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Mead Johnson Nutritionals Comments on the U.S. DRAFT Positions for the 24th CCNFSDU Session

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Dear Dr. Yetley:

Mead Johnson Nutritionals appreciates this opportunity to provide the following comments on the U.S. DRAFT Positions for the upcoming 24th CCNFSDU Session. As one of the largest manufacturers of infant formulas in the U.S. and internationally, we believe it is in the best interest of the infants who consume these products and the various markets we serve to have uniform standards that will assure safe and nutritionally adequate products around the world.

PROPOSED DRAFT STANDARD FOR INFANT FORMULA (AT STEP 4)

1. SCOPE

1.1 "This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. [The provisions in this standard are intended also for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements.]"

MJ Recommendation:

Although the U.S. Draft paper did not address the above section, we believe the sentence between brackets should be removed.

Rationale:

We believe 'thisstandard should be aimed at healthy term infants. Products intended for premature infants and other infants with special nutritional requirements are highly specific and too complex to include in this standard. If a standard for infants with special nutritional requirements is desired, it should be developed separately.

(new) **ANNEX 1**

General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula in (new) Section 3.1.3

MJ Comments:

In paragraph 1., delete "healthy" to be consistent with the decision at the last meeting to delete this term from the scope (1.1).

In paragraph 2., replace "normal growth" with either "adequate growth" or "acceptable growth". "Normal growth" has been debated at previous meetings as being too ambiguous. Perhaps one of the other terms would be more acceptable.

In paragraph 4., begin the sentence with "The values" instead of "They" to be clearer.

Also in paragraph 4., replace "consider" with "considering" or "take into account" to be more clear what is meant.

In paragraph 6.(d), we suggest the following: "(d) the inherent variability of nutrients in ~~raw~~ ingredients, ~~and in~~ ***including any*** water that may be added to the infant formula product ***during manufacturing*** ~~before or after it is purchased~~." The term "raw" is not used elsewhere to describe "ingredients" and deleting it would provide consistency without losing any meaning. Water is commonly used as an ingredient in manufacturing all forms of infant formula. The nutrient variability of any water added to prepare the formula for feeding, however, is beyond our control and should not be included in this list of principles.

In paragraph 7.(a), replace "ready to consume regular" with "prepared" to be consistent with the language in other paragraphs of the standard.

In paragraph 7.(a)(ii), replace "regular" with "prepared" for the same reason as just mentioned.

MJ Question: If the bracketed sentence in the scope (1.1) is deleted, would the last paragraph under paragraph 7. be needed?

3.1.2(a) Vitamins and (b) Minerals

MJ Comments:

As a general comment, the use of asterisks throughout this section should be replaced with something else like superscript letters or numbers to avoid confusion.

Iron (and zinc) - We support the U.S. proposed position to revise the footnote on iron to apply the same levels to cow's milk and soy-based formulas. We are not aware of any reliable data that shows the use of phytases makes a significant difference in iron bioavailability in soy formulas (note: the same is true with regard to zinc bioavailability). We do, however, recommend deleting the last sentence of the proposed revised footnote since this is a labeling issue and already addressed in Section 9.1.6.

Also, we support a higher level of 2.5 mg/100 kcal for the maximum for iron, as recommended by **AAP-CON** (1993) and in agreement with the recommendation from **ISDI** (30 July 2002).

Selenium – We agree with the **U.S.** position that a minimum level should be established for selenium. However, we support the minimum of 1.5 mcg/100 kcal from the **LSRO** report (1998), with a maximum of 8.5 mcg/100 kcal, similar to that established by **IOM** (2000).

3.2 OPTIONAL INGREDIENTS

MJ Comments:

3.2.3 We recommend the following additional revisions:

"When any of these ~~nutrients~~ ingredients is added, the formula shall contain sufficient amounts of ~~these nutrients~~ the substance ***either*** to achieve ~~the~~ its intended effect, ***or to provide mean levels found in human milk*** ~~based on levels in human milk~~."

Rationale: Contrary to the rationale in the **U.S.** draft position, Section 3.2.1 does not address the importance of considering the levels of these substances in human milk.

4. FOOD ADDITIVES

MJ Recommendation:

In addition to the food additives listed in Switzerland's proposal, we recommend adding gelatinized starch to the list of thickening agents, with a maximum level of 2.3 g/100 mL of prepared formula.

Rationale:

This starch is currently listed in EC Directive (91/321/EEC) for infant formulae although at a slightly lower maximum level. Mead Johnson Nutritionals has been adding a gelatinized starch to our Enfamil A.R. infant formula as a thickening agent for several years both in the **U.S.** and other countries. Including this starch to the Codex standard would facilitate the distribution of formulas of this type to those countries who rely on these standards.

9. LABELLING

9.1.5

MJ Recommendation:

In keeping with our recommendation to delete the bracketed sentence in 1.1, we recommend deleting this paragraph entirely. We do support the position presented by ISDI (attached separately) that appropriate claims that comply with the criteria in the attached ISDI position should be allowed for foods for infants.

Rationale:

We believe this standard should be aimed at healthy term infants. Products intended for premature infants and other infants with special nutritional requirements are highly specific and too complex to include in this standard. We support the development of a separate standard for products for infants with special nutritional requirements (FSMP).

PROPOSED DRAFT REVISION **OF** THE ADVISORY **LIST**(S) OF MINERAL SALTS **AND** VITAMIN COMPOUNDS FOR THE USE IN **FOODS FOR INFANTS** AND CHILDREN (CAC/GL 10/1979)

TITLE

MJ Comments:

We agree with the **U.S.** proposal to change the title as long as there is a clear definition of "young children". If not, there needs to be a proposed defmition, too.

SCOPE (new)

MJ Recommendation:

We recommend the following revisions to the opening paragraph:

"The nutrient compounds in these lists apply to ~~one or more of the following~~ food categories ***for infants and young children*** and their respective Codex standards+ ~~infant formula (IF), follow-up formula (FUF), Processed Cereal Based Foods for Infants and Young Children (PCPF), and Canned Baby Food (CBF).~~

Rationale:

Rather than include references to existing Codex standards, we believe the scope should be written more broadly which would allow the addition of more food categories and standards without re-writing the scope.

PROPOSED **DRAFT** GUIDELINES FOR VITAMIN ***AND*** MINERAL SUPPLEMENTS (AT **STEP 4)**

MJ Question: Are these guidelines intended to include vitamin and mineral supplements for pediatric consumers and pregnant/lactating women? It is not clear from the material we have seen.

PREAMBLE

MJ Recommendation:

The addition of the first sentence as proposed in the **U.S.** draft position seems to be ambiguous and unnecessary. In the interest of reducing further debate and inaction, we recommend keeping the preamble unchanged. Do other guidelines contain a stated purpose?

1. SCOPE

1.1 "These guidelines apply to vitamin and mineral supplements intended for use [by adults] in supplementing the daily diet ~~[if and where necessary]~~ with vitamins and/or minerals. ~~These guidelines apply to vitamin and mineral supplements which are regulated as foods.~~

MJ Recommendation:

We agree with the proposed changes but would like to insert the age/population group(s) for which these products are intended to clarify and answer the question posed above.

5.2 ["The name of the product ~~shall~~ **should** be "vitamin and mineral supplement" or "dietary mineral/vitamin preparation to supplement the diet with...", ~~with an indication of the nutrients contained therein.~~"]

MJ Recommendation:

This paragraph **(5.2)** is intended to address how the product should be named whereas **5.3** addresses how the nutrient information is to be formatted. Therefore, the last phrase of **5.2** should be retained to allow a product to be identified, for example "dietary mineral preparation to supplement the diet with iron."

5.7 "The label ~~must~~ **should** contain a warning statement [in the product contains an ~~significant~~ amount of a nutrient **that has been shown through science-based risk assessment to be a health hazard under *specified* conditions of use.** ~~With respect to the toxicity level~~."]

MJ Recommendation:

As written, the proposed language suggests that the intended conditions of use presents a health hazard. We don't believe that is the intent of the proposed warning statement. We believe it may be appropriate to **warn** consumers about health issues if there are other conditions of use that should be avoided, such as the accidental overdosing of iron-containing supplements.

We hope the above comments are helpful, and look forward to being part of the U.S. delegation to the upcoming Codex meeting. I will forward separately, before the August 30 deadline, the information requested to be considered as a member for the U.S. Delegation to the 24* CCNFSDU session. Please feel free to contact me if you have any questions regarding our comments in this letter.

Sincerely,

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