaluation of the scientific evidence.

The Committee could not come to a conclusion on the provisions for scientific evidence or reorganization of the text and agreed that an electronic working group (eWG) led by France with the assistance of interested delegations would revise the document in light of the comments.

Please refer to the above document(s) for additional background.

DRAFT POSITION

The United States would like to express its appreciation to the Delegation of France for their leadership in chairing an eWG to facilitate progress on this agenda item. The United States only received this document on September 19, 2008, and thus has not yet formulated a draft position. In the interim, we offer a few general comments below that were shared earlier as part of the eWG.

The United States believes that this document should focus on the ***systematic review*** of scientific evidence for the three categories of health claims as defined by Codex, and that the same principles for the review of scientific evidence generally apply to all three categories. We believe this type of information will be most useful to governments and may have the highest likelihood for reaching Committee consensus. The U.S. Food and Drug Administration (U.S. FDA) has evaluated health claims for about 15 years, and has recognized the importance of a systematic review of the scientific evidence. This importance is illustrated by the U.S. FDA's publication last year of ***draft*** guidance for industry on an "Evidence-Based Review System for the Scientific Evaluation of Health Claims". http://www.cfsan.fda.gov/~dms/hclmgui5.html

Moreover, the U.S. believes there are universal steps and a logical sequence in the systematic review of scientific studies to determine whether a health claim is substantiated, and that this document should generally be organized to reflect this-- considering Sec. 5 "Step-by-Step Process" (CX/NFSDU 07/29/6, September 2007) as a basis.

For example, these steps include:

- Identify the criteria for substantiation and other policies for health claims.
- Identify the proposed relationship between the food or food constituent and the health effect.
- Identify appropriate measurements for the food or food constituent and the health effect.
- Identify and categorize all relevant studies.
- Assess and interpret each relevant study.
- Evaluate the totality of the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING AT STEP 4

AGENDA ITEM No. 7

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, para 122-139)
- Draft recommendations and general principles (CX/NFSDU 08/30/7, September 2008)

Section 3.4.4 on the Codex *Guidelines on Nutrition Labelling* (hereafter referred to as "the Guidelines") provides a list of Nutrient Reference Values (NRVs) for protein and 14 vitamins and minerals for food labeling purposes. At the last meeting, the Committee recalled that an eWG coordinated by the Delegation of the Republic of Korea was requested to revise a discussion paper on revising and expanding this list and to address the following issues: principles for the establishment of NRVs and the need to establish NRVs for different population groups.

The Committee agreed that the scope of the document should be limited to vitamins and minerals, and that use of NRVs should be limited to food labeling purposes. It further agreed to develop general principles for the establishment of NRVs for the general population as a first step, and later consider general principles for establishing NRVs for infants and young children.

The Committee agreed to request the 31st Session of the Codex Alimentarius Commission to approve new work on the revision of the NRVs for vitamins and minerals. The Commission agreed to the Committee's proposal.

Please refer to the above documents for additional background.

DRAFT POSITION

The United States would like to express its appreciation to the Delegation of the Republic of Korea for their leadership in chairing an eWG to facilitate progress on this very challenging agenda item and for preparing CX/NFSDU 08/30/7 (hereafter referred to as "the document") for the Committee's consideration.

Below are a few preliminary comments on this document that mainly focus on paragraph 7 (and Recommendation #2).

Paragraph 7 in the document states:

> "Prior to starting this proposed work, the Committee needs to determine if it may be appropriate to update and extend the current NRVs in these guidelines as opposed to identifying only general principles for governments to derive their own set of food

> labeling values, considering the increased complexity in establishing the specific international food labeling values since the Helsinki consultation."

I. Increased Complexity of Establishing International Food Label Reference Values

The United States agrees that it is important for the Committee to consider the increased complexity of this proposed work compared to that previously undertaken by this Committee when it considered the recommendations of the 1988 Helsinki FAO/WHO Expert Consultation in establishing the existing NRVs[1].

Number of Nutrients. For example, NRVs are currently provided for *only 14 vitamins and minerals* in these Codex guidelines. In contrast, the U.S. Institute of Medicine (IOM) has established recommended intakes for *more than two dozen* vitamins and minerals. (These include "Recommended Dietary Allowances" for nutrients with an "Estimated Average Requirement" (EAR) or "Adequate Intakes" for those for which an EAR could not be determined.)

Number of Recommendations. Moreover, paragraph 10 of the document states that "many member nations and authoritative bodies have established multiple categories of nutrient intake values". As noted in a recent article in the Food and Nutrition Bulletin (United Nations University)[2]:

> "The amounts of nutrient intakes recommended vary considerably from country to country. Also the terms used to describe the intake values differ. For example, some countries recommend a single value that serves as a recommended intake for all members of a population subgroup, whereas other countries recommend four different values: a lower reference intake, an average requirement, a recommended intake for nearly all members of a population group, and an upper tolerable level or limit. …Furthermore, there is no standard method or approach for deriving these different nutrient intake values".

Insufficient Scientific Basis for Some Recommendations. In addition, other categories of nutrient reference values (e.g., the IOM "Adequate Intake" values) may be established when there are insufficient data to determine a statistical distribution of requirements (including EAR and RDA). These may be expressed either as a single value or range and are derived in different ways.

Special Considerations for Certain Nutrients. Moreover, if this new work were to encompass establishing an NRV for a mineral such as "sodium" (for which the Helsinki Consultation did not propose an NRV), the Committee might need to consider additional quantitative intake

[1] Throughout our comments, we use the term "NRV" to refer only to Nutrient Reference Values for food labeling purposes that have been established by the Codex Alimentarius, and not to other label reference values that may be established by governments.

[2] King JC, Vorster HH, and Tome DG. Nutrient intake values (NIVs): A recommended terminology and framework for the derivation of values. Food and Nutrition Bulletin, vol. 28, no. 1 (supplement). S16-S26.

recommendations provided in dietary guidance at the national, regional and/or international levels.

Additional Considerations in the Absence of Input by an Expert Consultation. Finally, the U.S. notes the increase in amount of work by CCNFSDU if it is to be done *de novo* as opposed to this Committee's previous role in consideration of recommendations for NRVs proposed by a Joint FAO/WHO Expert Consultation. However, regardless of who would propose revised and additional international food label reference values for vitamins and minerals (i.e., CCNFSDU or expert consultation), it is still unclear how a single food label reference value for each nutrient for global application would be derived.

II. Appropriateness of International versus Country- or Region- Specific Food Label Reference Values

Recommended intakes (and consequently food label reference intakes) may take into account factors specific to a country or region--such as the bioavailability of food sources for a nutrient such as iron. For example, the 1998 joint FAO/WHO expert consultation held in Bangkok proposed Recommended Nutrient Intakes for iron for four different levels of bioavailability (ranging from 5 to 15 percent). There is also increased recognition of the wide range of country/region specific factors that can influence nutrient absorption and utilization.[3] Moreover, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group.

Consequently, if the Committee decides to continue work to revise and expand the vitamin and mineral NRVs, the U.S. recommends: 1) retaining the language proposed in the preamble of the Annex in the document to clarify that it may be appropriate and desirable for a government to establish its own food label reference values, and 2) revising or deleting the introductory text to Sec. 3.4.4 in the Guidelines that states that the "Nutrient Reference Values should be used for labeling purposes in the interests of international standardization and harmonization"—thus implying that all food label reference values should be uniform.

III. Use of International versus Country- or Region- Specific Food Label Reference Values

Recommendation 2 in the document proposes that in considering whether to include specific international food labeling values in the Guidelines, the Committee may wish to consider the extent to which NRVs are used by member countries. The U.S. agrees that this input would be useful. In addition, the Committee may wish to consider whether to inquire about the extent to which: 1) food label reference values *have been developed* at the national level and regional level, and 2) interest among Codex members in guidance or principles for developing food label reference values at the national or regional level.

[3] Gibson, Rosalind. The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. *Food and Nutrition Bulletin,* vol. 28, no. 1 (supplement). 2007. The United Nations University. http://www.unu.edu/unupress/food/FNBv28n1_Suppl1_final.pdf

IV. Possible Options for CCNFSDU to Consider for General Population Reference Values

The Committee may wish to further consider the desirability and feasibility of the following options with respect to food label reference values for vitamins and minerals for the general population:

1) CCNFSDU Development of both Principles and Specific NRVs

2) CCNFSDU Development of Principles and Request for FAO/WHO Expert Consultation to Propose Specific NRVs

3) CCNFSDU Development of Principles to Guide the Development of Country or Regional Food Label Reference Values[4]

VI. Time Frame for Completing Work

If the Committee decides to proceed with option 1, the United States seeks clarification about the timeframe for completing this work as identified on p. 2 of the document. Specifically, the United States asks about the intended meaning of the third bullet (i.e., Is it intended to refer to the adoption of vitamin and mineral NRVs *for the general population* by 2012)?

[4] Presumedly, this option would then necessitate changing the connotation of an NRV in these guidelines and other Codex texts to refer to food labeling values established by governments as opposed to the Codex Alimentarius Commission.

DISCUSSION PAPER ON THE PROPOSAL FOR NEW WORK TO AMEND THE CODEX PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS

AGENDA ITEM No. 8

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, para 141-148)
- Discussion Paper (CX/NFSDU 08/30/8) *not yet available*

At the last meeting, the Delegation of Canada introduced a discussion paper. The Delegation indicated that the general Principles were adopted in 1987 and proposed new work to revise the General Principles that would address three issues: addition or enhancement of the levels of essential nutrients to foods by indirect means, including biofortification; discretionary addition of vitamins and minerals to food; and addition of bioactive substances that are non essential constituents of foods.

After some discussion, the Committee noted that the work on the revision might proceed in areas where it could be possible to get an agreement and requested that the Delegation of Canada prepare a revised document, narrowing its scope in light of the comments .

Please refer to the above documents for additional background.

DRAFT POSITION

The United States has not yet received the discussion paper.

DISCUSSION PAPER ON THE PROPOSAL FOR NEW WORK TO ESTABLISH A STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR UNDERWEIGHT INFANTS AND YOUNG CHILDREN

AGENDA ITEM No. 9

BACKGROUND

Reference:

- Report of the 29th CCNFSDU Session (ALINORM 08/31/26, para 134-140)
- Discussion Paper (CX/NFSDU 08/30/9) *not yet available*

At the last meeting, the Delegation of India urged the Committee to start working on a separate standard for Processed Cereal-Based Foods for Underweight Infants and Young Children so that nutritionally and energy dense composition in the proposed standard will help reduce the burden of malnutrition in developing countries. Several delegations and observers supported the spirit of the document and volunteered to join India to develop a revised version containing analysis and proposals on how the Committee could address this issue.

The Committee agreed that the Delegation of India with assistance from other interested parties working electronically would revise the document in light of comments at this session and prepare a more structured document for consideration by the next session of the Committee.

Please refer to above document(s) for additional background.

DRAFT POSITION

The United States has not yet received the discussion paper.

Table: Analytical Methods for Infant Formulas and Formulas for Special Medical Purposes Intended for Infants

Submitted by the United States to the CCNFSDU eWG on Infant Formula Methods, March, 2008

Table 1. Methods of Analysis for Infant Formula and Formulas for Special Medical Purposes Intended for Infants

Provision	Method	Principle	Performance Information	Type	Comment
Calories (by calculation)	Method described in CAC/Vol IX-Ed.1, Part III	Calculation method		III	This method is appropriate for infant formula
Protein	ISO 8698-1/2 | IDF20-1/2: 2001 | AOAC 991.20	Titrimetry, Kjeldahl digestion[5]	Validated	II	AOAC 991.20 Nitrogen (Total) in Milk; Kjeldahl Methods, First Action 1991, Final Action 1994; IDF-ISO-AOAC method. Official Methods of AOAC Int. (18th ed., 2005): 33.2.11. Reference: JAOAC 73: 849 -859 (1990). Results of interlaboratory study parameters obtained in collaborative study of this method, r value = 0.038 and R value = 0.049.
Amino acid profile	AOAC 960.47	Microbiological	Validated	II	AOAC 960.47 Amino Acids in Vitamin Preparations (Microbiological Method), First Action 1960; Official Methods of AOAC Int. (18th ed., 2005): 45.2.07. References: JAOAC 41: 420 - 423 ; 679 - 681 (1958) JAOAC 43: 34- 37 (1960).

[5] The calculation of the protein content of infant formulas prepared ready for consumption may be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

Provision	Method	Principle	Performance Information	Type	Comment
					Applicable only to materials containing free forms of amino acids in the absence of appreciable amount of protein.
Total fat	AOAC 996.06	Gas liquid chromatography	Validated	II	AOAC 996.06 Fat (Total, Saturated, and Unsaturated) in Foods, Hydrolytic Extraction Gas Chromatographic Method; First action 1996; Revised 2001. Official Methods of AOAC Int. (18th ed., 2005); 41.1.28A. References: J.AOAC Int. 80: 555 - 563 (1997) J.AOAC Int. 82: 1146 - 1155 (1999). The method has been validated in the following matrices: wheat-based cereal, peanut butter, fish sticks, parmesan cheese, chocolate cake, fruit snack, and ground beef. Total fat levels included: 1.46-46.3%

Provision	Method	Principle	Performance Information	Type	Comment
Fatty acids	AOAC 996.06	Gas liquid chromatography	Validated	II	AOAC 996.06 Fat (Total, Saturated, and Unsaturated) in Foods, Hydrolytic Extraction Gas Chromatographic Method; First action 1996; Revised 2001. See references for AOAC 996.06 Fatty acids can be obtained as part of this method. Retention data for fatty acids from 4:0 to 22:6 are provided. Method should be considered as a Type II method for quantitation of individual fatty acids.
Trans fatty acids	AOAC 996.06	Gas liquid chromatography	Validated	II	See references for AOAC 996.06 and J AOAC Int. 91:92-97 (2008) *Trans* fatty acids can be determined by gas chromatography using AOAC 996.06 or AOCS Ce 1h-05. Validated IR methods are also available. Method should be considered as a Type II method for quantitation of individual fatty acids, including trans.
	AOCS Ce 1h-05	Capillary GLC	Validated	II	AOCS Official Method Ce 1h-05. Determination of *cis*, *trans*, Saturated, Monounsaturated and Polyunsaturated Fatty Acids in Vegetable or Non-Ruminant Animal Oils and Fats by Capillary GLC. Approved 2005; Revised 2005. Performance statistics were extracted from the collaborative study report and are included with the

Provision	Method	Principle	Performance Information	Type	Comment
					method.
Total phospholipids	AOCS Ja7b-91	HPLC	Validated	IV	AOCS Official Method Ja 7b-91. Determination of Lecithin Phospholipids by HPLC; Reapproved 1997. Reference: Pure Appl. Chem. 64: 447 - 454 (1992) The method allows the direct determination of single phospholipids (PE, phosphatidylethanolamine; PA, phosphatidic acid; PI, phosphatidylinositol; PC, phosphatidylcholine) in lecithin by high-performance liquid chromatography. The method is applicable to oil-containing lecithins, deoiled lecithins, lecithin fractions; not applicable to lyso-PC and lyso-PE. A summary of statistics from the IUPAC phospholipid collaborative study is included with the method.

Provision	Method	Principle	Performance Information	Type	Comment
Total carbohydrates	AOAC 986.25	Determination by difference, i.e. the remainder after deducting fat, ash, crude protein, moisture and crude fibre from total solids.	Validated	II	AOAC 986.25 Proximate Analysis of Milk-Based Infant Formula. First action 1986; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005); 50.1.16. References: JAOAC 69: 777 - 785 (1986) JAOAC Int. 88: 714-719 (2005). Carbohydrates are determined by difference: Carbohydrate = total solids - (proteins + fat + ash). Using the difference method, carbohydrate values determined "by difference" can include fibers, organic acids, and a broad range of phenolic compounds. A recent literature report (Lilla, Z., Sullivan, Ellefson, W., Welton, K. & Crowley, R. 2005. Determination of "Net Carbohydrates" Using High Performance Anion Exchange Chromatography" JAOAC Int. 88: 714-719) addresses this problem. In the method, enzyme digestions are used to convert starches, dextrins, sugars and polysaccharides to their respective monosaccharide components. These are then quantified by high-performance anion exchange chromatography with a pulsed amperometric detector and expressed as total non-fiber saccharides or percent "net carbohydrates". The method has been tested in more than a dozen foods including sports drinks, sugar substitute, low-carbohydrate mashed potatoes, tortilla, protein bar, vegetables, maltodextrin, pasta, cheese puffs, powdered drink mixes, and coleslaw, among others.

Provision	Method	Principle	Performance Information	Type	Comment
Vitamin A[6]	AOAC 992.04 (retinol isomers)	Liquid chromatography	Validated	II	AOAC 992.04 Vitamin A (Retinol Isomers) in Milk and Milk- Based Infant Formula, Liquid Chromatographic Method; First Action 1992; Final Action 1995. Codex-Adopted-AOAC Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.02. Reference: J.AOAC Int. 76: 399 - 413 (1993). The method is applicable to the determination of all-*trans* retinol and 13-*cis* -retinol in milk and milk-based infant formula. Study matrices included powdered infant formula, powdered milk, and liquid infant formula. Adopted as a Codex Reference Method (Type II) for liquid chromatography of vitamin A (retinol esters) in infant formula and follow-up formula].

[6] Expressed as retinol equivalents (RE)

Provision	Method	Principle	Performance Information	Type	Comment
	AOAC 992.06 (retinol)	Liquid chromatography	Validated	II	AOAC 992.06 Vitamin A (Retinol) in Milk-Based Infant Formula Codex. Liquid Chromatogaphic Method; First Action 1992. Codex-Adopted-AOAC Method. Official Methods of AOAC Int. (18th ed., 2005): 50:1:03. Reference: J. AOAC Int. 76: 399- 413 (1993). Applicable to milk-based formulas with > 500 IU vitamin A per reconstituted quart. 13-*cis* vitamin A palmitate is not readily available. A standard curve for *all-trans* vitamin A palmitate is used to determine biological potencies for both, correcting for 13-*cis* -vitamin A at 0.75 potency relative to *all-trans* isomer. Adopted as Codex Reference Method (Type II) for liquid chromatography of vitamin A (retinol) in infant formula and follow-up formula.
Vitamin D_3[7]	AOAC 992.26	Liquid chromatography	Validated	II	AOAC Method 992.26 Vitamin D3 (Cholecalciferol) in Ready-to Feed Milk-Based Infant Formula. Liquid Chromatographic Method; First Action 1992; Final Action 995. Codex-AOAC Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.05. References: J. AOAC 68: 177- 182 (1985)

[7] Calciferol

Provision	Method	Principle	Performance Information	Type	Comment
Vitamin D	AOAC 995.05	Liquid chromatography	Validated	III	J. AOAC Int. 76: 1042 - 1056 (1993). The method is applicable to ready-to-feed milk-based infant formulas containing 488 to 533 IU/L vitamin D3. Adopted as Codex Reference Method (Type II) for liquid chromatography of vitamin D (D3, milk-based infant formula) in special foods. AOAC Method 995.05 Vitamin D in Infant Formulas and Enteral Products. Liquid Chromatographic Method. First Action 1995. Official Methods of AOAC Int. (18th ed., 2005): 50.1.23. References: J. AOAC Int. 75: 566 - 571 (1992) J. AOAC Int. 79 : 73 - 80 (1996). The method is applicable to the determination of 8 to 2600 IU (International Unit; 1 microgram vitamin D = 40 IU) vitamin D/quart (1 quart = 0.946 L) in infant formulas and enteral products. The results of the interlaboratory study supporting acceptance of the method are included in the method.
Vitamin E[8]	AOAC 992.03	Liquid chromatography	Validated	II	AOAC 992.03 Vitamin E Activity (all-rac-α -

[8] Alpha-tocopherol equivalent (α-TE)

Provision	Method	Principle	Performance Information	Type	Comment
					Tocopherol) in Milk-Based Infant Formula. Liquid Chromatography Method. First Action 1992; Final Action 1996. Codex-Adopted-AOAC Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.04. Reference: J. AOAC Int. 76: 399 - 413 (1993). The method is applicable to the determination of vitamin E activity in milk-based infant formula. The results of the interlaboratory study supporting acceptance of the method (milk-based liquid, ready-to-feed) are stated in the method. Adopted as a Codex Reference Method (Type II) for liquid chromatography of vitamin E (milk based infant formula) in special foods.

Provision	Method	Principle	Performance Information	Type	Comment
Vitamin K	AOAC 999.27	Liquid chromatography	Validated	III	AOAC Method 992.27 *trans*- Vitamin K1 (Phylloquinone) in Ready-to-Feed Milk-based Infant Formula. Liquid Chromatographic Method. First Action 1992; Final Action 1995. Codex-AOAC Method. Official Methods of AOAC Int. (18th ed.,2005): 50.1.06 References: JAOAC 68: 684 - 689 (1985) J. AOAC Int. 76: 1042 - 1056 (1993) The method is applicable to ready-to-feed milk-based infant formulas containing 75 to 130 micrograms/L *trans*-vitamin K1. Adopted as a Codex Reference Method (Type II) for liquid chromatography of vitamin K1 in infant formula and follow-up formula.

Provision	Method	Principle	Performance Information	Type	Comment
	AOAC 999.15	Liquid chromatography	Validated	II	AOAC Method 999.15 Vitamin K in Milk and Infant Formulas. Liquid Chromatographic Method. First Action 1999; Final Action 2003. Official Methods of AOAC Int. (18th ed., 2005): 50.1.25. Reference: J. AOAC Int. 83: 121- 130 (2000). The method is applicable to the detetmination of total vitamin K1 (phylloquinone) in infant formula and milk (fluid, ready-to-feed, and powdered) containing > 1 microgram vitamin K1/100 g solids). Matrices included in the interlaboratory study were as follows: unfortified whole liquid UHT milk; goat milk powder; milk-based infornat formula, oil-filled; whey-based infant formulas, partially oil-filled; soy-based infant formula, oil-filled; whey-based infant formula, oil-filled; NIST SRM 1846. The results of the interlaboratory study supporting acceptance of the method are included in the method.
Thiamin	AOAC 942.23	Fluorimetry	Validated	IV	AOAC 942.23 Thiamine (Vitamin B1) in Human and Pet Foods. Fluorometric Method. First Action 1942. Final Action year not specified. Official Methods of AOAC Int. (18th ed., 2005): 45.1.05. References: JAOAC 25: 456- 458 (1942); JAOAC 27: 534 - 537 (1944) ; JAOAC 28: 554 -

Provision	Method	Principle	Performance Information	Type	Comment
					559 (1945); JAOAC 31: 455 - 459 (1948); JAOAC 43: 45 - 46 (1960); JAOAC 43: 55 - 57 (1960); AND JAOAC 64: 1336 - 1338 (1981). The method is not applicable in presence of materials that adsorb thiamin or which contain extraneous materials which affect thiochrome. Codex-Adopted AOAC Method (Codex Reference Method (Type II) for thiamin in special foods).
Riboflavin	AOAC 986.27	Fluorimetry	Validated	II	AOAC 986.27 Thiamine (Vitamin B1) in Milk-Based Infant Formula. Fluorometric Method. First Action 1986; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.08. Reference: JAOAC 69: 777 - 785 (1986). The method is applicable to all food products. Thiamine content of extract is estimated by oxidizing thiamine to thiochrome and measuring fluorescence. Intensity of fluorescence is proportional to thiamine concentration.
	AOAC 985.31	Fluorimetry	Validated	II	AOAC 985.31 Riboflavin in Ready-to-Feed Milk-Based Infant Formula, Fluorometric Method. First Action 1985; Final Action 1988.

Provision	Method	Principle	Performance Information	Type	Comment
					Official Methods of AOAC Int. (18th ed., 2005): 50.1.07. Reference: JAOAC 68: 514 - 522 (1985). Official Methods of AOAC Int. (18th ed., 2005) cross-references AOAC 985.31 to AOAC 970.65 [45.1.08; Riboflavin (Vitamin B2) in Foods and Vitamin Preparations, Fluorometric method, First Action 1970; Final Action 1971]. AOAC 970.65 dates from the 1970s. Literature references for AOAC 970.65 date to 1940 and are not included here.
Niacin[9]	AOAC 985.34 (niacin (preformed) and nicotinamide)	Microbioassay and turbidimetry	Validated	II	AOAC 985.34 Niacin and Niacinamide (Nicotinic Acid and Nicotinamide) in Ready-to-Feed Milk-Based Infant Formula; Microbiological-turbidimetric method. First Action 1985; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.19. Reference: JAOAC 68: 514 - 522 (1985). The method is applicable to baby foods (meat based), beverages, juices, cereal products, cheese, dairy products, fruits and potato products. Note on LC method under development:

[9] Niacin refers to preformed niacin

Provision	Method	Principle	Performance Information	Type	Comment
					JAOAC Int. 84:789 (2001) and J AOAC Int. 85:654 (2002) These reports describe the development of a method for the determination of niacin in infant formula. The method met AOAC Peer-Verified Method criteria. No collaborative study has been performed and a single matrix (i.e., SRM 1846) was tested by two laboratories in the Peer-Verified procedure. Further study is required before it would be considered a validated method.
Vitamin B_6	AOAC 985.32	Microbioassay	Validated	III	AOAC Method 985.32. (Pyridoxine, Pyridoxal, Pyridoxamine) in Ready-to Feed Milk-Based Infant Formula Microbiological Method. First Action 1985; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.18. Reference: JAOAC 68: 514 - 522 (1985).
	AOAC 2004.07	Liquid chromatography	Validated	II	AOAC Method 2004.07. Vitamin B6 in Reconstituted Infant Formula, Liquid Chromatographic Method. First Action 2004. Official Methods of AOAC Int. (18th ed., 2005): 50.1.26. Reference: JAOAC Int. 88: 30 - 37 (2005). The method is applicable to the determination of vitamin B6 in milk- and soy based liquid infant formula at 0 -1mg/100g.

Provision	Method	Principle	Performance Information	Type	Comment
					Results of the interlaboratory study for vitamin B6 in reconstituted infant formula (milk- and soy-based) are included with the method.
Vitamin B_{12}	AOAC 986.23	Turbidimetry	Validated	II	AOAC Method 986.23 Cobalamin (Vitamin B12 Activity) in Milk-Based Infant Formula. Turbidimetric method (microbiological). First Action 1986; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.20. Reference: JAOAC 69: 777 - 785 (1986).
Pantothenic acid	AOAC 992.07	Microbioassay	Validated	II	AOAC Method 992.07 Pantothenic acid in Milk-Based Infant Formula, Microbiological Turbidimetric Method. First Action 1992; Final Action 1995. Official Methods of AOAC Int. (18th ed., 2005): 50.1.22. Reference: J. AOAC Int. 76: 399 - 413 (1993). The method is applicable to the determination of pantothenic acid in milk-based infant formula. Results of the interlaboratory study supporting acceptance of the method (milk-based liquid, ready-to-feed) are presented in the method.
Folic acid	AOAC 992.05	Microbioassay	Validated	II	AOAC Method 992.05 Folic Acid (Pteroylglutamic Acid) in Infant Formula. Microbiological Method. First Action 1992; Final Action 1995.

Provision	Method	Principle	Performance Information	Type	Comment
					Official Methods of AOAC Int. (18th ed., 2005): 50.1.21. Reference: J. AOAC Int. 76: 399 - 413 (1993). The method is applicable only to the free form of folic acid. Results of the interlaboratory study supporting acceptance of the method (milk-based, ready-to-feed) are listed in the method. AOAC Method 992.05 does not incorporate improvements in extraction procedure found in AOAC 2004.05.
	AOAC 2004.05	Microbioassay with Trienzyme Preparation	Validated	II	AOAC Method 2004.05 Total Folates in Cereals and Cereal Foods. Microbiological Assay-Trienzyme Procedure. Official Methods of AOAC Int. 18th ed., 2005): 45.2.09. Reference: J. AOAC Int. 88: 5 - 15 (2005). The method is applicable to cereal grains and cereal grain foods containing added folate (folic acid) or naturally occurring folates with levels from 7.6 microgram/100g to 100% folate. Collaborative study matrices included fortified and unfortified flour, enriched bread, enriched macaroni, oat cereal, wheat cereal, rice cereal, tortilla, baking mix, and infant formula SRM 1846. Interlaboratory study results of the trienzyme method for determination of folate in cereal grain and grain

Provision	Method	Principle	Performance Information	Type	Comment
					products are included in the method.
Vitamin C[10]	AOAC 985.33	2,6-dichloroindophenol titrimetry	Validated	II	AOAC Method 985.33 Vitamin C (Reduced Ascorbic Acid) in Ready-to-Feed Milk-Based Infant Formula; 2,6-Dichloroindophenol titrimetric method; First Action 1985; Final Action 1988; Revised June 2003. Official Methods of AOAC Int. (18th ed., 2005): 50.1.09. References: J. AOAC 68: 514 - 522 (1985). In this method, ascorbic acid is estimated by titration with colored oxidation-reduction indicator, 2,6-dichloroindophenol. EDTA is added as chelating agent to remove Fe and Cu interferences.
Biotin	J AOAC Int 89:1515-1518 (2006)	HPLC	Not validated	IV	There is currently no AOAC Official Method. A recent publication (Thompson, L.B., Schmitz, S.J. & Pan, S.-J, 2006. Determination of Biotin by High-Performance Liquid Chromatography in Infant Formula, Medical Nutritional Products and Vitamin Premixes. JAOAC Int. 89: 1515-1518) describes an HPLC method that has been tested with infant formulas, medical nutritional products and vitamin premix samples. Reference: J. AOAC Int. 89: 1515 - 1518 (2006).

[10] Expressed as ascorbic acid

Provision	Method	Principle	Performance Information	Type	Comment
Iron	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). First Action 1984; Final Action 1986. Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	AOAC Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. First Action 1985; Final Action 1988; Revised First Action 1997. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). The method is applicable to the determination of Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Interlaboratory study matrices include enteral

Provision	Method	Principle	Performance Information	Type	Comment
					product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method.
Calcium	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	AOAC Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). The method is applicable to the determination of

Provision	Method	Principle	Performance Information	Type	Comment
					Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method.
Phosphorus	AOAC 986.24	Spectrophotometry	Validated	III	AOAC 986.24 Phosphorus in Infant Formula and Enteral Products; Spectrophotometric Method. First Action, 1986; Final Action 1988. Revised First Action 1997. Official Methods of AOAC Int. (18th ed., 2005): 50.1.12. References: JAOAC 69: 777 - 785 (1986) J. AOAC Int. 80: 834 - 844 (1997). The collaborative study was performed with soy powder infant formula, whey powder infant formula, soy ready-to-feed formula and enteral formula. The results of the interlaboratory study supporting acceptance of the method are included in the method.

Provision	Method	Principle	Performance Information	Type	Comment
	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
Magnesium	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. Applicable to Ca, Mg,

Provision	Method	Principle	Performance Information	Type	Comment
					Fe, Zn, Cu, Mn, Na, and K. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method.
Sodium	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.

Provision	Method	Principle	Performance Information	Type	Comment
Potassium	AOAC 984.27	Atomic absorption spectrophotometry	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	AOAC Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. Applicable to Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as AOAC

Provision	Method	Principle	Performance Information	Type	Comment
					986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method.
Chloride	AOAC 986.26	Potentiometry	Validated	II	AOAC Method 986.26 Chloride in Milk-Based Infant Formula; Potentiometric Method. First Action 1986; Final Action 1988. Official Methods of AOAC Int. (18th ed., 2005): 50.1.10. Reference: JAOAC 69: 777 - 785 (1986). The product is dispersed with water and acidified; soluble chlorides are titrated potentiometrically with AgNO3. [Codex-Adopted-AOAC Method].
Manganese	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP

Provision	Method	Principle	Performance Information	Type	Comment
					emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	AOAC Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). Applicable to Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as 986.24 phosphorus).

Provision	Method	Principle	Performance Information	Type	Comment
Iodine	AOAC 992.24	Ion-selective potentiometry	Validated	II	AOAC Method 992.24 Iodide in Ready-to-Feed Milk-Based Infant Formula; Ion-Selective Electrode Method. First Action, 1992; Final Action, 1995. Codex-Adopted-AOAC Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.13. Reference: J AOAC Int. 76: 1042 - 1056 (1993). The method is applicable to ready-to-feed milk-based infant formula containing 75-150 microgram/L iodide. Protein in ready-to-feed (RTF) milk-based infant formula test portions is removed by acid-precipitation. Iodide in filtrate is determined using an ion-selective electrode and method of known addition. Nickel nitrate is added to reduce interferences to iodide response of electrode. The results of the interlaboratory study supporting acceptance of the method (ready-to-feed milk-based infant formula) are stated in the method.
Selenium	AOAC 996.17	Continuous hydride generation atomic absorption (HGAA)	Validated	II	AOAC 996.17 Selenium in Food and Premixes; Continuous Hydride Generation Atomic Absorption (HGAA) Method. First Action 1996; Final Action, 1997. Official Methods of AOAC Int. (18th ed., 2005): 4.8.16. Reference: J. AOAC Int. 80: 469 - 480 (1997).

Provision	Method	Principle	Performance Information	Type	Comment
					Interlaboratory study included samples with selenium levels from 0.25 to 5,450 micrograms/g. Accuracy of method was substantited by in-house analyses of NIST SRMs (1657 Wheat Flour; 1577a Bovine Liver; 1643c Trace Elements in Water). The results of the interlaboratory study supporting acceptance of the method are listed in the method.
	AOAC 2006.03	ICP-emission spectroscopy	Validated	II	AOAC 2006.03 Arsenic, Cadmium, Cobalt, Chromium, Lead, Molybdenum, Nickel, and Selenium in Fertilizers (Microwave Digestion and Inductively Coupled Plasma-Optimal Emission Spectrometry). First Action 2006. Official Methods of AOAC Int. (18th ed., 2005): 2.6.35. Reference: J. AOAC Int. 89: 1447 – 1466 (2006). Interlaboratory study included samples with selenium levels from 0.25 to 257 micrograms/g. The results of the interlaboratory study supporting acceptance of the method are included in the method.
Copper	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively Coupled Plasma Emission Spectroscopic Method

Provision	Method	Principle	Performance Information	Type	Comment
					(multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	AOAC Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). Applicable to Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method.
Zinc	AOAC 984.27	ICP emission spectroscopy	Validated	II	AOAC Method 984.27. Calcium, Copper, Iron, Magnesium, Manganese, Phosphorus, Potassium, Sodium, and Zinc in Infant Formula, Inductively

Provision	Method	Principle	Performance Information	Type	Comment
					Coupled Plasma Emission Spectroscopic Method (multielement method). Official Methods of AOAC Int. (18th ed., 2005): 50.1.15. Reference: JAOAC 67: 985 - 992 (1984). In this method, a test portion is digested in HNO_3 / $HClO_4$ and elements are determined by ICP emission spectroscopy.
	AOAC 985.35	Atomic absorption spectrophotometry	Validated	III	AOAC Method 985.35 Minerals in Infant Formula, Enteral Products, and Pet Foods; Atomic Absorption Spectrophotometric Method. Official Methods of AOAC Int. (18th ed., 2005): 50.1.14. References: JAOAC 68: 514 - 522 (1985) J. AOAC Int. 80: 834 - 844 (1997). Applicable to Ca, Mg, Fe, Zn, Cu, Mn, Na, and K. Interlaboratory study matrices include enteral product, ready-to-feed soy formula, soy powder and whey powder (same matrices as 986.24 Phosphorus). The results of the interlaboratory study supporting acceptance of the method are presented in the method.

Provision	Method	Principle	Performance Information	Type	Comment
Choline	AOAC 999.14		Validated	II	AOAC Method 999.14 Choline in Infant Formula and Milk, Enzymatic Colorimetric Method. First Action 1999; Final Action 2003. Official Methods of AOAC Int. (18th ed., 2005): 50.1.24. Reference: J.AOAC Int. 83: 131 - 138 (2000). Reference: JAOAC 87: 1297-1304 (2004) The method is applicable to the determination of choline in milk and infant formula containing 45-175 mg solids/100 g. The method does not apply to powdered infant formula/milk containing more than 100 mg vitamin C/100 g solids because of ascorbate suppression of color development. The results of the interlaboratory study supporting acceptance of the method are included in the method. Method AOAC 999.14 has been modified recently (See JAOAC Int 87:1297. 2004) and applied to the determination of choline in choline-containing dietary supplements. A procedure has been developed to allow the use of the method in samples in which vitamin C content is high enough to interfere with the analysis
Myo-inositol	None				No AOAC Official method available
L-Carnitine	None				No AOAC Official method available

Provision	Method	Principle	Performance Information	Type	Comment
Taurine	AOAC 997.05	Liquid chromatography	Validated	II	AOAC 997.05 Taurine in Powdered Milk and Powdered Infant Formulae. Liquid Chromatographic Method. First Action 1997; Final Action 2001. Official Methods of AOAC Int. (18th ed., 2005): 50.1.07A. Reference: J.AOAC Int. 80: 860 - 865 (1997). The method is applicable to the determination of taurine (endogenous and supplemental) in powdered milk and powdered infant formula containing 5 to 100 mg/100 g solids. The method is not applicable to protein-hydrolyzed materials. The multilaboratory study was carried out with milk-based infant formulas, soy-based infant formula, whole milk, goats-milk based infant formula. The results for the interlaboratory study supporting acceptance of the method are included in the method.
Total nucleotides	Int. Dairy Journal 17: 596-605 (2007)	Liquid chromatography	Not validated	IV	There is no AOAC Official Method. A recent literature report (Gill, B.D. and Indyk, H.E. 2007. Development and application of a liquid chromatographic method for analysis of nucleotides and nucleosides in milk and infant formulas. Int. Dairy Journal 17: 596-605) describes the simultaneous measurement of AMP, CMP, GMP IMP, UMP and their corresponding

Provision	Method	Principle	Performance Information	Type	Comment
					nucleosides. The method has been applied to the analysis of bovine and human milk, commercial milk-based infant and follow-up formulas, and skim milk powders. Performance parameters include measurement of recoveries and precision. No interlaboratory validation data. Reference: Int. Dairy Journal 17: 596-605 (2007).
Chromium (Section B only)	AOAC 2006.03	ICP-emission spectroscopy	Validated	II	AOAC 2006.03 Arsenic, Cadmium, Cobalt, Chromium, Lead, Molybdenum, Nickel, and Selenium in Fertilizers (Microwave Digestion and Inductively Coupled Plasma-Optimal Emission Spectrometry). First Action 2006. Official Methods of AOAC Int. (18th ed., 2005): 2.6.35. Reference: J. AOAC Int. 89: 1447 – 1466 (2006). Interlaboratory study included samples with selenium levels from 0.25 to 257 micrograms/g. The results of the interlaboratory study supporting acceptance of the method are included in the method
Molybdenum (Section B only)	AOAC 2006.03	ICP-emission spectroscopy	Validated	II	AOAC 2006.03 Arsenic, Cadmium, Cobalt, Chromium, Lead, Molybdenum, Nickel, and Selenium in Fertilizers (Microwave Digestion and Inductively Coupled Plasma-Optimal Emission Spectrometry). First Action 2006.

Provision	Method	Principle	Performance Information	Type	Comment
					Official Methods of AOAC Int. (18th ed., 2005): 2.6.35. Reference: J. AOAC Int. 89: 1447 – 1466 (2006). Interlaboratory study included samples with selenium levels from 0.25 to 257 micrograms/g. The results of the interlaboratory study supporting acceptance of the method are included in the method.