CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECCIAL DIETARY USES

Thirty-eighth Session

Hamburg, Germany, 5 – 9 December 2016

REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987)

Physical Working Group Report

Prepared by the New Zealand and France

The physical working group (PWG) was held on the 3rd December 2016 prior to the CCNFSDU meeting. The focus of the working group was on Section 3: Essential composition of follow-up formula for young children. The working group went through recommendations 7 to 19 of the Agenda paper (16/38/6). A summary of the discussions and the conclusions of the physical working group are outlined below. All recommendations as presented in the Agenda paper have been amended to reflect the discussions, new text is presented in a **bold and underlined font** and deleted text has been stroke through. When text was accepted by the Committee square brackets were removed, remaining square brackets included below represent where a conclusion could not be made during the physical working group and will be discussed in the Committee.

1. Recommendations related to Section 4 of the Agenda Paper

Section 4: Framework for the Essential Composition of Product for Young Children

Recommendation 7:

That CCNFSDU agree to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5.

Section A will refer to the essential composition and labelling of follow-up formula for older infants, and Section B will deal with the essential composition and labelling of product for young children.

> General agreement.

As agreed to at CCNFSDU36, there is recognition that follow-up formula plays a distinctly different role in the diets of older infants in comparison to that of young children. For this reason the Committee had agreed to review the compositional requirements for follow-up formula with a point of differentiation at 12 months.

At CCNFSDU37, it was agreed that the requirements for the essential composition of follow-up formula for young children (12 – 36 months) are to be based on a narrow set of mandatory requirements, with the option that national authorities may require additional mandatory nutrients based on the nutritional needs of their population.

There was general agreement with recommendation 7 of the Agenda paper that the Standard for Follow-up Formula should therefore be separated into two separate parts in order to differentiate between products. It is noted that one Codex Member and Three Codex Observers did not support this approach.

The approach taken in the 2016 eWG to determine the mandatory requirements for the essential composition of follow-up formula for young children was based on the outcome of the 2015 eWG which stated that the Standard should be;

- flexible in the composition to address key nutrients of concern which may vary regionally;
- less prescriptive, as follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to follow-up formula for older infants;
- consistent with compositional parameters for follow-up formula for older infants (where possible); contain the key nutrients of global concern in the diets of young children, as well as the key nutrients in cows' milk; and maintain nutritional integrity.

The 2016 eWG has further elaborated on the proposed approach and developed three principles to help guide and justify nutrient addition, as well as identify those nutrients requiring specific compositional parameters for follow-up formula for young children. These principles were discussed in the Committee and modified:

Principles for mandatory addition

Evidence to support:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is **widely** inadequate ~~on a global scale~~; and/or
2. contribution of adequate amounts of key nutrients from **[**cows'**]** milk, **[**and if appropriate breast milk,**]** where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety.

The purpose of the principles was to underpin the mandatory essential composition of follow up formula for young children and would not appear in the standard but would be captured in the Alinorm of the CCNFSDU meeting.

Regarding principle 1, it was noted by one Codex Observer that it might be more appropriate to state evidence should support widespread inadequacy of nutrients rather than nutrients being inadequate on a global scale. As there was sometimes limitations in the availability of data to determine if inadequacy was an issue on a global scale.

Regarding principle 2, there was significant discussion on this.

Some Codex observers were concerned that cows milk was being considered as WHO had clearly stated that these products are breastmilk substitutes and were not necessary. Another Codex observer stated that it was important to consider how the consumer will use these products and milk is considered an important role of milk in the diet.

It was requested that reference to breastmilk was also included in the principle 2 and this was captured in [ ] as some members objected to its inclusion as they considered these products were not substitutes for breastmilk.

It was noted that there was still a discussion on the role of product and that the Committee had already stated that these products were not necessary but were available on the market and therefore a standard was appropriate to ensure their nutritional integrity. It was also noted that infant formula and follow up formula for older infants could still be used for young children.

Regarding Principle 3 related to the integrity of the product, there were no suggestions from members to amend or change the text.

Role of Product

The Chair introduced discussion on the role of the product stating that the findings of the various eWGs were that the role follow up formula for young children varied significantly in different countries. It was used as part of the diet, a supplement to the diet along with family foods including milk or a replacement for cows' milk.

It was the fact of varying roles of product for young children that has reinforced the need for flexibility in the standard to ensure that product is appropriate for the country or region specific role it plays in the diet of young children. It is also noted that there is no unique role for these products for young children as they are not considered a necessity to satisfy the nutrient requirements of young children when compared with other foods that can be included in the diversified diet for young children, for example breast milk, formulas for infants and cow's milk all provide critical nutrients.

Comments from the pWG reinforced the varying roles of the product with some stating it was not necessary and others identifying specific roles in their countries.

Recommendation 8: Mandatory addition for national authorities drafting text prepared based on Agenda comments.

Recommendation 8:
That CCNFSDU agree to the following revised framework for the essential composition of follow-up formula for young children and identify the preferred option for the optional addition of other nutrients:
Mandatory (core) composition
It is proposed that the **mandatory (core) composition** of follow-up formula for young children include a

limited list of essential nutrients (specific recommendations are presented in Section 5).

For national authorities requiring the mandatory addition of other essential nutrients for their specific population, these nutrients should be chosen from the essential composition of follow-up formula for older infants. The nutrient levels must be:

- as per the min, max, GULs stipulated for follow-up formula for older infants; or
- amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.

Note: all footnotes relevant to these listed essential nutrients for older infants, also apply when added to follow-up formula for young children.

The Chair introduced the framework recommended for the composition of follow-up formula for young children. The eWG had favoured a two tiered framework/approach; that is tier (1) mandatory (core) composition, and tier (2) which defines the optional compositional requirements.

The pWG supported the proposed framework of a limited list of essential nutrients with the ability for national authorities to require the mandatory addition of other essential nutrients for their specific population, provided these nutrients are chosen from the essential composition of follow-up formula for older infants. It was recognised that this approach supported flexibility in the standard**.** Some members noted that they did not support the proposed list of nutrients for mandatory addition but noted that these would be discussed later in the agenda.

The pWG proposed the following drafting text to reflect the framework.

ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.4 For national **and/or regional** authorities **may lay down additional ~~requiring the~~** mandatory **requirements ~~addition of other~~ for other** essential nutrients in addition to those listed under 3.1.3 Section B, for their specific population, these nutrients should be chosen from the essential composition of follow-up formula for older infants 3.1.3 Section A. The nutrient levels must be:

- based on the nutrient composition of follow-up formula for older infants or;
- **[based on key nutrients from cows' milk];**
- amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.

Clean text version:

3.1 Essential composition

3.1.4 For national and/or regional authorities may lay down additional mandatory requirements for other essential nutrients in addition to those listed under 3.1.3 Section B, for their specific population, these nutrients should be chosen from the essential composition of follow-up formula for older infants 3.1.3 Section A. The nutrient levels must be:

- based on the nutrient composition of follow-up formula for older infants or;
- based on key nutrients from cows' milk;
- amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.

There was a request to include a reference to cows' milk in relation to setting the nutrient levels. It was suggested that this could be best captured as a separated point as the introductory clause is referring national and regional authorities to guidance for establishing nutrient levels that are not mandated in follow up formula for young children. Such detailed levels are provided in the standard for follow up formula for older infants. The reference to cows' milk would be more generic as its composition was not referenced in a Standard . A request was also made to include a reference to breast milk but it was noted that breastmilk was already used as the reference for the standard for follow up formula for older infants and was therefore already captured.

Recommendation 8: Framework for Optional Addition

The Chair introduced this section clarifying that it covered both the addition of optional nutrients (that are not part of the core/mandatory composition) and optional ingredients. For the addition of optional ingredients or substances, it is proposed that a principles based approach already agreed to for the follow-up formula for older infants will continue to be applied to product for young children. This will also mean that optional ingredients and substances already permitted for follow-up formula for older infants will also be permitted for young children. The pWG supported this approach but recommended, for clarity, that a reference be made to section 3.3.2.3 Section A (Follow-up formula for older infants), which highlights some of the nutrients that can be added to follow-up formula for older infants.

This was noted but no drafting as proposed.

The Agenda Paper presented two approaches for the optional addition of other *nutrients* (not included in the core/mandatory). It was deemed important to specify how other nutrients may be added to these products for the purpose of nutritional integrity.

Option 1: requires optional nutrient additions to be chosen from the essential composition of follow-up formula for older infants, and levels to only be amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants. This approach would provide more guidance as to safe and suitable nutrients and their levels for addition and could ensure a more harmonised approach for trade purposes.

Option 2: is a principles based approach, with optional nutrient additions required to be safe and suitable at the intended level of use, and at amounts sufficient to achieve the intended effect. This approach does not refer to any specific nutrients for addition or appropriate levels but provides greater flexibility.

There were mixed views in support of either option 1 or option 2.

Some observers recommended that optional additions should be kept to a minimum and that there should be clear specification about the levels of evidence and requirements for rigorous science. It was also commented that there was no reason to deviate from the GUL for older infants as these were not critical nutrients.

It was also stated that Section 3.2.4 (now presented as 3.2.3 below) for follow-up formula for young children (Section B) is about voluntary nutrients and this is for a different age group than older infants and that it may require greater variability.

There was general support for a principles based approach, grounded in strong scientific evidence. It was clarified that this was addressed in both option 1 and 2 and the drafting text was put on the screen to progress this. The proposed drafting text would be further discussed in the Committee.

3.2 Optional Ingredients

~~3.2.1 [National authorities may require the mandatory addition of other essential nutrients to address the nutritional needs of the local population than those listed under 3.1.3, Section B. These nutrients should be chosen from the essential composition of follow-up formula for older infants, 3.1.3 Section A. The nutrient levels must be as per the minimum, maximum and GULs stipulated for follow-up formula for older infants (3.1.3 Section A); or amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated.~~> transferred to section 3.1.4 Section B.

3.2.1 [In addition to the [essential] compositional requirements listed under 3.1.3 Section B, other ingredients or substances may be added to follow-up formula for ~~**older infants**~~ **young children** where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

3.2.2 [When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect.]

3.2.3 [Additional nutrients may also be added to follow-up formula for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants; or amended **by national/regional authorities** if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants. All footnotes relevant to these listed essential nutrients for older infants, would also apply when added to [name of product] for young children].

~~**>>OPTION 2<<**~~

~~3.2.2 [In addition to the essential compositional requirements listed under 3.1.3 Section B, other [nutrients,] ingredients or substances may be added to [name of product] for young children where the~~

~~safety and suitability of the optional [nutrient,] ingredient [or substance] for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]~~

~~3.2.3 [When any of these [nutrients,] ingredients or substances is added, the [name of product for young children] shall contain sufficient amounts to achieve the intended effect.]~~

Clean text version:

3.2 Optional Ingredients

1. 3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients or substances may be added to follow-up formula for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

2. 3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect.

3. 3.2.3 Additional nutrients may also be added to follow-up formula for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants; or amended by national/regional authorities if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants. All footnotes relevant to these listed essential nutrients for older infants, would also apply when added to [name of product] for young children.

2. Recommendations related to Section 5 of the Agenda Paper

Section 5: Requirements for the Essential Composition of Follow-up Formula for Young Children

3. Recommendation 9: Energy Density

Recommendation 9:

That CCNFSDU agree to the following requirements for energy density:

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 mL not less than 60 kcal (250 kJ) and not more than 70 kcal (293 kJ) of energy.

National/regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.

~~**Additional option for further discussion:**~~

~~[For products formulated for young children of more than 24 months of age, the product when prepared ready for consumption shall contain per 100 mL not less than 45 kcal (kJ)]~~

There was widespread support in the physical working group to include parameters for energy density. The rationale to do so was based on need to anchor all mandatory composition which are presented per 100 kcal; Without establishing an energy density range, the levels of nutrients in products would be considerably more variable.

One Codex Member Organisation stated that they preferred not to establish energy density requirements as there was difficulty in recognising the variation in dietary guidelines whereby some countries recommended lower fat milk products are consumed from 24 months of age.

A minimum energy density of 60 kcal/100 mL aligns with the energy density requirements for follow-up formula for older infants, infant formula and full fat cows' milk. If the standard was to accommodate reduced fat cows' milk, then this energy density would need to be reduced to 45 kcal/100 mL.

The additional option for consideration to enable lower energy products to be formulated only for young children from 24 months of age was not supported by the working group. A consistent approach was sought for the Committee which did not result in several sub-divisions in the standard. Some members highlighted their preference for a broad energy range to enable flexibility, whereas others supported a narrower range due to their national guidelines which did not recommend the introduction of reduced fat milk.

A footnote was suggested which would allow for national and/or regional authorities to deviate from the minimum energy density based on their national/regional dietary guidelines. This approach was designed to enable flexibility based on dietary guidelines rather than to introduce a split in the standard. This approach was supported by the physical working group and the square brackets were removed from the text.

4. Recommendation 10: Energy contribution from macronutrients

Recommendation 10:

That CCNFSDU agree to include a maximum limit for total carbohydrates as follows:

[Available carbohydrates]

The level of available carbohydrates should not exceed [12 [**or 12.5**] g per 100 kcal (2.9 g per 100 kJ)]

[The level of protein shall not be less than 1.8 g/100 kcal].

[The level of total fats shall not be less than [**3.5**] [or 4.0] [**or 4.4**] g/100 kcal].

That CCNFSDU agree that no requirements are needed for:

- Minimum levels for carbohydrate
- Maximum limit for protein
- Maximum limit for fat

Recommendation 10 relates to the establishment of minimum and maximum levels for macronutrients. While there was widespread support to establish values for all macronutrients, one Codex Member Organisation did not support the need to mandate the minimum requirements for protein or fat. Those supporting detailing requirements for all macronutrients looked to ensure that product for young children contains a nutritionally appropriate and balanced range of macronutrients. Others preferred a more flexible approach which only specified requirements which were of importance globally for either addressing issues of inadequacy or nutritional integrity.

It was suggested that the PWG work through proposed minimum and maximum requirements for each macronutrient. Firstly the committee discussed the need to establish requirements and then the applicable minimum and maximum levels. It was highlighted that parameters for macronutrients cannot be looked at in isolation and that further work was required to ensure that proposals were appropriate. It was agreed that a small working group would meet to continue to model the various scenarios proposed during the PWG and to report back to the Committee.

During the working group it was not decided if protein or fat minimum levels would necessarily be set and that this would be discussed further in the Committee.

Carbohydrate

A clarification on the terminology used to describe carbohydrates was requested prior to beginning the discussion on carbohydrates, particularly as it relates to the difference between total and available carbohydrate.

Within the Codex Guidelines on Nutrition Labelling it is required that where nutrient declaration is applied, the available carbohydrates (i.e. dietary carbohydrate, excluding dietary fibre) and total sugars are declared (3.2.1.2; CAC/GL 2-1985). The following definitions are relevant to calculating the available carbohydrate content of food:

> 2.7 *Sugars* means all mono-saccharides and di-saccharides present in food.
>
> 2.8 *Dietary fibre* means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:
>
> - edible carbohydrate polymers naturally occurring in the food as consumed,
> - carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
> - synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

Available carbohydrates are dietary carbohydrates excluding dietary fibre. Non digestible carbohydrates and dietary fibre are not included in the definition of available carbohydrates and their addition would be captured under the Optional ingredients section. The current follow-up formula standard states that carbohydrates must be nutritionally available. The proposed text for follow-up formula for older infants for carbohydrates lists them as available carbohydrate rather than total.

Minimum requirements for carbohydrate

The Chairs stated that the recommendation of the agenda paper was that there was no need to establish minimum requirements for carbohydrate. Carbohydrates are not limited in the diet and would not be necessary to ensure the nutritional integrity of the product.

There were no objections to this proposal and it was agreed that there was no need to establish minimum requirements for carbohydrates.

Maximum limit for carbohydrate

There was consensus within the eWG that requirements were necessary in order to limit the addition of free sugar to these products and ensure the nutritional integrity and suitability of product due to global concerns of excessive sugar intakes.

The Chairs introduced the maximum limit proposed in the Agenda paper of 12 g/100 kcal. One Codex Members suggested that this could be increased slightly to 12.5 g/100 kcal and this was supported by two Codex Members. As stated above, the maximum limit proposed would be looked at together with all macronutrients in a side session and reported back to the Committee. The PWG agreed that maximum limits be established for carbohydrate.

Protein

Minimum requirement for protein

There was widespread support from the working group to establish minimum requirements for protein. This was based on the view that protein requirements are necessary to ensure the nutritional integrity and balance of product.

One Codex Member Organisation strongly opposed the requirement for a mandatory minimum for protein or fat. It was stated that the need for these mandatory requirements should only be set for necessity, for example where there is a global need. It was highlighted that intakes of protein and fat were not an issue and that protein intakes may even be excessive in Europe and may be linked to a risk of higher obesity. It was recognised that in other parts of the world and a minimum could be very important but highlighted that this could be left to national and/or regional authorities to establish. No agreement could be reached that this was a suitable approach and this will be discussed further in the Committee.

The working group proceeded to look at the minimum levels that could be appropriate if a minimum was to be established. There was general support for the minimum level proposed in the Agenda paper of 1.8 g/100 kcal. This level is aligned with the recommendation proposed for protein minimum levels in follow-up formula for older infants in recommendation 1 of the Agenda paper (CX/NFSDU 16/36/8). This recommendation has not yet been agreed by the Committee. It was noted that the minimum for follow-up formula for older infants may change and that the European Food Safety Authority was currently reviewing the safety and suitability of a minimum protein requirement of 1.61 g/100 kcal for follow-up formula for older infants.

It was noted that the need to establish a minimum protein level would be further discussed in the Committee and that modelling would be looked at the proposed minimum levels, taking into account that the minimum for protein of 1.8 g/100 kcal for older infants has not yet been agreed by the Committee.

Maximum limit for protein

The establishment of minimum and maximum levels for energy density and carbohydrates will impose limits on the amounts of protein and fat which can be added. There was widespread agreement that it was not necessary to establish a maximum limit for protein. One Codex Member preferred to establish a maximum limit of 3.0 g/100 kcal but this was not supported by any other member and the conclusion was that no maximum limit be established.

Nitrogen conversion factor

One observer raised the issue of the nitrogen conversion factor and footnote 2 from the essential composition for follow up formula for older infants. They commented on the need to consider this during the discussions on protein and recommended that until nitrogen conversion factors are scientifically evaluated the value of 6.25 for nitrogen should be used. Another observer requested that the figure of 5.71 remain in square brackets. The chair commented that discussions on the nitrogen conversion factor and footnote 2 would be in the plenary and in association with discussions on minimum and maximum protein levels for follow up formula for older infants.

Fat

Minimum level for fat

There was widespread support from the working group to establish minimum requirements for fat. This was based on the view that fat requirements are necessary to ensure the nutritional integrity and balance of product.

One Codex Member Organisation strongly opposed the requirement for a mandatory minimum for protein or fat. It was stated that the need for these mandatory requirements should only be set for necessity, for example where there is a global need. It was highlighted intakes inadequate of fat were not an issue. It was recognised that in other parts of the world and a minimum could be very important but highlighted that this could be left to national and/or regional authorities to establish. No agreement could be reached that this was a suitable approach and this will be discussed further in the Committee.

The working group proceeded to look at the minimum levels that could be appropriate if a minimum was to be established. Three options were proposed:

- 3.5 g/100 kcal
- 4.0 g/100 kcal
- 4.4 g/100 kcal to align with the standard for follow-up formula for older infants.

Some calculations were conducted to see the impact of the proposed options. If product is manufactured to the maximum limit for carbohydrate of 12.5 g/100 kcal and minimum limit for the fat levels considered by the working group then the amount of protein that would be required to provide an energy density of 65 kcal/100 mL (recommendation 9) would be as follows:

Fat	**Protein**
3.5 g/100 kcal	4.6 g/100 kcal
4.0 g/100 kcal	3.5 g/100 kcal
4.5 g/100 kcal	2.6 g/100 kcal

Analysis of a range of further scenarios are presented in the appendix 2 of the Agenda Paper CX/NFSDU 16/36/8.

Maximum level for fat

There was no discussion on whether a maximum limit for fat should be established.

Conclusion

To conclude, there was no support to establish a minimum level for carbohydrate, nor maximum limits for protein. The working group did not discuss the need to establish a maximum limit for fat, the recommendation in the Agenda Paper is that it is not necessary to do so. Discussions will continue in the Committee as to the need to establish minimum limits for protein and fat. A working group has been established to review the suitability of the proposed maximum level for carbohydrate and minimum levels for protein and fat taking into account the comments from the PWG. This will be presented back to the Committee.

Recommendation 12: Quality of Dietary Fat

Recommendation 12: Quality of Dietary Fat

That CCNFSDU agree to include a mandatory requirement for the addition of α- linolenic acid as follows:

The level of α-linolenic acid (in the form of glycerides) should not be less than 50 mg per 100 kcal (12 mg per 100 kJ)

[Linoleic acid : min 300 mg/100kcal*]

* [this can be decided by national or regional authorities]

α-linolenic acid

The Committee discussed the mandatory requirements for quality of dietary fat. In previous electronic working groups quality of dietary fat was consistently found to be inadequate in sub-groups of this population group globally. Alpha-linolenic acid and DHA were specifically found to be limited, however this differed regionally.

Regarding the mandatory requirement for the addition of alpha-linolenic acid. Almost all pWG members supported the inclusion of mandatory requirements and supported a minimum amount of 50 mg of alpha-linolenic acid per 100 kcal, to align with the requirements specified for follow-up formula for older infants and

Codex Standard for Infant Formula. The working group supported no GUL or maximum limit for alpha-linolenic acid. One member stated that α-linolenic acid and *Linoleic acid* should be treated the same way and that their preference was that either they should both be mandatory additions or both voluntary additions. There was general agreement that alpha-linolenic acid was necessary to include as a mandatory nutrient.

Linoleic acid

The Chair stated that the Agenda paper recommendation was that linoleic acid was not necessary as a requirement in the standard as intakes were adequate in several countries. Many members did not support linoleic acid not being an essential requirement as either intakes were limited in their country or, that it is an essential fatty acid generally found in vegetable oils and needed to balance the saturated fat content of formula, or required to improve the quality of fat and general nutritional integrity of the product. Others did not consider that linoleic acid was a nutrient of global concern and necessary to add. It was suggested that this could be left to national and/or regional authorities as a footnote but no agreement could be achieved as to whether this adequately addressed the issue.

If a minimum was to be established, the working group generally supported a minimum level for linoleic acid of 300 mg per 100 kcal. This is the level that is included in the Codex Standard for Infant Formula and also the requirement for follow-up formula for older infants. The inclusion of linoleic acid as a mandatory nutrient addition will be further discussed in Committee.

Recommendation 13: Commercially Hydrogenated oils

Recommendation 13:

That CCNFSDU agree to limit commercially hydrogenated fats and oils with the following statement:

Proposed text for standard:

[~~**Commercially**~~ **Partially and fully** hydrogenated oils and fats shall not be used in [name of product] for young children~~]~~

or

The content of trans fatty acids shall not exceed [3%] of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in follow-up formula.]

There was general support within the pWG that product for young children should not contain industrially produced sources of trans fatty acids but how this should best be captured in the drafting received significant discussion. Sources of trans fatty acids in follow-up formula for young children can either be from those naturally present in cows' milk or from the use of commercially hydrogenated fats and oils.

Some members commented that the drafting should refer only to partially hydrogenated oils and fats. A fully hydrogenated fat would contain no trans fats although they would contain saturated fats. It was commented that breast milk was a significant source of saturated fats and we should not be limiting these, supporting reference to partially hydrogenated fats and oils only.

Some requested a reference to "commercially" to distinguish between industrially produced and naturally trans fatty acids however it was clarified that the use of the term "commercially produced oils" would cover any vegetable oil and was not the appropriate terminology. In the normal processing of oils, there can contain significant amounts of trans fatty acids.

The working group discussed whether reference to the level of trans fatty acids, as is referred to in the standard for follow up formula for older infants, may better reflect the intent of the requirements. It was noted that the level of 3% trans fatty acids is used in the standard of follow-up formula for older infants. However it was also raised that a level of 3% would not be achievable for product for young children if it the products was predominantly milk based.

It was agreed that both statements would be taken to the Committee for further discussion.

Recommendation 14: Types of carbohydrates

Recommendation 14:

That CCNFSDU agree:

Lactose should be the preferred carbohydrates in [name of product] based on milk protein. ~~Only precooked and/or gelatinised starches gluten-free by nature may be added.~~ Sucrose and/or fructose should not be added, unless needed as a carbohydrate source **[in the absence of lactose].** Sugars other than lactose should not exceed [**20%**] of available carbohydrate.

~~Additional options for further discussion:~~

~~Lactose should be the preferred carbohydrates in formula based on milk protein [and should provide not less than 50% of total carbohydrates].~~

Recommendation 14 relates to a footnote to specify suitable carbohydrates to be used in product for young children. The eWG and pWG supported establishing requirements which would state the preference of types of carbohydrates to be used and limit the addition of sugars other than lactose to product for young children. The footnote used for FUF for older infants was used a starting point and the pWG worked through sentence by sentence of the footnote.

The pWG supported that lactose is the preferred source of carbohydrate in product based on milk protein as no additional wording was proposed in the working group, the alternative option was deleted.

Discussion on the need to include reference to precooked and/or gelatinised starches to be gluten-free by nature if added, was supported by some members but the general position of the pWG was that such as statement was not necessary for products for young children due to the diversified diet that would be consumed by this age group.

In follow-up formula for older infants it is stated that sucrose and fructose should not be added unless needed as a carbohydrate source. It was highlighted htat these were the This sentence was supported for inclusion in the standard for follow up formula for young children with the recommended addition of the statement of “in the absence of lactose”. The additional statement remains in [ ] as it was not fully supported by the pWG.

With regards to the final sentence, which refers to the maximum limit of sugars to be used in formula, it was pointed out this is already a significant reduction from the follow up formula for older infants and is in alignment with the more conservative statement from the WHO.

It was questioned whether the last two sentences were a duplication although it was pointed out that one was one is about source of carbohydrate and the other about the amount of carbohydrate but agreed that it was possible to simplify the two sentences.

Some members commented that for lactose free products we would need to make an allowance for levels of available carbohydrate greater than 10%. It was suggested that sucrose and fructose are the sweeter of the sugars and perhaps to have 20% carbohydrate limit for all sugars since overall available carbohydrate is lower. This would then cater for lactose free products as well.

This section does require further discussion in the Committee.

Recommendation 15:

That CCNFSDU agree to the following recommendation on iron and vitamin C levels in [name of product] for young children:

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	1.0	3.0*****	-
mg/100 kJ	0.25	0.7*****	-

For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.–

*** National and/or regional authorities can deviate from the maximum iron based taking into account the nutritional needs of the population.**

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 kcal	align with FUF-OI	-	70
mg/100 kJ	align with FUF-OI	-	17

There was consensus amongst the eWG that iron is considered a nutrient which is inadequate in the diets of young children globally, thus fulfilling one of the principles required to establish mandatory requirements.

The PWG agreed to the minimum and maximum levels for iron and footnote specified in the Agenda paper and removing the square brackets. One Codex Member Organisation and one Codex Member preferred to

establish a maximum level of 2.0 mg/100 kcal for the purpose of alignment with the standard for Follow-up Formula for older infants. A number of countries could not agree to this maximum limit and a maximum level of 3.0 mg/100 kcal was established. A footnote was proposed for the maximum limit which stated that national and/or regional authorities can deviate from the maximum iron based taking into account the nutritional needs of the population.

The mandatory addition of vitamin C was agreed to in the PWG with full support that the minimum level align with that agreed to for follow-up formula for older infants which is yet to be discussed by the Committee. There was agreement to establish a GUL of 70 mg/100 kcal. As such, the square brackets have been removed from the text.

Recommendation 15 was agreed to by the PWG

Recommendation 16:

That CCNFSDU agree to the following recommendation for calcium, riboflavin and vitamin B12 levels in [name of product] for young children:

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	90*	-	280
mg/100 kJ	22*	-	67

<u>*national/regional authorities can deviate from the minimum calcium content taking into account the nutritional needs of the local population.</u>

Riboflavin

Unit	Minimum	Maximum	GUL
µg/100 kcal	80	-	650
µg/100 kJ	19	-	155

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 kcal	0.1	-	2.0
µg/100 kJ	0.024	-	0.48

The eWG considered it important that product for young children provide a significant contribution of calcium to the diet of this age group due to its role as a substitute for cows' milk. Four options for the minimum level were suggested by members of the working group, but after discussion on the importance of cows' milk in the diet, issues of technological feasibility and current requirements, the PWG came to full agreement to establish a minimum of 90 mg/100 kcal. There was full support for the establishment of a GUL of 280 mg/100 kcal.

The PWG discussed the need for including a calcium to phosphorus ratio. Some Codex Members supported this for the purpose of nutritional integrity and to retain a nutritionally balanced product. It was discussed that there was no need to establish a ratio as it did not fulfil the principles for addition. The working group was able to come to consensus, and no ratio was established as proposed in the Agenda paper. As such there are no square brackets for the inclusion of calcium to this product.

The recommendation for riboflavin was agreed to after the GUL was increased to 650 µg/100 kcal. This increase was to accommodate the levels of riboflavin in cows' milk.

The recommendation as proposed in the Agenda paper for vitamin B12 was agreed to. There are no remaining square brackets proposed for the mandatory addition of calcium, riboflavin and vitamin B12 and recommendation 16 was agreed to by the PWG.

Recommendation 16a:

If the Committee consider there is sufficient evidence to require the mandatory addition of zinc to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of zinc to [name of product] for young children with the following levels:

Zinc

Unit	Minimum	Maximum	GUL

mg /100 kcal	0.5	-	1.8
mg /100 kJ	0.12	-	0.43

The Agenda paper had recommended that the zinc was considered for optional addition to product for young children only. There was widespread support in the PWG that zinc should be included as a mandatory nutrient as it met the amended principle 1 and was widely inadequate in the diets of young children. This view was not supported by the European Union as it was not deemed to meet any of the principles for mandatory addition. It was stated that zinc inadequacy was not an issue in Europe, and therefore not a global issue; nor is cows' milk a significant contributor of zinc in the diet.

One Codex Organisation suggested that the GUL be extended to 2.1 mg/100 kcal. This suggestion was not supported by the working group. Based on the majority views of the working group. One Codex Member had noted their preferred GUL of 1.5 mg/100 kcal based on the possibility that intakes could exceed the upper tolerable limit and stated that their acceptance of a GUL of 1.8 mg/100 kcal was a compromise. The square brackets for the minimum and GUL were removed.

The European Union's reservations to require zinc as a mandatory nutrient are noted to be discussed further in the Committee.

Recommendation 17:

If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin A to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of vitamin A to [name of product] for young children with the following levels and associated footnote:

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)]/100 kcal	60	180	-
µg RE[10)]/100 kJ	14	43	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

The Agenda paper had recommended that vitamin A was considered for optional addition to product for young children only. There was widespread support in the PWG that vitamin A should be included as a mandatory nutrient as it met the amended principle 1 and was widely inadequate in the diets of young children. The minimum and maximum values proposed as an alternative approach in the Agenda paper were agreed to and the square brackets removed.

This view to mandate the addition of vitamin A was not supported by the European Union as it was not deemed to meet any of the principles for mandatory addition.

Based on the majority views of the working group the square brackets for the minimum and maximum were removed. The European Union's reservations to require vitamin A as a mandatory nutrient are noted to be discussed further in the Committee.

Recommendation 18:

~~If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin D to follow-up formula for young children,~~ That CCNFSDU agree to the mandatory addition of vitamin D to [name of product] for young children with the following levels:

Vitamin D

Unit	Minimum	Maximum	GUL
µg /100 kcal	[1.5] or [**1.0**]	[4.5] or **[3.0**]	-
µg /100 kJ	[0.36] or [**0.24**]	[1.08] or [**0.72**]	-

The Agenda paper had recommended that vitamin D was considered for optional addition to product for young children only as inadequacy was not problem for all countries and where it was supplementation or fortification programmes are in place to address the issue. There was widespread support in the PWG that

vitamin D should be included as a mandatory nutrient as it met the amended principle 1 that it was widely inadequate in the diets of young children.

Considering the values, the Agenda paper had proposed a minimum value of 1.5 and a maximum value of 4.5. OneCodex Member Organisation, 2 Codex Members and an observer proposed additional values, in line with the ones recommended for the Follow up formulas for older infants:

- 1.0 was proposed as an additional option for the minimum and
- 3.0 was proposed as an additional option for the maximum.

These values were suggested as they are the minimum and maximum limits proposed for follow-up formula for older infants. All values were kept between brackets for further discussion at the Committee but there was full support that vitamin D should be considered mandatory.

Recommendation 19:

That CCNFDSU agree to the following recommendation for sodium levels in [name of product] for young children:

Sodium

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	85	-
mg/100 kJ	-	20	-

The Agenda paper recommends that a maximum limit of 85 mg/100 kcal is established for sodium. This level is the current maximum limit for sodium in the follow-up formula standard. There was only one objection raised to this proposal. The European Union did not support the inclusion of a maximum limit. It was considered unnecessary and would be overly complicated and burdensome for some manufacturers using cows' milk as a major ingredient. Cows' milk contains sodium naturally, and levels particularly in reduced fat cows' milk are in excess of this maximum and would therefore be problematic.