CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 8 **CX/NFSDU 12/34/11**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fourth Session

Bad Soden am Taunus, Germany
3 – 7 December 2012

PROPOSAL TO REVIEW THE CODEX STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)[1]

Prepared by New Zealand

1 INTRODUCTION

At the 32nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) it was agreed that the New Zealand Delegation would prepare a discussion document on the revision of all or part of the Standard for Follow-up Formula (CODEX STAN 156-1987) for consideration by the Committee at its 33rd session in November 2011.

The aim of this document is to highlight areas where diversification of standards for follow-up formula is occurring internationally, and where scientific and technological advances have occurred. As proposed at the 32nd Session of CCNFSDU, New Zealand has examined options for a review. These options range from a full review of the standard to partial review of the main aspects for consideration which are detailed below. These options are presented in the Project Document in Annex One.

2 BACKGROUND

The Codex Standard for Follow-up Formula (CODEX STAN 156-1987, hereafter referred to as 'the Standard') applies to food that is intended for use as a liquid part of the weaning diet for infants and young children aged 6 to 36 months. The Codex Standard is the basis for international trade in follow-up formula products and contains provisions which establish the essential composition, quality, safety and labelling requirements, as well as including provisions for the addition of 'optional ingredients'. However, since the Standard was developed over 20 years ago, follow-up formula has undergone significant development and is now a high growth commodity. The Standard does not incorporate the key directions of the recently reviewed Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)) and may not be providing the guidance required by countries.

Most countries market follow-up formula for infants 6 months of age or older. Data on the global consumption of follow-up formula is limited, and comparison between countries is difficult. In 2008, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) reported that 'it is clear that a large proportion of infants in the 6-12 month age group are consuming follow-up formula, e.g. 65 per cent in Guatemala and in Ireland 60 per cent of infants at 6 months have consumed follow-up formula (FAO/WHO 2008). UBIC consulting reported that the infant formula market is growing rapidly with the development of markets like Asia, particularly China (with a growth rate of 20 per cent p.a. in 2009), Eastern Europe, and to a lesser extent, the Middle East and Latin America (UBIC Consulting 2010). In China consumption has more than doubled in the past five years with reports of 127,100 tonnes of follow-up formula and 173,100 tonnes of growing-up milk products consumed in 2010 (Euromonitor 2011). According to Euromonitor International, the estimated global consumption of follow-up formula in 2010 was in the vicinity of 438,000 tonnes. This compares to the estimated global consumption of 309,000 tonnes in 2005 (My Decker Capital 2010). Notably, it is developing countries within the Asian region that have some of the

[1] presented as CX/NFSDU 11/33/10 at the 33rd Session of the CCNFSDU

highest reported levels of consumption of follow-up formula and growing-up milk products. In particular, of those countries included in the survey, Indonesia is identified as being the second highest consumer of both follow-up formula and growing-up milk products, totalling 161,000 tonnes in 2010 (Euromonitor 2011).

There is an increasing diversification of follow-up formula regulations internationally, and this is expected to continue. With advances in technology, research into infant nutrition and changes in consumption patterns, some countries have updated, or are in the process of updating their domestic regulations. The European Union (EU), Australia and New Zealand have modified their regulations for follow-up formula since the establishment of the Codex Standard. There are other countries that still either use the Standard or have adopted regulations that closely follow the Standard (for example, the Philippines, Taiwan and China). Added to this diversity, a number of countries that are currently working on, or have already developed, specific regulations for growing-up milk (for example, Australia and New Zealand, Malaysia). In many instances, the age range for the growing-up milk products overlaps or falls within that used in the Standard for follow-up formula products.

3 RATIONALE FOR ASPECTS TO BE COVERED

The main aspects to be addressed are:

- the definition of follow-up formula,
- the scope of the Standard,
- the compositional requirements for follow-up formula, and
- labelling requirements.

3.1 Description

Some country authorities adhere to the definitions within the Standard; however others choose to define follow-up formula differently for the purposes of their national regulations. The key points of difference in definitions are the age range for follow-up formula, and whether or not follow-up formula is considered as a breast-milk substitute. Clarification and agreement would therefore be sought on appropriate definitions in the Standard.

The Standard contains the following definitions:

- **Follow-up formula** means 'a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children'.
- **Infants** are defined as 'a person not more that 12 months of age'.
- **Young children** means 'persons from the age of more than 12 months up to the age of three years (36 months)'.
- **Follow-up formula** is further defined as a 'food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have proved to be suitable for infants from the 6th month on and for young children'.

3.1.1 Age range

Discrepancies have arisen in the different regulations countries have developed for follow-up formula with regards to the specified age-range for which the product is intended. The current Codex Standard states that follow-up formula is suitable for infants and young children aged between 6 and 36 months. Several countries use the age range of 6 to 12 months, others follow the Codex age range for follow-up formula products of 6 to 36 months, and others regulate follow-up formula products for consumption by infants over the age of 4 months (e.g. Chile).

Recently revised regulations, such as those of the EU, and Australia and New Zealand, tend to narrow the age range for follow-up formula products to 6 to 12 months. This range coincides with the age that follow-up formula intake is reported to gradually decrease (FAO/WHO 2008). This is consistent with industry reports that many young children move onto growing-up milk formulas after 12 months of age. In addition to the trend in narrowing the age range of follow-up formula in national regulations, separate national regulations for growing-up milk products for young children have been or are being developed (Australia and New Zealand, Malaysia). There is also the situation whereby the age range within some follow-on formula regulations overlaps that used in infant formula regulations.

Taking into consideration the growth in production and consumption of both follow-up formula and growing-up milk products and the differences in the age ranges that they are targeted at, it is proposed that the age range of follow-up formula is reviewed by the Codex Committee. There has been some interest from industry and public health groups to restrict the age range for follow-up formula to 6 to 12 months, and to

explicitly include growing-up milk within the current Standard, or to develop a new standard for growing-up milk products for young children aged 12 to 36 months.

In addition to considering the age range for follow-up formula, a review may also explore the appropriate 'starting age' for follow-up formula. It appears that the majority of countries use 6 months as the appropriate 'starting age' for FUF in their regulations. The 2009 European Food Safety Authority (EFSA) Scientific Opinion on the appropriate age for introduction of complementary feeding of infants (EFSA 2009) concluded that the introduction of complementary food into the diet of healthy term infants in the EU between the age of 4 and 6 months is safe and does not pose a risk for adverse health effects. In addition, while the WHO Expert Consultation on the Optimal Duration of Exclusive Breastfeeding recommends exclusive breastfeeding to 6 months, it acknowledges that exclusive breastfeeding to 6 months can lead to iron deficiency in susceptible infants. It also notes that the available data are insufficient to exclude several other potential risks with exclusive breastfeeding for 6 months, including growth faltering and other micronutrient deficiencies in some infants (WHO 2001). However, both EFSA and WHO note that exclusive breastfeeding for up to six months provides greater protection against the risk of infectious morbidity, this is particularly important in a developing country setting (EFSA 2009; WHO 2001). Whilst the information on non breast-fed infants is limited, a review may consider the above information when considering appropriate age ranges for follow-up formula.

The lack of harmonisation in age ranges applied internationally could create a barrier to trade.

3.2 Essential Composition and Quality Factors

The Standard is now over 20 years old, and there is concern that the scientific and technological advances made in infant and young child nutrition, and infant formula product composition, along with changes in consumption patterns, mean the Standard may be out-dated. This is especially important as many countries rely on the Standard as the basis for their regulations, and the Standard is the default standard for international trade in follow-up formula. Advancements in the science underpinning infant nutrition was considered in detail as part of the review of Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)) and could be taken in to consideration as part of a review of the Standard for follow-up formula.

3.2.1 Protein

The current prescribed level of protein in the Standard of not less than 0.7g per 100 available kilojoules, with the total quantity of protein not being more than 1.3 g per 100 available kilojoules, is considered by some to be too high (Lönnerdal and Chen 1990, Koletzko *et al* 2009, de la Hunty 2009). Recently revised national regulations generally have lower minimum and/or maximum protein levels for follow-up formula products. For example, in the EU the minimum and maximum protein levels are significantly lower, ranging from 0.45 to 0.8g per 100 available kilojoules. The lack of conformity in protein compositional requirements is causing difficulties in trade as a formula produced for Europe may have to be reformulated for a market that follows the Codex Standard to meet the minimum protein requirements set out in the Standard.

Historically follow-on formula contains higher levels of protein than infant formula but the rationale for this is being questioned by some researchers, as protein requirements decrease with age (Lönnerdal and Chen 1990). In a study comparing low protein follow-up formula to commercially available follow-up formula, blood urea nitrogen levels were lower and more similar to breastfed infants in the lower protein formula group. Suggesting that lower protein follow-up formula may be more appropriate (Lönnerdal and Chen 1990). Furthermore, higher protein has been associated with significantly higher weight gain in the first two years of life, while lower protein might reduce the risk of being overweight in later life (Koletzko 2009, de la Hunty 2009). Based on consideration of this evidence, the maximum and minimum protein levels within the Standard may need to be further investigated.

3.2.2 Analysis of Protein Content

There appears to be consensus amongst expert groups that the determination of protein levels in infant and follow-up formula should be based on total nitrogen content multiplied by a conversion factor of 6.25 (Koletzko *et al* 2005, Koletzko 2006, Scientific Committee on Food 2003). This was updated in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)). Additionally, there have been recent advances in the methodology for measuring protein quality. The follow-up formula Standard states that protein quality should be determined using the protein efficiency ratio (PER) based on the rat bioassay, however the WHO now recommend the Protein Digestibility Corrected Amino-acid score (PDCAAS) method in place of PER (WHO/FAO/UNU 2002).

3.2.3 Setting Maximum Nutrient Levels

Recent expert consultations on setting nutrient levels in infant formula and follow-up formula and recently revised national regulations (e.g. in the EU, Australia and New Zealand, and China) have set either maximum or guiding upper levels of intake for many minerals for which maximum upper levels are not specified in the Standard. The rationale for setting maximum levels for nutrients was that infant formula and follow-up formula should only contain components that meet a nutritional purpose, provide another benefit, or are necessary for technological purposes, so as not to place a metabolic or physiological burden on infants (Koletzko 2006; Koletzko *et al* 2005). This was considered in detail in the review of Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)). Maximum levels were determined for nutrients which have a documented adverse effect, and guiding upper levels were set for nutrients with no documented adverse effect. The use of maximum nutrient levels could be considered with regard to follow-up formula to ensure consistency of the two Codex standards that apply to infant formula and follow-up formula.

3.2.4 Optional ingredients

The Standard contains permission for the addition of 'optional ingredients' provided their 'usefulness' has been scientifically shown. This differs to the permission for 'optional ingredients' contained within the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)) which states that 'the suitability for the particular nutritional uses of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk'. In addition, the Codex Standard for Infant Formula lists several substances that may be added provided the maximum or guidance upper level is not exceeded. The addition of 'optional ingredients' to follow-up formula could be considered as part of a review. This consideration could include:

- safety and suitability of optional ingredients;
- the need for minimum, maximum or guiding upper levels;
- level of scientific justification in relation to suitability; and
- whether a positive list of permitted substances be established.

3.2.5 Other specific questions relating to essential composition and quality factors

There are a number of other questions that could be posed as part of a review of the Standard, including:

- Is it necessary to have different levels for iron and zinc in soy-based formulas?
- Should there be different protein levels prescribed for hydrolysed protein-based, and soy protein-based follow-up formulas?
- Are specifications for the fat composition of follow-up formula required, e.g. minimum and maximum limits for essential fatty acids, and saturated and trans-fatty acids?
- Should the definition of 'sugars' be reconsidered?
- Should the use of sesame seed oil and cotton oil be prohibited in follow-up formula products?

3.3 Labelling

3.3.1 Health Claims

The use of claims on food products for infants and young children continues to be a contentious issue. The current Codex Guideline for Use of Nutrition and Health Claims (CAC/GL 23 – 1997) states under section 1.4 that 'nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation". The follow-up formula Standard does not contain any explicit provisions for nutrition and health claims. Some recently updated regulations permit specific content claims on follow-up formula. In the EU some health claims specifically for follow-up formula products have been approved. For example, claims linking DHA consumption with vision are now permitted as a health claim on follow-up formula in Europe (Nutraingredients 2011).

3.3.2 The International Code of Marketing of Breast-milk Substitutes

The WHO International Code of Marketing of Breast-milk Substitutes (the WHO Code) applies to marketing and marketing-related practices in relation to the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods; feeding bottles, and teats (WHO 1981).

The promotion of follow-up formula is a controversial issue due to differences in opinion as to whether follow-up formula falls within the scope of the WHO Code. There is concern amongst many in the international community that the promotion of follow-up formula is not sufficiently regulated, whereas others believe that follow-up formula is not a breast-milk substitute and does not need to be regulated as such.

In the original WHO briefing note on follow-up formula in the context of the International Code of Marketing of Breast-milk Substitutes it is stated that,

> on the assumption that follow-up formula is not marketed or otherwise represented to be suitable as a breast-milk substitute, strictly speaking it does not fall within the scope of the International Code. However, WHO has also made clear that, taking into account the intent and spirit of the Code, there would appear grounds for the competent authorities in countries to conclude otherwise in the light of the way follow-up formula is perceived and used in individual circumstances (WHO 2001).

Many UNICEF publications state that follow-up formula is just as much of a breast-milk substitute as infant formula, and so falls within the scope of the WHO Code. In a 2008 UNICEF report it was proposed that national legislation should strengthen marketing and labelling provisions for all foods marketed as suitable for infants and young children including follow-up formula (UNICEF 2008).

The WHO briefing note on "Follow-Up Formula in the Context of the International Code of Marketing of Breast-milk Substitutes" is presently being considered for revision by the WHO pending review of new and emerging information on the subject.[2]

The revision of the WHO briefing note on follow-up formula in the context of the WHO Code will aid Codex in determining whether labelling provisions should be aligned with the WHO Code. If the Labelling section of the Standard is reviewed, the work of the WHO will need to feed into the review process to ensure that Codex reflects its obligations to the WHO as outlined in the resolution at the 58th meeting of the World Health Assembly (WHA 58.32 2005), which is:

> to establish standards, guidelines and recommendations on foods for infants and young children formulated in a manner that ensures the development of safe and appropriately labelled products that meet their known nutritional and safety needs, thus reflecting WHO policy, in particular the WHO global strategy for infant and young child feeding and the International Code of Marketing of Breast-milk Substitutes and other relevant resolutions of the Health Assembly.

3.4 Other issues

A full review of the Standard may raise the question of whether follow-up formula is an appropriate part of the diets of older infants and young children. The WHO and a number of international public health organisations take the position that follow-up formula is not a necessary part of older infant or young child diets (WHA 39.28 1986).

4 OPTIONS FOR THE COMMITTEE TO CONSIDER

A review of the Standard would be guided by the recognition of the need to maintain consumer choice, allow flexibility for product innovation, and reducing barriers to trade, while ensuring follow-up formula products are safe and suitable for infants as a particularly vulnerable population group.

Based on the issues discussed above, New Zealand presents two options for the Committee to consider. The options are:

Option A: Retain the status quo. There would be no review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)

or

Option B: Review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)

If Option B is the preferred option of the Committee, a further decision will be required to determine whether the review should be a limited review or a full review.

[2] See http://www.who.int/nutrition/publications/infantfeeding/en/index.html.

4.1 Option B(i): Limited Review

A limited review of the current Codex Standard for Follow-Up Formula (CODEX STAN 156-1987) would be limited to a review of the description, essential composition, and quality factors of follow-up formula.

4.2 Option B(ii): Full Review

In addition to reviewing the description, essential composition and quality factors of follow-up formula as per option B(i) above, a full review would include a review of the labelling provisions of the Standard. This would involve consideration of labelling of follow-up formula and the relationship to the WHO Code. A full review may also consider the need for the expansion of the Standard to cover growing-up milk products (also known as 'toddler milks') or the development of a new standard for these products.

A project document based on these two options is attached in Annex One.

5 REFERENCES

De la Hunty A. 2009. *The EU Childhood Obesity Project*. Nutrition Bulletin **34**: 403-406

EFSA. 2009. *Scientific Opinion on the appropriate age for introduction of complementary feeding of infants.* EFSA Journal; 7(12): 1423.

FAO/WHO. 2008. *Enterobacter sakazakii (Cronobacter spp.) in powdered follow-up formulae*. Microbiological Risk Assessment Series No. 15. Rome. 90pp.

Koletzko B, Baker S, Cleghorn G, Neto UF, Gopalan S, Hernell O, Hock QS, Jirapinyo P, Lönnerdal B, Pencharz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D. 2005. *Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group*. Journal of Pediatric Gastroenterology and Nutrition **41**:584-599

Koletzko B. 2006. *Standards for Infant Formula Milk.* British Medical Journal **332**: 621-622

Koletzko B, von Kries R, Closa R, Escribano J, Scaglioni S, Giovannini M, Beyer J, Demmelmair H, Gruzfield D, Dobrzanska A, Sengier A, Langhendries J, Cachera MR, Grote V. 2009. *Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial*. American Journal of Clinical Nutrition **89**: 1836-45

Lönnerdal B, Chen CL.1990. *Effects of Formula Protein Level and Ratio on Infant Growth, Plasma Amino Acids and Serum Trace Elements*. Acta Paediatrica. **79**: 266-273.

My Decker Capital. 2010. *Infant Formula Industry in China*. Available at: www.mydeckercapital.com Accessed: May 10, 2011.

Nutraingredients. 2011. DHA claims enter EU law books. Available at: http://www.nutraingredients.com/Regulation/DHA-claims-enter-EU-law-books. Accessed: June 20, 2011.

Scientific Committee on Food. 2003. Report of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae. (SCF/CS/NUT/IF/65 Final. 2003). Brussels: European Commission.

UBIC Consulting. 2010. *Ingredients for the World Infant Formula Market*. Available at: www.ubic-consulting.com. Accessed: May 10, 2011.

UNICEF. 2008. *Realising Children's rights to Adequate Nutrition through National Legislative Reform. Available at: http://www.unicef.org/policyanalysis/files/Realising_Children_Rights_to_Adequate_Nutrition_through_National_Legislative_Reofrm.pdf.* Accessed: 22 February, 2011.

WHO. 1981. *International Code of Marketing of Breast-milk Substitutes.* Geneva: World Health Organization.

WHO. 1986. *Infant and young child feeding*: *WHA 39.28*. Geneva: World Health Organization.

WHO. 2001. *Follow-up formula in the context of the international code of marketing of breast-milk substitutes*. Geneva: World Health Organization. Available at: www.who.int/nutrition/**follow-up_formula**_eng.pdf. Accessed: 22 February, 2011.

WHO. 2001. *The optimal duration of exclusive breastfeeding*. *Report of an Expert Consultation*. Geneva: World Health Organization. Available at: http://whqlibdoc.who.int/hq/2001/WHO_NHD_01.09.pdf. Accessed: 22 February, 2011.

WHO/FAO/UNU. 2002. *Protein and amino acid requirements in human nutrition: Report of a Joint WHO/FAO/UNU Expert Consultation*. Geneva: World Health Organization.

WHO. 2005. *Infant and young child nutrition: WHA 58.32*. Geneva: World Health Organization.

WHO. 2010. *Infant and young child nutrition*: *WHA 63.23*. Geneva: World Health Organization.

ANNEX ONE

PROPOSAL TO REVIEW THE CODEX STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)

PROJECT DOCUMENT

Prepared by New Zealand

1 PURPOSE AND SCOPE OF THE NEW WORK

The purpose of the proposed new work is a review of the Codex Standard for Follow-up Formula (CODEX STAN 156-1987, hereafter called 'the Standard'). The Codex Standard for Follow-up Formula was issued in 1987. The category of food covered by the Standard has been subject to significant development over the 24 years since its development. There is a concern that the Standard may not provide adequate guidance to members in relation to the range of existing and potential follow-up formula products, and that it does not incorporate the key directions taken in the recent review of the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)). A review of the Standard would explore the lack of harmonisation in regulations for follow-up formula across member countries, and will include consideration of issues such as technological developments in follow-up formula production and composition over the past 24 years, the age range of the intended population, and product definition.

An interlinked set of social and technological developments over the past 20-30 years has prompted a growing interest from industry to provide consumers with a wider selection of infant formula products. ACNielsen reported a 12 per cent increase in global infant formula product sales from 2006 to 2007. According to Euromonitor International, the estimated global consumption of follow-up formula in 2010 was in the vicinity of 438,000 tonnes. This compares to the estimated global consumption of 309,000 tonnes in 2005. The growth in the follow-up formula market has been greatest in Asia, particularly China. Eastern Europe, and to a lesser extent the Middle East and Latin America are also experiencing growth in their infant formula products markets. It is expected that the global market for infant formula products will continue to grow rapidly due to factors such as rising disposable income levels and the growing number of working mothers.

If the Committee endorses a review of the Standard there are two approaches for the scope of the review. The question of whether to undertake a review and the selection of the preferred approach concerning the scope of a review are to be decided by the plenary at the CCNFSDU meeting in November 2011. The two approaches for the scope of the review are:[3]

Option B (i): Limited review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987); or

Option B (ii): Full review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987)

The details of these two approaches are outlined below.

2 RELEVANCE AND TIMELINESS

The current Standard is outdated. There is a marked diversification of national follow-up formula standards across members, and this is expected to continue in the absence of an up-to-date international reference point. Several countries have already modified their regulations for follow-up formula since the development of the Standard, while other countries either use the current Standard or have adopted regulations that closely follow it. In addition, a number of countries are currently working on, or have already developed, regulations for 'growing-up milk' products. In many cases, the age range for growing-up milk products in these regulations overlaps the age range used in the Standard. A similar situation is also evident between member countries in the overlap of age ranges for some follow-up formula and infant formula regulations. A revised Standard may be useful for promoting international harmonisation in the regulation of follow-up formula products.

[3] Option A is to retain the status quo and not undertake a review of the Codex Standard for Follow-Up Formula (CODEX STAN 156-1987).

3 MAIN ASPECTS TO BE COVERED

As part of the review of the Standard, the aspects that may need to be considered depend on the proposed scope. These aspects are described below under each scope option (B(i) limited review, and B(ii) full review).

B (i) Limited Review

A limited review of the Standard would look at the following aspects:

Description

There are discrepancies between member countries' follow-up formula regulations, particularly with regard to the defined age-range for which follow-up formula products are intended. The current Standard states that follow-up formula is suitable for infants and young children aged between 6 and 36 months. There are broadly two approaches in country regulations to the age range for follow-up formula, whereby some country regulations are consistent with the age range (6 – 36 months) in the Standard, while others provide a narrower age range of 6-12 months.

The Standard contains the following definitions:

- ***Follow-up formula*** means 'a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children'.
- ***Infants*** are defined as 'a person not more that 12 months of age'.
- ***Young children*** means 'persons from the age of more than 12 months up to the age of three years (36 months)'.
- ***Follow-up formula*** is further defined as a 'food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have proved to be suitable for infants from the 6th month on and for young children'.

Essential Composition and Quality Factors

There is a concern that scientific and technological developments and changes in consumption patterns since the introduction of the Standard mean that it may no longer provide adequate guidance to member countries. This is especially important as many countries rely on the Standard for domestic regulation, and the Standard is the default for inter-country trade in follow-up formula.

There has been considerable advancement in the science underpinning the nutritional needs of infants. This was considered in detail in the review of Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007)). There is an argument that these advances should be considered as part of a review of the follow-up formula Standard. The main areas of concern include (but are not limited to):

- the minimum and maximum levels of protein in the current Standard;
- maximum or guiding upper limits for vitamins and minerals; and
- the provisions for optional ingredients.

B (ii) Full Review:

In addition to reviewing the Description and Essential Composition and Quality Factors (as per Option B (i)) of the Standard, the other main aspect of a full review would be to look at the Labelling section of the current Standard. Health claims and the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes should be considered as part of a full review.

Labelling

The use of health claims on food products for infants and young children continues to be a contentious issue. The current Codex Guideline for Use of Nutrition and Health Claims (CAC/GL 23 – 1997) states under section 1.4 that 'Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation". The Standard does not contain any explicit provisions for nutrition and health claims. However, this could be considered as part of a full review.

The International Code of Marketing of Breast-milk Substitutes

The 1981 WHO International Code of Marketing of Breast-milk Substitutes (the WHO Code) applies to marketing and related practices in relation to the following products:

- breast-milk substitutes, including infant formula;
- other milk products, foods and beverages, including bottle-fed complementary foods;
- feeding bottles, and teats.

There is a divergence in approaches between member countries as to whether follow-up formula is defined as a breast-milk substitute, and whether follow-up formula products fall within the scope of the WHO Code. The WHO urges all Member States to take action to give effect to the principles and aim of the WHO Code as appropriate to their social and legislative framework.

Additional Requirements of the Codex Standard (Section 9.6) states that 'the products covered by this standard are not breast-milk substitutes and shall not be represented as such'. It is worth noting that the WHO briefing note on "Follow-Up Formula in the Context of the International Code of Marketing of Breast-milk Substitutes" is presently being considered for revision by the WHO pending review of new and emerging information on the subject.

Other Issues

A full review of the Codex Standard could explore the option of expanding the scope of the current standard to explicitly include growing-up milks as these products generally fall within the age range of the Standard. Another option would be to consider the development of a new standard to cover growing-up milk products.

4 ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

4.1 General criterion

The proposed revision of the Standard is focused on establishing whether this standard provides for the adequate supply of nutrients through the provision of safe follow-up formula products which are scientifically demonstrated to support the nutritional requirements of the infants for whom these products are intended, in order to promote normal growth and development.

Due to scientific and technical developments, there may be a need to ensure the Standard represents the optimal composition that might be achieved, while also considering safety and suitability.

The diversification of national regulation for follow-up formula products across member countries may present significant issues for the international trade of these products. For example, differences in the regulations applied to exports of follow-up formula may disadvantage countries seeking to ensure that follow-up formula product exports are safe and suitable for the intended consumer and equally may disadvantage consumers if the regulations are too liberal. International standards can provide guidance on the appropriate level of regulation to ensure safety and suitability while facilitating trade.

The new work can contribute to facilitating international trade by providing clear international guidance on provisions for follow-up formula products.

4.2 Criteria applicable to commodities

a) Volume of production and consumption in individual countries and volume and pattern of trade between countries.

Follow-up formula is manufactured in many countries and has become a commodity of increasing trade significance with consistent growth in international trade over the past decade. According to Euromonitor International, the estimated global consumption of follow-up formula in 2010 was in the vicinity of 438,000 tonnes. This compares to the estimated global consumption of 309,000 tonnes in 2005. Much of the growth in sales and consumption has been in developing countries. China and Indonesia have the highest volume of consumption of follow-up formula of all the countries included in the Euromonitor survey with a reported market of 127,100 and 30,400 tonnes, respectively in 2010.

b) Diversification of national legislation and apparent resultant or potential impediments to international trade.

The Standard is 24 years old and has not been reviewed during this time. It is apparent from a review of national regulation for follow-up formula that differences exist between countries. Although we are not aware of any evidence of market failure in those markets that have adopted the Standard in its entirety or partially, it appears that some countries have since reviewed and updated their national legislation for this commodity due to developments in scientific research. The differences in national regulations may create barriers to the international trade in safe and suitable follow-up formula products.

An updated Standard would assist in providing an improved technical and scientific basis for establishing national regulations.

c) International or regional market potential.

Follow-up formula products are widely traded. A revised Standard should enhance opportunities for insuring global and regional trade.

d) Amenability of the commodity to standardisation.

While there is general support for the harmonisation of food regulations for follow-up formula to assist in eliminating any impediments to international trade, many industry representatives are keen to retain permissions for the addition of 'optional ingredients' to follow-up formula to allow for innovation and product development.

e) Coverage of the main consumer protection and trade issues by existing or proposed general standards.

Updating the Standard to ensure that it is based on robust and up-to-date science will facilitate an internationally harmonised approach to this commodity and thereby contribute to consumer protection whilst ensuring fair practices in trade.

f) *Number of commodities which would need separate standards indicating whether raw, semi-processed or processed.*

One of the critical issues to be addressed in the review of the Standard is the intended age range for follow-up formula. Depending on the age range determined, there may be a need to consider either expanding the scope of the Standard to explicitly include growing-up milk products, or to develop a new standard to cover growing-up milk products.

g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body (ies).

A review of the Standard would require technical support and input from recognised international experts in the area of infant and young child nutrition, as well as from governments and relevant international organisations.

5 RELEVANCE TO CODEX STRATEGIC GOALS

The proposed work is consistent with the Commission's strategic goals with particular reference to the following:

Goal 1: Promoting sound regulatory frameworks - Revision and update of the current Codex Standard will greatly assist in promoting sound regulatory frameworks for these products.

Goal 2: Promoting widest and consistent application of scientific principles and risk analysis- The revision of the current standard will draw on the latest scientific evidence and facilitate the development of a risk based standard for regulation of these products.

Goal 5: Promoting maximum and effective participation of members - The products covered by the proposed work is of significant global interest and the revision process will be carried out with the input and participation of as many members as possible.

6 INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING DOCUMENTS

Codex has developed standards for other foods that cover this age range, including:

- Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981(Rev.2007))
- Standard for Processed Cereal-based foods for infants and young children (CODEX STAN 74-1981)
- Standard for Canned Baby Foods (CODEX STAN 73-1981)
- Guidelines on formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 09-1991)

7 IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

A review of the Standard would require technical support and input by recognised international experts in the area of infant and young child nutrition.

8 IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

A review of the Standard would require technical support and input by recognised international experts in the area of infant and young child nutrition.

9 PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

Subject to approval, the proposed time line for completion of the new work is as follows:

November 2011	Endorsement of new work proposal by CCNFSDU and establishment of electronic working group to develop draft discussion document and draft revised standard
July 2012	Approval of new work by CAC
November 2012	Consideration of draft revised standard at step 2 by CCNFSDU and advancement to step 3
November 2013	Consideration of draft standard and further work with technical experts and EWG
November 2014	Consideration of draft standard and advancement to Step 5
July 2015	CAC adoption of draft standard to step 5
November 2015	Discussion of draft standard and advancement to step 8
July 2016	Adoption of draft standard at step 8

The revision and progression of work between sessions will be carried out through electronic/physical working groups to ensure timely development of the standard.