



29 September 2006

**ISDI COMMENTS on
Advisory list of nutrient compounds for the use in foods for special dietary uses
intended for use by infants and young children at step 3**

Answer to CX/NFSDU 06/28/6-Revised

In this document ISDI will not reiterate the entire comments made in its previous document 06/124 but would like to focus on additional comments or on comments that were not taken into account in the Codex document CX/NFSDU 06/28/6-Revised.

A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

| Nutrient Source | Purity Requirements by | | Use in Food Categories for Infants and Young Children | | | | | ISDI Comments |
|---|------------------------|--------------------------------------|---|-----|------|-----|------|---|
| | CAC ² | international and/or national bodies | IF | FUF | PCBF | CBF | FSMP | |
| 4. Source of Sodium (Na) | | | | | | | | |
| New Zealand: [4.11 - Sodium chloride(iodised)] | | USP, Ph Eur, BP, JP | ? | ? | ? | ? | ? | Delete this section Iodine levels in foods for special dietary should be tightly controlled and should therefore be added specifically rather than through iodised salt. |

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

| Nutrient Source | Purity Requirements by | | Use in Food Categories for Infants and Young Children | | | | | ISDI Comments |
|--|------------------------|--------------------------------------|---|-----|------|-----|------|--------------------------------|
| | CAC ² | international and/or national bodies | IF | FUF | PCBF | CBF | FSMP | |
| 4. Vitamin E | | | | | | | | |
| 4.6 DL-alpha-Tocopheryl acid succinate | | NF, MP, MI, USDP, Ph Eur, FCC | - | - | - | - | {√} | Martindale, 29th edition, 1989 |

| | | | | | | | | |
|--|---|----------------------------------|---|---|---|---|---|---|
| [4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate] | ? | FCC, USP | - | - | - | - | √ | |
| 10. Sources of Folic Acid | | | | | | | | |
| 10.2 Calcium-L-methylfolate | | Notified as GRAS (US FDA) | √ | - | - | - | √ | Approved in the EU and included in Directive 2001/15/EC on substances that may be added for PARNUTS |

C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

| Nutrient Source | Purity Requirements by | | Use in Food Categories for Infants and Young Children | | | | | ISDI Comments |
|---|------------------------|--|---|-----|------|-----|------|--|
| | CAC ² | international and/or national bodies | IF | FUF | PCBF | CBF | FSMP | |
| 2. Carnitine | | | | | | | | |
| 2.3 L-Carnitine tartrate | | FCC, Ph Eur | √ | √ | | | √ | This component is also allowed for use in the EU for Infant Formulae and Follow-up Formulae. |
| 6. Nucleotides | | | | | | | | |
| 6.1 Adenosine 5-monophosphate (AMP) | | FCC, FSANZ | √ | √ | | | √ | There is no FCC criteria for this component. |
| 6.5 Uridine 5-monophosphate sodium salt | | FSANZ, Jap Food Stan | √ | √ | | | √ | Those purity criteria correspond to the disodium forms and not to the sodium forms. |
| 6.6 Guanosine 5-monophosphate sodium salt | | FCC, JECFA (2000), FSANZ, Jap Food Stan | √ | √ | | | √ | |
| 6.7 Inosine 5-monophosphate sodium salt | | FCC, JECFA (2000), FSANZ, Jap Food Stan | √ | √ | | | √ | |
| 6.11 Disodium Uridine 5-monophosphate salt | | FSANZ, Jap Food Std | √ | √ | - | - | √ | Food Standards Australia New Zealand (Std 1.3.4) Japan's Specifications and Standards for Food Additives, 7th ed (2000) |
| 6.12 Disodium Guanosine 5-monophosphate salt | | FCC, JECFA, FSANZ, Jap Food Std | √ | √ | - | - | √ | FCC 5th ed (2005), JECFA, Food Standards Australia New Zealand (Std 1.3.4), Japan's Specifications and Standards for Food Additives, 7th ed (2000) |

| | | | | | | | | |
|---|--|--|-----|-----|---|---|-----|--|
| 6.13 Disodium Inosine 5-monophosphate salt | | FCC, JECFA, FSANZ, Jap Food Std | ✓ | ✓ | - | - | ✓ | FCC 5th ed (2005), JECFA, Food Standards Australia New Zealand (Std 1.3.4), Japan's Specifications and Standards for Food Additives, 7th ed (2000) |
| {9. Other Compounds} | | | | | | | | |
| {9.1 ARA (arachidonic acid rich single cell oil derived from the soil fungus <i>Mortierella alpina</i>)} | | US GRAS (2001), FSANZ | {✓} | {✓} | | | {✓} | ISDI does not believe that these ingredients should be specifically specified unless we want to make an extensive list of lipid sources used in infant nutrition products since these ingredients are not pure, but a mixture of oils. |
| {9.2 DHA (docosahexaenoic acid rich single cell oil derived from the microalgal species <i>Cryptocodinium cohnii</i>)} | | US GRAS (2001), FSANZ | {✓} | {✓} | | | {✓} | |

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

| | INS no. | Additive/Carrier | Maximum Level in Ready-to-use food [mg/kg] | ISDI Comments |
|-----|---------|---|--|--|
| (a) | 414 | EC: Gum Arabic (gum acacia) | 10 100 | ISDI supports the EC proposal and would like to see the maximum level for Arabic Gum increased. |
| (b) | 551 | EC: Silicon dioxide | 10 | ISDI supports the EC proposal for this carrier. |
| (c) | 421 | EC: Mannitol | 10 | ISDI supports the EC proposal for this carrier. |
| (l) | | Fish gelatine | | ISDI supports the addition of Fish Gelatine as it is used as a carrier for Vitamin E. Since Fish Gelatine is a food ingredient, ISDI believes that no maximum level in needed. |
| (m) | | Glycyl Tristearate | | ISDI supports the addition of Glycyl Tristearate as is it used as a carrier for certain forms of Vitamin E and Ascorbic Acid |
| (u) | 420 | ISDI: Sorbitol (carrier in L-Ascorbic Acid) | ? | ISDI would like to withdraw its request for this nutrient. |

ANNEX 1: REFERENCES & ABBREVIATIONS

ISDI references:

- “Opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes ('Parnuts').” Expressed 12 May 1999 by the European Scientific Committee on Food
(http://europa.eu.int/comm/food/fs/sc/scf/out31_en.pdf)
- Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to Calcium sulphate for use in foods for particular nutritional uses. Expressed 10 December 2003
(http://www.efsa.eu.int/science/afc/afc_opinions/193/opinion_afc_03_en1.pdf)
- Report on the essential requirements for weaning foods. Adopted 27 October 1989 and 30 March 1990 by the the European Scientific Committee on Food
(http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_24.pdf)
- Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as amended by Directive 2004/5
(http://europa.eu.int/eur-lex/en/consleg/pdf/2001/en_2001L0015_do_001.pdf)
- Commission Directive of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children
(http://europa.eu.int/eur-lex/en/consleg/pdf/1996/en_1996L0005_do_001.pdf)

Abbreviations:

| | |
|---------------|---|
| IF | Infant Formula |
| FUF | Follow-Up Formula |
| PCBF | Processed Cereal-Based Food |
| CBF | Canned Baby Food |
| FSMP | Food for Special Medical Purposes |
| BP | British Pharmacopoeia |
| BPC | British Pharmaceutical Codex |
| DAB | Deutsches Arzneibuch |
| DAC | Deutscher Arzneimittel-Codex |
| FCC | Food Chemicals Codex |
| FSANZ | Food Standards Australia New Zealand |
| FU | Farmacopoea Ufficiale della Repubblica Italiana |
| JP | The Pharmacopoeia of Japan |
| Jap Food Stan | Japanese Food Standard |
| NF | The National Formulary/USA |
| Ph Eur | Pharmacopoeia Europaea |
| Ph Franç | Pharmacopée Française |
| Ph Helv | Pharmacopoea Helvetica |
| Ph Int | International Pharmacopeia |
| USP | The United States Pharmacopeia |