Agenda Item 6

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-eighth Session

FAO Headquarters, Rome, Italy, 4 – 9 July 2005

LIST OF PROPOSED DRAFT STANDARDS AND RELATED TEXTS

SUBMITTED AT STEP 5

Comments submitted (as of 23 May 2005)

CCASIA

PROPOSED DRAFT STANDARD FOR GINSENG PRODUCTS (ALINORM 05/28/15; para. 26 and Appendix II)

International Alliance of Dietary/Food Supplement Associations (IADSA)

At its last meeting in July 2004 the Codex Alimentarius Commission (CAC) approved as new work the development of a standard for ginseng products with the understanding that the Codex Coordinating Committee for Asia (CCASIA) would undertake initial work on the elaboration of a Codex standard inclusive to all varieties of ginseng and applicable to ginseng products consumed as foods and not as medicinal drugs. The decisions as to whether the standard should be finalised as a regional or international standard, and if the latter was the case, which Committee should finalise the standard, would be taken by the CAC after adoption at Step 5.

The CCASIA met in September 2004 and considered the proposed draft standard for ginseng products. It decided to move the text, with some changes, to Step 5 for consideration by the CAC in 2005 and further development in the Codex process as an international standard, preferably by the Codex Committee on Processed Fruits and Vegetables.

Several modifications were made to the proposed draft standard for ginseng, now at Step 5. This draft has therefore been improved and resolves some of the concerns that were considered at the 2002 meeting of the Codex Committee on Processed Fruits and Vegetables when the draft was at Step 3. Despite this progress some of the concerns have not been addressed yet.

1. GENERAL COMMENT

As a first and general comment, IADSA would like to bring the attention of the Commission to the fact that taking into account its characteristics and the way it is being developed, this draft standard should focus on Panax Ginseng and therefore the standard should only regulate this specific species of Ginseng.
This would facilitate to advance in the development of this standard as integrating all species of ginseng in one
standard would require scientific expertise that Codex does not have at this moment in time. Therefore it should
be replaced the word “ginseng” with ‘Panax Ginseng’ every time it appears throughout the text. The title should
then read Proposed Draft Standard for Panax Ginseng Products.

2. SPECIFIC COMMENTS

In addition, IADSA provides the following comments addressing the different issues concerning the current draft
standard for ginseng products.

A. Concerning Existing Standards for Ginseng

The draft standard at Step 5 has modified some of the standards set in the World Health Organisation (WHO)
monograph for Panax Ginseng. In particular, total ash (an indication of purity) is limited to 4.2% in the WHO
document (which is consistent with the Japanese Pharmacopoeia) while the draft standard would allow 6.0%.

B. Clarity

Many of the issues identified as lacking clarity have now been resolved. Nevertheless, additional points made in
the comments filed on the previous draft at Step 3 are still of concern:

- Scientific names. The species \textit{Panax ginseng} C.A. Meyer was recorded in some older texts as \textit{Panax schinseng} T. Nees and the plant is still occasionally referred to that older name. For greatest clarity, the
  first mention of the species should be written as “Panax ginseng C.A. Meyer, syn. \textit{P. schinseng} T. Nees”. On the other hand, the draft at Step 5 still excludes \textit{Panax japonicus}.

- Extraction solvents are narrowly defined. The definition of “ginseng extract products” continues to be
  limited to those that are “manufactured by extracting soluble components of the dried ginseng
  root…using water and/or ethanol…” There are several other solvents that can be used in the processing
  of ginseng extracts and there is no reason to imply that those made with water and/or ethanol are
  superior, or that other solvents can not be used. No scientific rationale is presented to support this
  unnecessary limitation.

  Therefore IADSA would like to propose to replace in section 2.1.2 the words “using water and/or
  ethanol” by ‘using water and/or appropriate food-grade organic solvent’.

C. New concerns identified in the draft standards at Step 5

Several additional concerns should be addressed in relation to the draft proposed standard at Step 5. These
include:

- Given current specific concerns on contamination of ginseng, it must be argued that the standard
  proposed for pesticides is not sufficiently specific. The use of illegal fungicides, especially
  pentachloronitrobenzene (PCNB, or quintozene) has been broadly reported for at least five years. If a standard is
  developed this should be meaningful, address known problems and should be flexible enough to account for
  newly emerging issues.

- The draft at Step 5 states that the minimum fill must be “not less than 97%.” This is not sufficient and it
  should be required 100% of the listed amount of all added ingredients to be present in the product.

- The “labelling” section of the current draft would require the name of a ginseng ingredient to be either
  “white ginseng;” “red ginseng;” “white ginseng extract;” or “red ginseng extract.” This standard would not be in
  conformity with national labelling regulations for dietary supplements that contain ginseng. Section 7.1 should
  be modified as follows: ‘The name of the product types shall be “White Asian Ginseng”, “Red Asian Ginseng”,
  “White Asian Ginseng Extract Products”, or “Red Asian Ginseng Extract Product”’.

- There is almost certainly resistance to the precedent of “country-of-origin” labelling. If this becomes
  required for ginseng, when does it become required for the other ingredients in herbal dietary supplements? …
  and what does the label look like if a manufacturer of a dietary supplement (or a food for that matter) must
disclose country-of-origin for all ingredients? Section 7.2 should be deleted.

- The same concern as above exists for the requirement for the inclusion of the scientific name on labels.
  In some countries the use of scientific names is required only if there is not a “standardised common name”
established for a species in the reference that has been “incorporated by reference” in national regulations.
The requirement in section 7.4 that ginseng products must be labelled with clear markings that they are not intended for medicinal purposes (and are used for specified population groups) is redundant and unnecessary. Any requirement to include additional information on a small package is always cause for concern. Section 7.4 should be deleted.

CCFFP

PROPOSED DRAFT STANDARD FOR STURGEON CAVIAR AT STEP 5 (ALINORM 05/28/18; para. 148, Appendix VI)

United States of America

The United States supports adoption by the Commission of the Proposed Draft Standard for Sturgeon Caviar at Step 5. We do not anticipate any adverse implications for our economic interests with this Proposed Draft Standard. Any comments specific to the content of the document will be submitted at Step 6.

CCFH

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR EGGS AND EGG PRODUCTS (ALINORM 05/28/13; para. 156 and Appendix IV)

Guatemala

2.5 DEFINICIONES

Sugerimos los siguientes textos para las definiciones de huevo y huevo de incubadora que a continuación se detallan, pues consideramos que es necesaria su especificación:

Huevo - es el producto de figura ovoide, proveniente de la ovoposición de las aves; se componen de cáscara y sus membranas, yema y clara, destinado a consumo humano.

Huevo de incubadora - Es un huevo fértil cuyo destino usual es la incubación para la producción de aves.

3.2.1 Gestión de la parvada y salud animal

….El manejo de la parvada es de fundamental importancia en la reducción del riesgo de enfermedades humanas causadas por el consumo de huevos. Las buenas prácticas pecuarias también deberían ser utilizadas para reducir la probabilidad de la presencia de patógenos (es decir, de enfermedades avícolas aviares)…

Guatemala sugiere el término aviar en la versión en español, ya que avícola es la industria, al referirse propiamente a las enfermedades se hace como “aviares.”

3.3 RECOLECCIÓN, MANIPULACIÓN, ALMACENAMIENTO Y TRANSPORTE DE HUEVOS

(Segundo párrafo)

Se deberían implementar las medidas adecuadas higiénicas durante el desecho de los huevos no inocuos y los huevos no idóneos

Guatemala opina que el uso de la palabra higiénicas es más claro que el uso de la palabra adecuadas.

3.5 Documentación y mantenimiento de Registros:

Nuevamente aparece en la primera viñeta el término “enfermedades avícolas”, se sugiere cambiar por “enfermedades aviares”

Guatemala sugiere el término aviar en la versión en español, ya que avícola es la industria, al referirse propiamente a las enfermedades se hacemos como “aviares.”

5.1. CONTROL DE PELIGROS ALIMENTARIOS

Viñeta 1: Huevo de incubadora huevo fértil incubado

Guatemala sugiere sustituir huevo de incubadora por huevo fértil incubado.
CCFO
PROPOSED DRAFT AMENDMENT TO THE STANDARD FOR NAMED VEGETABLE OILS; INCLUSION OF RICE BRAN OIL (ALINORM 05/28/17; para. 43, Appendix V)

Brazil
Section 3) Essential Composition and Quality Factors

Brazil agrees with the adoption of the document in step 5; however, it reinstate that some bands do not contemplate the obtained values on the analyses of rice oil produced in the country.

Based on studies done by Official Laboratory with 46 samples of rice oil national manufacture, and based on sample findings of rice oil of national industries, Brazil suggests increasing the band for some fatty acids, in bold, as Table 1 below.

Table 1: Fatty acid composition of vegetable oils as determined by gas liquid chromatography from authentic samples (expressed as percentage of total fatty acids)

<table>
<thead>
<tr>
<th>Fatty acid</th>
<th>Rice Bran oil</th>
<th>Fatty acid</th>
<th>Rice Bran oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>C6:0</td>
<td>ND</td>
<td>C18:2</td>
<td>29-21-40</td>
</tr>
<tr>
<td>C8:0</td>
<td>ND</td>
<td>C18:3</td>
<td>0,1-2,9</td>
</tr>
<tr>
<td>C10:0</td>
<td>ND</td>
<td>C20:0</td>
<td>ND-0,9</td>
</tr>
<tr>
<td>C12:0</td>
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<td>C14:0</td>
<td>0,2  0,1-0,6</td>
<td>C20:2</td>
<td>ND</td>
</tr>
<tr>
<td>C16:0</td>
<td>13-23</td>
<td>C22:0</td>
<td>ND-0,5</td>
</tr>
<tr>
<td>C16:1</td>
<td>ND-0,5</td>
<td>C22:1</td>
<td>ND</td>
</tr>
<tr>
<td>C17:0</td>
<td>ND</td>
<td>C22:2</td>
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<td>C17:1</td>
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</tr>
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<td>C18:0</td>
<td>0,9- 2,5 4,0</td>
<td>C24:1</td>
<td>ND</td>
</tr>
<tr>
<td>C18:1</td>
<td>38-46 34-54</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Justification: The bands proposed do not attend to the rice oil manufactured in Brazil.

CCNEA

DRAFT REGIONAL STANDARD FOR CANNED HUMUS WITH TEHENA (ALINORM 05/28/40; para. 34, Appendix III)

Lebanon
Title

The spelling of the product name does not comply with the Arabic pronunciation nor with the name currently used worldwide on the labels:

“Canned Hummus with Tahina (Chickpea Dip)

4.1 Acidifying Agents

Permit the use of other acidifying agents which reduces the pH of the product without giving it an acidic taste (ex: gluconic acid, lactic acid etc…)
9.1 Name of the Food

The draft standard specified that “the product name of the food shall be “Canned Humus with tehena (processed chickpeas with tehena)”:

- It is not practical to use the word “Canned” on the label
- Is it necessary to use the same spelling of the product name used in the standard?

DRAFT REGIONAL STANDARD FOR CANNED FOUL MEDAMES (ALINORM 05/28/40; PARA. 43, Appendix III)

Lebanon

Parts 3.4.1 and 3.4.2

Adopt one drained weight for the product, to give the manufacturer the possibility (for practical reasons) to lower the fava beans content in order to use some other optional ingredients (tomato sauce, tahina)

“Drained weight shall be not less than 65% of the net weight”

DRAFT REGIONAL STANDARD FOR TEHENA (ALINORM 05/28/40; PARA. 53, Appendix III)

Lebanon

2.1 Product Definition

It is important in this part to specify the physical status of the product:

“It is a viscous liquid” / “It should be pourable”

CCRVDF

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS (ALINORM 05/28/31, Appendix V)

Argentina

Pirlimicina: con respecto al LMR establecido en leche se considera que debe revisarse dado que el criterio utilizado por JECFA en la reunión 62, estuvo basado en la potencial inhibición de los iniciadores (starter) de cultivos en lácteos y no basados sobre la seguridad del alimento para humanos.

Australia

Flumequine (in black tiger shrimp): Australia supports the request by JECFA for details of the approved use for flumequine. In addition it is suggested the MRL should be established for (extrapolated to) all shrimp and prawns. Australia notes that further data requested by JECFA is still to be submitted and evaluated.

Pirlimycin: Australia has concerns about the way the MRL for pirlimycin in milk was established (i.e. based on inhibition of dairy starter cultures). This is a food-processing issue and is not related to consumer safety. While Australia supports the right of any country to regulate milk on this basis, we do not support this as a basis for elaboration of an international standard. The proposed MRL will result in the unnecessary discard of milk, which has been determined to be safe for human consumption. Australia supports the re-evaluation of this MRL at the next CCRVDF meeting and shares the concerns of other delegations that JECFA is exceeding its frame of reference.

Cypermethrin and alpha-cypermethrin: Australia supports harmonisation with JMPR/CCPR and the move to Step 5. Australia notes that the residue definition for marker residue should be “cypermethrin” and not “total of cypermethrin residues” as the latter is redundant (cypermethrin is defined as the sum of 8 isomers).
**Doramectin** (in cow’s milk): Australia supports the recommendation to progress the MRLs to Step 5. Australia shares the concerns of other delegations that JECFA is exceeding its frame of reference by inappropriately commenting on withdrawal times and GPVD, which are risk management issues.

**Canada**

Canada supports the adoption, by the 28th Session of the Commission, of the draft MRLs recommended by the 62nd JECFA and advanced to Step 5 by the 15th Session of the CCRVDF, specifically:

- Flumequine draft temporary MRL black tiger shrimp.
- Pirlimycin for cattle tissues and cattle milk.
- Cypermethrin and alpha-Cypermethrin for cattle and sheep tissues, and cattle milk.
- Doramectin for cattle milk.

**Egypt**

It is accepted for:

- **Flumequine**: ADI 0-30 µg/kg bw in Black Tiger Shrimp
- **Pirlimycin**: ADI 0-8 µg/kg bw
- **Cypermethrin and alpha Cypermethrin**: ADI of 0-20 µg/kg bw
- **Doramectin**: ADI 0-1 µg/kg bw in cattle milk.

**United States of America**

**Flumequine**: The U.S. supports the temporary MRL for Black Tiger Shrimp (*P. monodon*) muscle tissue.

**Pirlimycin**: The U.S. supports the cattle tissue MRLs but does not support the MRL for cattle milk. The recommended MRL is much lower than the U.S. tolerance and it could impart unnecessary discard of milk. There is some concern that the JECFA terms of reference do not indicate consideration of food processing in recommending MRLs. The U.S. considers this latter point to be a risk management decision for national authorities.

**Cypermethrin and alpha-Cypermethrin**: The U.S. supports the harmonized ADI and MRLs for cattle and sheep tissues.

**Doramectin**: The U.S. can support the MRL in cattle milk for international trade purposes. The U.S. notes that doramectin is not approved for use in female dairy cattle over 20 months of age in the U.S. The U.S. questions the purpose of the footnote with respect to good veterinary practice considerations included as part of the JECFA assessment as it may not be relevant globally. The U.S. is of the opinion that the footnote may raise unnecessary concerns for food safety and for international trade.