August 23,2002

Dr. Elizabeth Yetley
U.S. Delegate
Codex Committee on Nutrition and Foods for Special Dietary Use
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-450) 2B-014
5100 Paint Branch Road
College Park, MD 20740

02-022N
02-022N-15
Kenneth Mercurio

Re: Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)—Proposed U.S. positions for the 24th session of the Committee

Dear Dr. Yetley:

Nestlé USA, Inc. (Nestle) is a major U. S. producer of infant formula, baby cereal, clinical nutrition products and other fortified foods. We appreciate the opportunity to comment on several items to be discussed at the referenced Codex meeting in November. Most of our comments reference the draft U.S. positions distributed at the July 30,2002 stakeholder meeting. However, we will also comment on other agenda items as well as anticipated interventions from other delegations and NGOs.

Agenda Item 3 Nutrient Content Claims

Nestle **agrees** with the U.S. position regarding the upcoming dietary fiber definition from IOM, and labeling on a per-serving basis.

Agenda Item 4 Infant Formula Standard

Section 1. Scope

1.1 **Nestlé strongly advises the U.S. delegation to take the position that this standard should not apply to infants with special nutritional requirements.** The second sentence should read:

"The provisions in this standard are not intended for infants with special nutritional requirements."

If the second sentence were to have the brackets removed, the standard would be applicable to products intended both for normal healthy infants and for infants with special nutritional requirements. Formula for unhealthy infants should not be included in this standard, but should be included in an equivalent Codex standard on foods for special medical purposes (FSMP). If both types of formula products were to be included here, then the compositional requirements of the standard could be inappropriate for infants with special needs. Conversely, if a specialized product were adapted to a particular nutritional situation, it might pose a health hazard to normal healthy infants. (Also see related comments applying to section 9.1.5.)

Section 3. Essential composition

3.1.2 Nestlé supports the draft U.S. position and new Annex 1

3.1.2(d) Protein

(i) The first sentence should say ***"their*** partial hydrolysates", not ***"protein*** partial hydrolysates." This will make it clear that the partial hydrolysates refer only to cow's milk as mentioned in the sentence, and not other protein sources. The second sentence should be changed slightly to allow for the possibility of protein sources other than milk and soy. This possibility is consistent with Codex STAN **72-1981.** Thus, we recommend the second sentence read: "...nitrogen content x **6.25** for soya ***and other*** protein isolates and ***their*** partial hydrolysates."

Also, the amino acid levels in Annex 1, which are supposed to be the levels found in breast **milk,** are not actually representative of human milk protein. The FAO should update this annex.

3.1.2 (e) Fat and Fatty Acid

Nestle supports a trans fatty acid content not to exceed **5%** of the total fat content, not **4%.** The reason is that milkfat can contain up to **6%** trans fatty acids, and it is possible to make infant formula with a fat mix containing 80% milkfat.

3.2 Optional ingredients

3.2.1 Nestle **agrees** with the U.S.-suggested wording **except** for one point. We think the **U.S.** should, in recommending your new text, correct an existing problem with the wording. Both the proposed **U.S.** text and the existing text use the phrase "...(nutrients/substances) ordinarily found in human milk..." But this section obviously deals with more than simply substances found in human milk because §3.2.4 refers to lactic acid cultures. This is as it should be, because the goal of this section **3.2** is to allow for ingredients that give infant formula the qualities needed for babies to be as healthy as if they were breast fed. In other words, some ingredients like lactic acid cultures may not be in human milk, but they can **mimic** qualities and effects of human milk, with the appropriate goal being the health of the baby.

Therefore, Nestlé **recommends that the U.S. delegation alter slightly its proposed text** for **3.2.1** as follows:

"In addition to the essential nutrients listed under **3.1.2,** other ingredients may be added in order to provide substances ordinarily found in human milk, as well as inmedients that **give** formula aualities that result in babies being as healthy as if they were breast fed, to ensure that the formulation is suitable as the sole source of nutriture of the infant."

3.2.2

Last year the **U.S.** draft position suggested omitting the word "usefulness", and Nestlé supported this change. We agreed with the stated U.S. rationale, because in some cases substances may be added to milk, such **as** nucleotides, which are justified by the fact they are in human milk even though there has not been a clear demonstration of efficacy. We note that this year's written U.S. position is silent on this point, but encourage the delegation to again take this stand to focus on safety and not require a demonstration **of** usefulness.

In focusing on safety, Nestlé thinks it would simplify the proposed text to say: "Optional ingredients must be shown to be safe and suitable for infants by a qualified scientific body such **as** JECFA." Nestlé suggests that the acceptability of safety and suitability should be demonstrated to a qualified body, and thinks it helps to clarify meaning to add "such **as** JECFA"

3.2.3 Nestlé **agrees** with the **U.S.** draft position to modify the text of this section.

Section **4.** Food Additives

Nestle is still reviewing the draft **U.S.** position and may offer comments in the coming weeks.

Section 9. Labeling

9.1.4 Nestlé supports changing the text of this sentence back to what it was in the original standard, namely, "...or any milk derivative ***may*** be labeled ..." (not ***shall).*** The problem with "shall" is that it is difficult to guarantee complete absence of milk protein and any other milk derivatives, and would therefore require threshold levels of permissible residual milk content. Since the ingredient list would show whether or not milk or milk derivatives were used, we think it is sufficient to keep this disclosure as voluntary, not mandatory.

9.1.5 This paragraph is in brackets, and Nestle **strongly recommends deleting it** entirely. **As** we recommended in § 1.1 Scope on page 1, the Scope of this standard should be limited to normal healthy infants.

We note in the U.S. rationale that you are relying on the prohibition of health claims for infant foods to give this section the proper meaning. However, there is the phrase, "unless specifically provided for in relevant Codex standards." Nestle's position is that the relevant Codex standard to cover infant formula for special nutritional needs should be a Codex standard on foods for special medical purposes **(FSMP).**

Besides, the whole section 9.1.5 does not make sense to us at Nestlé. It says that the special requirements must be clearly labeled, yet no health claims are allowed. What is a labeling of special requirements if not a mention of a special health condition, which in turn is the definition of a health claim? The standard cannot have it both ways – addressing special nutritional needs but not allowing the reason for the special nutritional need to be mentioned on the label. To overcome this inherent problem, we **ask** that the Delegation **persuade the Committee to delete this entire section.**

9.1.6 Nestlé **agrees** with the **U.S.** position to favor the second of the two options.

9.6 Additional Labeling Requirements

9.6.1 (b) Nestlé strongly **agrees** with the U.S. position to support the second option, because addressing diarrhea and other illnesses departs **from** the intent of the International Code and should not be accepted.

9.6.5 Nestlé recommends that this provision be deleted because there is no doubt that the two products would be labeled differently according to the two Codex standards, which **are** different for the two products. The standards dictate different names, different composition, and different labeling. **(Of** course, under the current **U.S.** regulations, the two products have identical standards.)

Agenda Item 6 Processed Cereal-Based Foods for Infants and Young Children

Section 1 Scope

There are two proposed wordings, both in brackets. Nestle strongly prefers the first because it reflects the recommendation of the **WHO** Expert consultation and protects the health of infants, yet allows for flexibility for introducing cereal at an earlier age or when deemed necessary by a health professional.

Section 2 Description

Nestle recommends deleting the word "primarily" because some cereal products contain milk or protein-rich pulses at levels greater than 25%. Leaving in "primarily" would force those other ingredients to be less than 25% for no good reason.

Section 3 Essential Composition

3.1.1 As above, we **think** the word "primarily" should be deleted for the same reason (that milk and pulses should be allowed at a higher percentage than the characterizing cereal).

3.3 Protein In 3.3.1 a "reference" protein is mentioned, but none **is** referenced. Nestle supports the use of casein **as** the reference protein, which is consistent with FDA regulations.

3.4 Carbohydrates In 3.4.1 and 3.4.2, the **U.S.** questions the use of honey because **of** the botulism potential. Nestle thinks this is an unfounded concern given that § 3.8.2 specifically addresses the prevention of botulism in honey, Thus, the U.S. should support the continued allowance for honey.

3.6 Minerals In 3.6.1, we support the sodium levels of 100 mg/100 kcal for infants under 1 year, and 200 mg/10 kcal in products for older children. These levels are perfectly safe, and the brackets should be removed.

3.8.1 Optional Ingredients

Nestlé agrees with the **U.S.** suggestion to modify the second part of the sentence to introduce the concept of intended use, but we **disagree** that ingredients must be ***shown to be*** safe and suitable. We strongly feel that the broad range of optional ingredients do not need a *specific* ***demonstrution*** of safety but rather criteria such **as** common usage and expected safety by experts. Using maltodextrin, fruits and vegetables as examples, we see no need to undergo a safety evaluation of these ingredients because common usage and evaluation **are** sufficient for us to know they **are** safe for the intended age of the babies.

The suggested text which we ask the **U.S.** delegation to introduce is **as** follows:

"In addition to the ingredients listed under 3.1, other ingredients can be used that are safe and suitable for the intended use."

3.8.3 According to past interventions and published comments, certain other delegations and NGOs propose that the age of introduction of cocoa be increased from **9** months to **12** months because of risk of allergy. Nestlé suggests that the **U.S.** delegation oppose this proposal because many ingredients can cause allergies; some of the most serious and common allergens are found in milk and soy, which are basic ingredients in infant products. If an infant has **an** allergy to cocoa, another flavor of cereal may be chosen.

Section **4** Food Additives

Nestlé is still reviewing the **U.S.** proposals and positions as elaborated in its draft, and may submit comments on this in the coming weeks.

4.4 Flavors Nestlé strongly suggests that the **U.S.** delegation actively oppose any attempts to prohibit flavors in infant foods, which is baseless and counterproductive. All the proposed flavors have been evaluated for their safety. Also, the argument for prohibiting flavors, based on potential allergic reactions, is weak because almost all ingredients can theoretically be allergens, and the basic ingredients in these products, milk and soy, are major allergens. And, if a child is allergic to a particular flavor, other flavors are available and may be chosen.

Section **8** Labeling

8.3 Nestlé **opposes** any proposals to prohibit the portrayal of infants and young children on the product label. Pictures of children serve to **identify** the product and to illustrate the age group for which they are intended. These proposals have said that such portrayals could suggest an inappropriate age of introduction, but this is already forbidden under the Codex General Standard for the Labelling of Pre-packaged Foods (Codex STAN 1-1985 Rev 1-1991 Section 3.1.) which reads: "Pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect".

There also is no evidence to suggest that photos of children on products for the older infant results in a reduction of breastfeeding.

8.6.4 The second sentence in this paragraph should be deleted because it is redundant. **The** first sentence requires a statement indicating the age for intended use, so there is no purpose for stating the second sentence.

8.7 It is obvious that the brackets around "not" need to be removed.

Agenda Item 7 Advisory List of Mineral Salts and Vitamin Compounds

Nestlé supports the draft comments from the **U.S.** delegation.

Thank you again for the opportunity to comment on these numerous issues on the agenda **for** the upcoming meeting. Should you **wish** to discuss or clarify any **of** our recommendations, please feel free to contact me at **(818) 549-6353 or** Melanie Fairchild at **(818) 549-5868.**

Sincerely,

Kenneth Mercurio
Director, Regulatory and Nutrition