June 2007

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **ORIGINAL LANGUAGE ONLY**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirtieth Session

Rome, Italy, 2-7 July 2007

COMMENTS ON PROPOSED DRAFT STANDARDS AND RELATED TEXTS SUBMITTED AT STEP 5

(Comments submitted as of 5 June 2007)

CODEX COMMITTEE ON FOOD ADDITIVES
COMITÉ DU CODEX SUR LES ADDITIFS ALIMENTAIRES
COMITÉ DEL CODEX SOBRE ADDITIVOS ALIMENTARIOS

Proposed Draft Guidelines for the Use of Flavourings (with exception of Section 4 and Annexes A and B) (ALINORM 07/30/12 Rev. para. 123 and Appendix XI)

JAPAN

We are pleased to provide our comments on the Proposed Draft Guidelines for the Use of Flavourings (Appendix XI, ALINORM 07/30/12 Rev.) which will be forwarded to the 30th Session of the Codex Alimentarius Commission for adoption at Step 5.

Regarding the **Section 2.2** (the definition of "Flavourings"), we would like to propose the following modification (adding the phrase in boldface to the first sentence) since the report does not seem to reflect what was agreed at the 39th CCFA correctly:

2.2 Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives -CAC/GL 36-1989) **rather than to enhance nutritional quality or to fulfill other technological effects**. Flavourings do not… (*and the rest part continues*)

FAO/WHO COORDINATING COMMITTEE FOR ASIA
COMITÉ DE COORDINATION FAO/OMS POUR L'ASIE
COMITÉ COORDINADOR FAO/OMS PARA ASIA

Proposed Draft Standard for Ginseng Product (ALINORM 07/30/15 para. 68 and Appendix III)

INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS (IADSA)

IADSA would like to provide the following comments to the Codex Alimentarius Commission in response to the Circular letter CL 2006/53-ASIA circulated with the Report of the 15th Session of the Codex Coordinating Committee for Asia (ALINORM 07/30/15) and following the decision of the Committee to forward the Proposed Draft Standard for Ginseng Product (Appendix III) to the Commission for adoption at Step 5.

2. DESCRIPTION

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* C.A. Meyer 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.

In addition, the species *Panax ginseng* C.A. Meyer was recorded in some older texts as *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. *P. schinseng* T. Nees". On the other hand, the draft still excludes *Panax japonicus.*

2.2.2 Ginseng Extract

Extraction solvents are narrowly defined. The definitions of "ginseng extract products" continue to be limited to those that are "manufactured when soluble components of … are extracted, using water, ethanol or their mixture…" 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, ethanol or their mixture' are superior or that other solvents cannot be used. No scientific rationale is presented to support this unnecessary limitation.

Therefore IADSA would like to propose to replace the words "… using water, ethanol or their mixture…" by '… using water, <u>appropriate food-grade organic solvent</u> or their mixture…'

3.2.1 Dried Ginseng

The proposed draft standard differs from 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%. IADSA would like to request to limit to "no more than <u>4.2%</u>" the provision for Ash.

4.1 Pesticide Residues

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.

6.1 Minimum Fill

The draft states that the minimum fill must be "not less than 97%." This is not sufficient and it should be required <u>100%</u> of the listed amount of all added ingredients to be present in the product.

7.1 Name of the Product

This section should be modified as follows: '… the products manufactured with Panax ginseng C.A. Meyer can be named "White Asian Ginseng", "Red Asian Ginseng", "White Asian Ginseng Extract Products", or "Red Asian Ginseng Extract"'.

7.2 Name of the Ginseng Species and Country of Origin

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?

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. IADSA therefore proposes to delete this section 7.2.

7.4 Other Labelling Requirements

The requirement that ginseng products should 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. For these reasons, IADSA considers that section 7.4 should be deleted.

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
COMITÉ DU CODEX SUR LES POISSONS ET LES PRODUITS DE LA PÊCHE
COMITÉ DEL CODEX SOBRE PESCADO Y PRODUCTOS PESQUEROS

Proposed Draft Code of Practice for Fish and Fishery Products (Live and Raw Bivalve Molluscs, Lobsters and Crabs and relevant Definitions) (ALINORM 07/30/18, para. 92, Appendix IV)

EUROPEAN COMMUNITY

The ECMS support the advancement of these sections of the Code of Practice to Step 5 but wish however to submit the following comments in view of preparing the discussion at next session of CCFFP.

Section 2 Definitions for the purpose of this code

Point 2.3 LIVE AND RAW BIVALVE MOLLUSCS

Conditioning: It is necessary to underline that this notion only applies to products intended for human consumption.

Conditioning *means placing live bivalve molluscs, coming from harvesting areas approved for direct consumption, relaying areas or depuration center, in tanks, floats or natural sites to remove sand, mud or slime and improve product acceptability*

The definition for depuration should be more precise by referring to the reduction of *E. coli* contamination.

Depuration *means the reduction of microorganisms, evaluated by the reduction of the level of E. coli contamination, used as an indicator of the presence of faecal contamination, to a level acceptable for direct consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial sea water suitable for the process, which may be treated or untreated*

The ECMS suggest to add a definition for depuration centers as follows:

Depuration center *means any approved establishment for the depuration of live bivalve molluscs.*

Section 7 Live and raw bivalve molluscs

Point 7.1 GENERAL REMARKS, ADDITION TO THE PRE-REQUISITE PROGRAMME

The first sentence of para 3 and 6 should be modified to take into account the consumption of live bivalve molluscs:

The main hazard known for the production of bivalve molluscs is microbiological contamination of waters in which they grow, especially when the bivalve molluscs are intended to be eaten live or raw.

Especially when the bivalve molluscs need to undergo relaying or depuration to be eaten live or raw, …

In para 3, Azaspiracid is the name of the substance and not the associated symptom. The sentence should therefore be modified as follows:

Biotoxins produced by some algae can cause various forms of serious poisoning like diarrhetic shellfish poisoning (DSP), paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), amnesic shellfish poisoning (ASP) or poisoning caused by Azaspiracid (AZP).

2nd sentence of para 4:

To control the hazards, … … molluscs safety. The identification, classification and monitoring of ~~these waters~~ these areas is a responsibility for competent authorities ….

7th sentence of para 4: It is necessary to precise that harmful substances should not be present in the edible parts of the animals:

Harmful chemical substances should not be present in the edible part in such amounts that the calculated dietary intake exceeds the permissible daily intake.

3rd sentence of para 4: A single indicator for faecal contamination should be proposed. The criteria « **faecal coliform** » or « total coliforms » should be deleted in this paragraph in **Appendix IV (7.2.2, 7.2.2.1, etc**.) and l'**Appendix V**, because « ***Escherichia coli*** » is a much better indicator for faecal contamination. « *E. coli* » is also the criteria chosen by WHO in the guidelines for potable water. Moreover, many total coliforms have no faecal origin :

To control the hazards, … … and primary producers. E. coli/~~faecal coliforms or total coliforms~~ may be used as an indicator for the possibility of faecal contamination. …

Para 5: It is necessary to precise that depuration and relaying are efficient to reduce the bacteriological contaminations to an acceptable level but have no effect on viruses, what is confirmed by para 7.5 *« Depuration alone is not suitable for cleansing bivalve molluscs from more heavily contaminated areas or areas subject to contamination by hydro-carbons, heavy metals, pesticides, viruses, vibrio or biotoxins »*.

Bivalve molluscs from waters subject to microbiological contamination, as determined by the authority having jurisdiction, can be made safe by relaying in a suitable area, ~~or~~ by a depuration process to reduce the level of bacteria ~~and the level of viruses if the process is continued long enough~~, or by processing to reduce or limit target organisms. Depuration is a short-term process commonly used to reduce low levels of bacterial contamination but inefficient for significant reducing of viruses using common process, but long term relaying is required if there is a greater risk if contamination.

It should be underlined that live bivalve molluscs destined to purification and relaying can only be marketed by a distribution centre or establishment; this appears in the chart (7.1) but should be more explicit.

Point 7.2 CLASSIFICATION AND MONITORING OF GROWING AREAS

Salmonella spp should be added as an example of « enteric bacterial pathogens », Heavy metals (lead, cadmium, mercury) as example for « chemical contaminants ».

- *enteric bacterial pathogens (e.g. Salmonella spp.);*
- *enteric viral pathogens (e.g. Norovirus, viruses causing hepatitis);*
- *naturally occurring bacterial pathogens (e.g. Vibrio spp.);*
- *biotoxins (e.g. ……AZP)*
- *chemichal contaminants (e.g. heavy metals such as lead, cadmium or mercury)*

Point 7.2.1 CLASSIFICATION OF GROWING AREAS

6th paragraph: radiation of bivalve molluscs has no scientific basis

Classified growing areas should be clearly defined by the official agency having jurisdiction as either:

- *suitable for harvesting for direct human consumption, relaying in acceptable water or depuration in an approved depuration centre or approved processing to reduce or limit target organisms e.g. heat treatment, ~~radiation~~, hydrostatic pressure, IQF; or*
- *non-suitable for growing or harvesting bivalve molluscs.*

Point 7.2.2 MONITORING OF GROWING AREAS

Para 1 and 2nd indent of para 6: The risk for human public health is linked to the consumption of bivalves and it is not sufficient to only carry out an analysis of water. The ECMS are indeed of the opinion that both examination of mollusc's flesh and monitoring of the water should be carried out, as only one of these two measures is not sufficient to guarantee the safety of the product to the consumer.

Growing areas should be routinely monitored for changes in water quality and~~/or~~ bivalve molluscs quality, and sub-standard areas patrolled to prevent harvesting for purposes other than that established by the official agency.

- The bivalve molluscs harvested meet the end product specification. This can be determined by examination of molluscs flesh ~~or through adequate monitoring of the water~~.

1st and 2nd indent of para 5: It is necessary to keep the possibility to adapt the sampling frequency to the level of contamination and to the associated health risk in a certain area.

The 2nd indent is in contradiction with 7.2.2.2

- Classification/reclassification of growing areas~~, by sanitary survey, monitoring of E. coli/faecal coliforms or total coliforms~~ within two or three categories according to requirements at an appropriate frequency based on the likely variation of contamination and on the risk of contamination and other sanitary control measures as applicable (see 7.2.2.2).

~~- Classification/reclassification of growing areas by monitoring of pathogens at an appropriate frequency based on the risk of contamination in bivalve mollusc meat (see 7.2.2.2)~~

3rd indent of para 5 :

- Closure/Reopening of ~~growing waters~~ growing areas by the monitoring ….

Point 7.2.2.1 *E. COLI*/FAECAL COLIFORMS/TOTAL COLIFORMS

1st para :

All growing areas should be monitored for the presence of E. coli/~~faecal coliforms or total coliforms~~ at an appropriate frequency based on the likely variation of contamination and the risk of contamination.

para 4 : The last sentence dealing with the detection of bacteriophages should be deleted, as it is in contradiction with para 7.2.2.2

~~Bacteriophage and viral detection could also be used as indicators when validated analytical methods become available in the future.~~

Point 7.2.2.2 PATHOGEN MONITORING

2nd sentence :

Shellfish sanitation program… pathogens. However, where there has been shellfish borne outbreak caused by an identified such as Salmonella and others (pathogenic Vibrio and virus), monitoring the ~~shelfish meats~~ bivalve molluscs may be appropriate as part of the process of ~~reopening~~ closure/reopening of the affected harvest area. ……

Point 7.2.2.3 MARINE BIOTOXIN CONTROL

para 3 : One negative result is not enough. Numerous observations and experiments show that two weeks og negative results are needed.

The official agency having jurisdiction should close immediately and effectively patrol affected areas when acceptable levels are exceeded in edible portions of bivalve molluscs meats. These areas should not be opened before toxicological investigation has made clear that the bivalve molluscs meat is free from hazardous amounts of biotoxins, through, at least, two consecutive negative tests.

Bullets of para « Spatial representational sampling »: group bullets 1 and 6 as they are linked.

- *Hydrography, known upwellings, fronts, current patterns and tidal effects which may trigger advection of offshore toxic micro-algal blooms into growing areas.*
- *Access to sampling stations in all weather conditions during harvesting.*
- *Desirability of toxin and micro-algal sampling at the same sampling station.*

• *In addition to primary (routine) stations, the need for secondary (complementary) and offshore stations.*

• *Existence of in-situ growth (for example, toxic micro-algae from cyst beds).*

• ~~*The advection of offshore toxic micro-algal blooms into growing areas.*~~

POINT 7.3 HARVESTING AND TRANSPORTATION OF LIVE BIVALVE MOLLUSCS

6th bullet, last sentence: It is suggested to increase the temperature of storage to 15°C.

• *On removal from water……with solid carbon dioxide. In most cases storage above ~~10~~15°C (~~50~~59°F) or below 2°C (35°F) should be avoided.*

7th bullet, last sentence: water used to clean the live bivalve molluscs could be reused if treated.

• *Bivalve molluscs should be free from excessive…… molluscs already cleaned. The water could ~~should not~~ be re-circulated after being treated properly to become clean.*

Point 7.4 Relaying areas

1st sentence of para 2: Relaying is already defined in section 2.3.

~~*Relaying is intended to reduce the level of biological contaminants of microbiological contamination that may be present in bivalve mollusks which have been harvested from contaminated areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing.*~~ *Bivalve mollusks harvested …… directly on the bottom.*

1st bullet: the management of the relaying zone should fulfil the "all in all out" principle.

Relaying operations should be strictly supervised by the official agency having juridiction to prevent … …. These areas should be adequately separated from the bivalve molluscs in adjacent waters to prevent cross contamination and commingling. The "all in, all out" system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.

Point 7.5 DEPURATION

Para 1, 2nd sentence: the efficiency of depuration to eliminate vibrios is questionable.

Depuration alone is not suitable for cleansing bivalve molluscs from more heavily contaminated areas or areas subject to contamination by hydro-carbons, heavy metals, pesticides, viruses, vibrio or biotoxins.

para 3: Depuration in reproduction period should be inadvisable rather than forbidden.

For natural functioning and therefore depuration to occur it is essential that the molluscs have not been overstressed or damaged during harvesting or handling prior to depuration and ~~are not~~ should not be in a seasonally weak or spawning condition.

3rd sentence of 4th bullet: Washing with potable water could lead to stress for the bivalve molluscs.

Dead or damaged … …commensal organisms. If necessary the bivalve molluscs should be washed with clean sea water ~~or potable water~~ before the depuration process.

Page 62, 5th bullet: the last sentence should be clarified.

• *The length of the period of depuration should be adapted……depuration parameters. It should be taken into account that viruses and Vibrio spp. are more persistent during depuration than the indicator bacteria mostly used for microbiological monitoring (E. coli and faecal coliforms) and that the reducing of their number is far from being precisely technically controlled.*

Point 7.6 PROCESSING OF BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT

Page 64, last bullet: Water treatment systems should be approved by the comptent authority.

• *Recirculating wet storage systems must contain approved water treatment systems.*

Point 7.6.4.2, 3rd bullet: this recommendation should be enlarged to cover freezing:

• *Shucked and post harvest treated product should be packed and chilled or frozen as soon as possible.*

Point 7.6.4.2, 4th bullet: It would be advisable to refer to the section dealing with freezing (section 8.3) :

• *Freezing should take place quickly (see section 8.3). Slow freezing will damage meat.*

Point 7.6.4.2, 5th and last bullets: There are redundant provisions for the labelling of raw treated products between the standard and the code of practice.

Point 7.6.5.2: Storage temperatures (frozen or refrigerated products) should be indicated for raw treated products.

Point 7.6.6: temperatures should be mentioned for the transport of bivalve molluscs.

Point 7.7 PROCESSING TO REDUCE OR LIMIT TARGET ORGANISMS

The introductory paragraph could be clarified as follows: *« As with all live and raw bivalve molluscs, these bivalve molluscs must meet all microbiological criteria associated with traditional harvest water controls designed to prevent faecal contamination and resulting introduction of enteric pathogens as well as toxins and other contaminants. However, these ~~traditional harvest water~~ growing areas controls are not designed for control of pathogens that are independent from faecal contamination. Processing to reduce or limit target microorganisms may include the application of low heat, hydrostatic pressure (e.g., 60K lb/6 min.), irradiation, and individual quick freezing. »*

Last sentence of the introductory paragraph: Irradiation of bivalve molluscs is forbidden by the EC legislation.

Processing to reduce or limit target microorganisms may include the application of low heat, hydrostatic pressure (e.g., 60K lb/6 min.), ~~irradiation~~, and individual quick freezing.

Point 7.9 DOCUMENTATION

When a consignment of bivalve molluscs reaches a distribution centre or establishment and has been subject to depuration or relaying, the accompanying document should contain the references of these operations: date and duration, name of the depuration establishment, identity of the responsible. The destination of the batch is also necessary for the transport.

Depuration centres or tanks and distribution centres and establishments should only accept lots of live bivalve molluscs with documentation issued by or accepted by the official agency having jurisdiction. This document should contain at least the following information :

- *the gatherer's identity and signature;*
- *the date of harvesting;*
- *name or species and quantity of bivalve molluscs;*
- *the location of the growing area and the health status of this area (suitable for harvesting for direct human consumption, suitable for relaying, suitable for depuration, suitable for approved processing to reduce or limit target organisms)*;
- *the destination of the batch;*
- *if appropriate the date and duration of depuration and the responsible's identity and signature;*
- *if appropriate the date and duration of relaying, the location of the relaying area and the responsible's identity and signature.*

PERU

El Perú está de acuerdo en términos generales con las propuestas de Normas.

Proposed Draft Standard for Live and Raw Bivalve Molluscs (ALINORM 07/30/18, para. 111, Appendix V)

EUROPEAN COMMUNITY

The ECMS are in favour of the advancement of the Standard at Step 5 but note that the Codex Committee on Food Hygiene (CCFH) did not endorse the hygiene provisions of the Proposed Draft Standard for Live and Raw Bivalve Molluscs at its 38th Session.

The ECMS are still of the opinion that the detection of faecal coliforms does not provide a reliable indication of a pathogenic risk. Studies have shown that, although *E.coli* merely give an indication that can only be used to keep an eye on the situation, they correlate better with the presence of pathogens than faecal coliforms taken together.

The following detailed comments are provided in preparation for next session of CCFFP.

PART I — Live bivalve molluscs

Point I.3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

Point I.3.1: Consulting specialists ("specialists familiar with the species concerned") seems sensible in point II.2.2 to ensure that the treatment applied to reduce or eliminate micro-organisms allows the shellfish to retain the essential sensory characteristics of live bivalve molluscs after processing, but is pointless in this case (live shellfish).

Live bivalve molluscs should possess organoleptic characteristics associated with freshness, as well as an adequate response to percussion (i.e. the shellfish will close by themselves when tapped) and freedom from extraneous matter~~, as determined by specialists familiar with the species concerned~~.

Point I.3.2 ICE FOR PACKING

As with the proposed draft Code of Practice for Fish and Fishery Products (point 2.3), imposing the same microbiological criteria for **clean seawater** as for potable water is problematic. Seawater does contain micro-organisms (cf. the conformity criteria for *E. coli* and faecal coliforms in live bivalve molluscs) and operators can determine the quality of the water by monitoring their own water supply, just as the risk of pathogens in production areas can be assessed by monitoring the production areas.

The criterion "**free from objectionable substances**" also needs to be clarified.

For reasons of functionality, please indicate precise **references** to the appropriate paragraphs of the latest edition of the **WHO Guidelines** for verifying the quality of clean seawater on the basis of a risk analysis according to the cleanliness of the seawater, in particular the monitoring criteria and associated reference methods in accordance with the Codex principles (CAC/GL 21-1997). The controls must be realistic in the light of the potential health risk in order to avoid discouraging the use of clean seawater because of the cost of compulsory analyses, where these are not essential.

Point I.5. HYGIENE AND HANDLING

Point I.5.3: Irrespective of the type of analysis (microbiological, biotoxins), it should be indicated that these apply only to the edible parts, particularly given that this is stated in section I.7.1 on sampling.

Live bivalve molluscs shall not contain in the edible parts (the whole part or any part intended to be eaten separately) numbers of faecal coliforms or E. coli bacteria in excess of testing regimes as follows:

Point I.5.3(i): It is important to specify the **unit of measurement** for the maximum limits for *E. coli* because the sampling specifications (next line) refer to *Escherichia coli*/g, following the example of the ISO MPN test methods, which also express the quantity in terms of a number per gramme. It should be noted, however, that Regulation (EC) No 2073/2005 expresses the standard for bivalve molluscs in terms of *E. coli per* 100 g of flesh and intra-valvular liquid.

Point I.5.3(ii): Not only should the "**330 faecal coliforms**" criterion be removed in favour of the *E. coli* indicator, but there is little point statistically in introducing a second "**330 *E. coli***" limit after the initial analysis of the "faecal coliforms" because of the high degree of imprecision in the counting process using the Most Probable Number (MPN) technique. The theoretical confidence interval is higher than a logarithmic unit, excluding the uncertainty of measurement to be determined by the laboratory, in particular for values close to the method's threshold. Furthermore, there is no ISO method for the simultaneous analysis of faecal coliforms and *E. coli* for bivalve molluscs.

Point I.5.3(iii): At this stage we do not have the knowledge or methods to propose a limit value for *Vibrio parahaemolyticus* based solely on the bacteria count per gramme of flesh, particularly given that only a small minority of *Vibrio parahaemolyticus* (those coding for haemolysins) are pathogenic. It is not possible with current detection methods to routinely distinguish pathogenic from non-pathogenic *Vibrio parahaemolyticus* or, consequently, to set a criterion according to the principles set out in document Codex CAC/GL 21-1997.

(iii) Live bivalve molluscs must not contain Salmonella in 25 g flesh ~~and Vibrio parahaemolyticus 100MPN/g flesh~~.

NB: In an opinion of 19 and 20 September 2001, the European Commission's Scientific Committee on Veterinary Measures relating to Public Health (SCVMPH) concluded that the scientific data currently available did not support setting specific criteria for pathogenic *V. parahaemolyticus* in seafood, while recommending establishing codes of practice to ensure that good hygiene practices have been applied.

Point I.5.3(vii):

In the edible parts of bivalve molluscs (the whole or any part intended to be eaten separately) the total content of biotoxins from the brevetoxin (BTX) group must not exceed 20 mouse units or equivalent.

Reference should be made to the Codex standards for contaminants, which must be complied with by all bivalve molluscs placed on the market.

Point I.6. LABELLING

Need to distinguish requirements for retail from those for wholesale.

The consumer must be given the information specified in points I.6.1 to I.6.3, the date of packaging and the indication "**the bivalve molluscs must be alive when sold**".

* *The entry « the bivalve molluscs must be alive when sold » must be visible on the retail packaging*

* *The date of packaging*

It should be specified clearly that the package labelling on goods intended for wholesale should include the information set out in points I.6.1 to I.6.4.

Point I.6.4(1): Consumers are not concerned at this stage: non-retail containers.

i) Clearly identify the product ~~for consumers~~ as stated in I-6.1

Point I.7. SAMPLING, EXAMINATION AND ANALYSES

Not all the analysis methods for determining the various pathogens are indicated (for example, the method for determining *Salmonella* is not mentioned).

Point I.7.4: Delete "**faecal coliforms**" from the title, as the only faecal contamination indicator that can be used for products placed on the market is *Escherichia coli.*

I.7.4. Methods of Analysis of Escherichia coli ~~and faecal coliforms~~ in shellfish meats

1st paragraph of point I.7.4: The references for certain analytical methods are imprecise, very old and refer here to water and bivalve molluscs (Examination of Seawater and Shellfish, 4th ed. 1970), and faecal coliforms in meat (APHA, Washington DC), whereas the products being placed on the market are live bivalve molluscs.

Recommended Procedures… … . The ISO/TS 16649-3 ~~standard — Enumeration of beta glucuronidase-positive Escherichia coli in live bivalve molluscs.~~ - Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli - Part 3: Most probable number technique using 5-bromo-4-chloro-3-indolyl-beta-D-glucuronide or other validated methods in accordance with the protocol set out in ISO 16140 or other internationally accepted similar protocol

Table in paragraph I.7.5: The ELISA method for determining Domoic Acid toxins has been validated by the AOAC and should therefore be indicated as a type III method.

Footnote [1] to the table in paragraph I.7.5: Specify the names of the toxins as well as their abbreviations, as they have not been referred to earlier in the document.

When using the MBA for detecting lipophilic marine biotoxins, false positives may occur due to the presence of other substances such as YTX (Yessotoxins), PTX (Pectenotoxins) and CI (Cyclic Imines), which are not known to cause human illness. When false positives are suspected, confirmatory testing, using an internationally validated method, can be carried out in order to identify the type(s) of marine biotoxins present.

Point I.8. DEFINITION OF DEFECTIVES

Point I.8.2: If over 5% of the shellfish are found to be dead or damaged, the entire batch must be rejected and not just the sample.

~~Sample~~ Batch shall be rejected if dead or damaged bivalve molluscs exceed 5% by count.

a) PART II — Raw bivalve molluscs

As a general point, the above observations concerning part I on labelling, analysis methods, sampling, etc. must also be included in this part.

Point II.3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Same comment as before (comment 02) concerning clean seawater.

Point II.3.2: As in paragraph I-3.2, specify in the last sentence the appropriate references for verifying the quality of clean seawater in accordance with the Codex principles (CAC/GL 21-1997) to ensure that clean seawater can be used while avoiding imposing stricter conditions in real terms than those for potable drinking water.

Point II.5. HYGIENE AND HANDLING

The wording of sections II.5.2 and II.5.3 raises the question of which organisms are targeted by the treatment methods recommended. In section II.5.3, for example, bivalve molluscs must comply with the criteria of I.5.2 (*E. coli, Salmonella* and biotoxins) both before and after treatment: so what is the point of treatment?

It would therefore be appropriate to indicate which germs can successfully be treated using these methods (vibrio? virus?) and to specify in this part the points of control to verify that the procedure used is being properly implemented.

Point II.5.2: Numbering error.

II.5.2. The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

Point II.5.3: Numbering error in the reference to the microbiological and biotoxin criteria.

II-5.3 Bivalve molluscs should meet the requirements of ~~I-5.2 —~~ I-5.3 prior to shucking, freezing, or processing to reduce target organisms. After shucking, freezing or processing to reduce target organisms, they should retain visual characteristics associated with freshness, including, where relevant, shells free of dirt.

Point II.6. LABELLING

Point II.6.3: (Although a provision on the use-by date is already included in the general standard, reference should still be made to the minimum durability date, given the specific format of this standard in two parts).

The label shall specify the conditions for storage and/or temperature that will maintain the quality during transportation, storage and distribution, including the date of minimum durability.

Point II.6. LABELLING

Point II.7.5.1: Numbering unnecessary, given that there are no other headings under point II.7.5.

Point II.7. SAMPLING, EXAMINATION AND ANALYSES

Same comment as above concerning faecal coliforms.

PERU

El Perú está de acuerdo en términos generales con las propuestas de Normas.

CODEX COMMITTEE ON NUTRITION AND FOOD FOR SPECIAL DIETARY USES
COMITÉ DU CODEX SUR LA NUTRITION ET LES ALIMENTS DIÉTÉTIQUES OU DE RÉGIME
COMITÉ DEL CODEX SOBRE NUTICIÓN Y ALIMENTOS PARA REGÍMENES ESPECIALES

Draft Revision to the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for the Use by Infants and Young Children (ALINORM 07/30/26, para. 130 and Appendix V)

ARGENTINA

Argentina agradece la posibilidad de realizar los siguientes comentarios.

Referencias

Texto en negrita: Propuesta de nuevo texto de Argentina

~~Texto tachado~~: Propuesta de Argentina de texto para eliminación

Texto en cursiva: texto citado del documento original

2. CRITERIOS PARA LA INCLUSIÓN Y LA SUPRESIÓN DE COMPUESTOS DE ~~NUTRIENTES~~ DE LAS LISTAS DE REFERENCIA

Argentina sugiere cambiar en el título de esta sección, y en el documento en su versión en español, la frase "de nutrientes" por "nutritivos" a fin de que coincida con la versión en inglés. De este modo, el título resultará de la manera siguiente:

2. CRITERIOS PARA LA INCLUSIÓN Y LA SUPRESIÓN DE COMPUESTOS NUTRITIVOS **DE LA LISTA DE REFERENCIA**

2.1

e) El cumplimiento de los criterios mencionados se demostrará por medio de criterios científicos ~~generalmente~~ aceptados.

Argentina considera apropiado eliminar el término "generalmente**" dado que su traducción al español no manifiesta la intención de la frase. La redacción de la viñeta resultaría:**

"El cumplimiento de los criterios mencionados se demostrará por medio de criterios científicos aceptados".

A: LISTA DE REFERENCIA DE SALES MINERALES Y OLIGOELEMENTOS PARA USO EN ALIMENTOS PARA REGÍMENES ESPECIALES DESTINADOS A SU UTILIZACIÓN POR LACTANTES Y NIÑOS PEQUEÑO

Argentina sugiere cambiar en el título de este apartado, "PEQUEÑO" por "PEQUEÑOS".

El título resultaría:

"A: LISTA DE REFERENCIA DE SALES MINERALES Y OLIGOELEMENTOS PARA USO EN ALIMENTOS PARA REGÍMENES ESPECIALES DESTINADOS A SU UTILIZACIÓN POR LACTANTES Y NIÑOS **PEQUEÑOS**"

1. Que aportan Calcio (Ca)

Las fuentes de calcio utilizadas deberán incluir aquellas de mayor solubilidad, dado que esta característica es un prerrequisito para su biodisponibilidad.

Algunas fuentes como fosfatos, especialmente el tribásico, tienen baja solubilidad, lo que no es aconsejable su uso.

Antecedentes Bibliográficos:

- Whittaker P. Iron and zinc interactions in humans. Am J Clin Nutr 1998;68:442S-6S.
- Krebs NF. Overview of zinc absorption and excretion in the human gastrointestinal tract. J Nutr 2000; 130:1374S-7S.
- Special Issue on Recent Intervention Trials with Zinc: Implications for Programs and Research. Food and Nutrition Bulletin, vol. 22, no. 2, The United Nations University, 2001. United Nations University Press
- Guéguen L, Pointillart A. The Bioavailability of Dietary Calcium. J Am Coll Nutr 2000; 19: 119S–136S.
- Heaney, R. P., Dowell, S. D., Bierman, J., Hale, C. A. & Bendich, A. Absorbability and cost effectiveness in calcium supplementation. J Am Coll Nutr 2001; 20: 239–246.
- Hurrell RF. How to ensure adequate iron absorption from iron-fortified food. Nutrition Reviews 2002; 60: S7-15.

1.10

Argentina sugiere corregir en el punto 1.10 *Fosfato ácido de calico (fosfato cálcico, dibásico)*, "calico" por "calcio".

2. Que aportan Hierro (Fe)

Las fuentes de hierro elemental (reducido, electrolítico y carbonílico) poseen muy baja biodisponibilidad, razón por la cual Argentina considera que no sería aconsejable su uso en PCBF y FSMP. Su adición podría justificarse en los CBF debido a que durante el proceso de elaboración podrían convertirse en formas iónicas.

8. Que aportan Zinc (Zn)

Con respecto a las fuentes de Zinc (Zn), Argentina considera que tanto el carbonato como el óxido son insolubles y poco absorbidos.

Antecedentes Bibliográficos:

- Whittaker P. Iron and zinc interactions in humans. Am J Clin Nutr 1998;68:442S-6S.
- Krebs NF. Overview of zinc absorption and excretion in the human gastrointestinal tract. J Nutr 2000; 130:1374S-7S.
- Special Issue on Recent Intervention Trials with Zinc: Implications for Programs and Research. Food and Nutrition Bulletin, vol. 22, no. 2, The United Nations University, 2001. United Nations University Press
- Guéguen L, Pointillart A. The Bioavailability of Dietary Calcium. J Am Coll Nutr 2000; 19: 119S–136S.
- Heaney, R. P., Dowell, S. D., Bierman, J., Hale, C. A. & Bendich, A. Absorbability and cost effectiveness in calcium supplementation. J Am Coll Nutr 2001; 20: 239–246.

- Hurrell RF. How to ensure adequate iron absorption from iron-fortified food. Nutrition Reviews 2002; 60: S7-15.

Fuente de Nutrientes:

Puntos: 1.13 L-Lisina; 2.16 Succinato ferroso; 2.17 Bisglicinato ferroso; 4.12 Sulfato sódico; 13.3 Fluoruro de calcio.

Con respecto a las distintas fuentes de nutrientes correspondientes a los puntos arriba mencionados, Argentina considera que se debería ser muy restrictivo y cauto en la elección de la fuente, limitándose sólo a aquellos nutrientes científicamente avalados y de mayor biodisponibilidad, debido a la vulnerabilidad del grupo etario al cual están destinados estos alimentos.

B: LISTA DE REFERENCIA DE COMPUESTOS VITAMÍNICOS PARA SU UTILIZACIÓN EN ALIMENTOS PARA FINES DIETÉTICOS ESPECIALES DESTINADOS A LOS LACTANTES Y NIÑOS PEQUEÑOS.

Fuente de Nutrientes:

Punto: 4.5 Succinato ácido de D-alfa tocoferil.

En relación a estas dos fuentes de nutrientes, Argentina reitera el concepto ya mencionado anteriormente. Si bien no se cuenta con antecedentes científicos, Argentina considera que se debería ser muy restrictivo y cauto en la elección de la fuente, limitándose sólo a aquellos científicamente avalados y de mayor biodisponibilidad, debido a la vulnerabilidad del grupo etario al que van destinados estos alimentos.

Punto 5.4 L-ascorbato cálcico

Donde dice **"L-Ascorbato cálcico**" debe decir "**L-Ascorbato sódico**", dado que en el ítem 5.2 de la misma Lista figura el L-Ascorbato cálcico.

Punto 6.1 Hidrocloruro de tiamina cloruro

Donde dice "**Hidrocloruro de tiamina cloruro**" debe decir "**Tiamina clorhidrato**"**,** dado que es la forma apropiada de nombrar al compuesto en el documento en su versión en español.

LISTA DE COMPUESTOS DE NUTRIENTES QUE CARECEN DE REQUISITOS OFICIALES DE PUREZA

Argentina está de acuerdo en retirar del cuadro, todos los compuestos para los cuales no existen antecedentes científicos que avalen su inclusión, debido a la vulnerabilidad del grupo etario al que van destinados estos alimentos.

D: LISTA DE REFERENCIA SOBRE ADITIVOS ALIMENTARIOS PARA FORMAS ESPECIALES DE NUTRIENTES

Por razones de estabilidad y seguridad de manipulación, algunas ~~vitaminas~~ y otros nutrientes tienen que ser transformados en preparados idóneos, por ejemplo productos recubiertos de goma arábiga o preparados mediante frotamiento en seco ("dry rubbed preparations"). A tal efecto se podrán utilizar los aditivos alimentarios previstos en la norma específica del Codex correspondiente. Además, podrán utilizarse los siguientes aditivos alimentarios como sustancias inertes portadoras de nutrientes:

Argentina sugiere eliminar el término "**vitaminas**", dado que el mismo quedaría incluido dentro del término "nutrientes". El párrafo resultaría del siguiente modo:

"Por razones de estabilidad y seguridad de manipulación, algunos nutrientes tienen que ser transformados en preparados idóneos, por ejemplo productos recubiertos de goma arábiga o preparados mediante frotamiento en seco ("dry rubbed preparations"). A tal efecto se podrán utilizar los aditivos alimentarios previstos en la norma específica del Codex correspondiente. Además, podrán utilizarse los siguientes aditivos alimentarios como sustancias inertes portadoras de nutrientes:"

Comentarios sobre el Cuadro:

Argentina solicita mayores aclaraciones, justificación técnica u objetivos que se pretenden alcanzar, así como las razones que motivaron la inclusión del cuadro en la presente norma general, dado que considera que no queda clara la función que cumple su incorporación.

AUSTRALIA

Australia supports Section A (mineral salts and trace elements) and Section B (vitamins) of the draft revised advisory list. However, Australia notes that in Section C, the nucleotides 'Disodium Uridine 5-monophosphate', 'Disodium Guanosine 5-monophosphate', and 'Disodium Inosine 5-monophosphate' are contained in square brackets. Australia has previously provided purity specifications[1] for these nucleotides and therefore recommends the removal of the square brackets.

MEXICO

En la lista de compuestos de nutrientes que carecen de requisitos oficiales de pureza, además de evaluar si algún miembro ha enviado dichos requisitos, México propone eliminar de la lista el **monohidrato de creatina**, en virtud de que no existe evidencia alguna sobre su posible efecto benéfico en la alimentación infantil. Existe cierta evidencia del uso de esta sustancia como complemento alimenticio únicamente para deportistas adultos.

NEW ZEALAND

Section C: Advisory list of Amino Acids and other Nutrients for Uses in Foods for Special Dietary Uses Intended for Infants and Young Children

New Zealand supports the removal of square brackets from the entries:

6.5 Disodium Uridine 5-monophosphate salt

6.6 Disodium Guanosine 5-monophosphate salt

6.7 Disodium Inosine 5-monophosphate salt

It is our understanding that the following are equally correct names for the above nucleotides and both variants should be given in the revised advisory list:

6.5 Uridine 5-monophosphate disodium salt

6.6 Guanosine 5-monophosphate disodium salt

6.7 Inosine 5-monophosphate disodium salt

We agree that significant progress was made at the last Session of the CCNFSDU, and support the advancement of the list for adoption at Step 5 by the 30th Session of the Codex Alimentarius Commission.

UNITED STATES OF AMERICA

We agree that significant progress was made on the revision of the Advisory List in the 28th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses and support the Committee's advancement of the list for adoption at Step 5 by the 30th Session of the Codex Alimentarius Commission.

INTERNATIONAL SPECIAL DIETARY FOOD INDUSTRY (ISDI)

The Draft Revised Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for the Use by Infants and Young Children has been moved forward to Step 5 and hence is sent to the Codex Commission for adoption.

ISDI notes that some items have been modified and approved at the last CCNFSDU session and ISDI supports those changes.

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[1] The details of Australia's nucleotide purity specifications can be found in the Australia New Zealand Food Standards Code, which is available on the Food Standards Australia New Zealand website at http://www.foodstandards.gov.au/_srcfiles/Standard_1_3_4_Identity_&_Purity_v83.pdf.

Therefore, ISDI supports the adoption at step 5 of the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants by the Codex Commission in July 2007.

N.B.: ISDI will send its further detailed comments on the Draft Revised Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for the Use by Infants and Young Children for consideration by CCNFSDU at Step 6.

CODEX COMMITTEE FOR FRESH FRUIT AND VEGETABLES
COMITÉ DU CODEX SUR LES FRUITS ET LÉGUMES FRAIS
COMITÉ DEL CODEX SOBRE FRUTAS Y HORTALIZAS FRESCAS

Proposed Draft Standard for Bitter Cassava (ALINORM 07/30/35 para. 82 and Appendix VI)

ARGENTINA

Argentina agradece la posibilidad de realizar comentarios al presente documento, los cuales se detallan a continuación.

Argentina está de acuerdo en que la norma de yuca amarga se unifique con la de yuca dulce, haciendo las salvedades necesarias y particulares para la yuca amarga.

Asimismo, Argentina está de acuerdo con la propuesta de ampliar los rangos para incluir a la yuca amarga, contenida en el Punto 3, en el cual se abordan las "Disposiciones relativas a la clasificación por calibre".

Argentina apreciaría se aclare el significado de la expresión **calidad comestible**, que figura en los ítems 2.2. Clasificación: 2.2.2. Class I y 2.2.3. Class III, en las que se establece que "Los defectos no deben, en ningún caso, afectar la calidad comestible de la pulpa del producto". Argentina no advierte la diferencia que supone dicha frase con relación a la expresión "Los defectos no deben, en ningún caso, afectar la pulpa del producto".

CODEX COMMITTEE ON CONTAMINANTS IN FOODS
COMITÉ DU CODEX SUR LES CONTAMINANTS DANS LES ALIMENTS
COMITÉ DEL CODEX SOBRE CONTAMINANTES DE LOS ALIMENTOS

Proposed Draft Maximum Level for 3-MCPD in Liquid Condiments Containing Acid-Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) (ALINORM 07/30/41 para. 88 and Appendix X)

INTERNATIONAL HYDROLYZED PROTEIN COUNCIL

The International Hydrolyzed Protein Council (IHPC) is an international non-governmental organization with headquarters in Washington, D.C. and represents manufacturers, users, or sellers of hydrolyzed proteins throughout the world. Hydrolyzed proteins include acid-hydrolyzed vegetable proteins (acid–HVPs), autolyzed yeasts and yeast extracts.

IHPC fully supports the proposed maximum level (ML) of 0.4mg/kg of 3-MCPD in liquid condiments containing acid-HVPs, excluding naturally fermented soy sauce. We believe the proposed ML is warranted by JECFA's recent thorough evaluation of the PMTDI for 3-MCPD and the remedial action performed by acid-HVP and soy sauce manufacturers to date.

Proposed Draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) During the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid-HVPs (ALINORM 07/30/41 para. 93 and Appendix XI)

INTERNATIONAL HYDROLYZED PROTEIN COUNCIL

IHPC would like to thank the United Kingdom for leading the effort to revise the proposed draft Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs. We believe the proposed draft Code of Practice appropriately reflects the several strategies available for controlling 3-MCPD levels. These strategies ultimately involve variable and proprietary combinations of time, temperature, and acid-concentration parameters that individual manufacturers must consider while producing acid-HVPs with specific organoleptic properties.

CODEX COMMITTEE FOR PROCESSED FRUIT AND VEGETABLES
COMITÉ DU CODEX SUR LES FRUITS ET LÉGUMES TRAITÉS
COMITÉ DEL CODEX SOBRE FRUTAS Y HORTALIZAS ELABORADAS

Proposed Draft Standard for Codex Standard for Jams, Jellies and Marmalades (ALINORM 07/30/27 para. 146 and Appendix VI)

BRAZIL

Brazil supports to forward the body of the standard to Step 5.

Proposed Draft Standard for Certain Canned Vegetables (General Provisions) (ALINORM 07/30/27 para. 114 and Appendix VII)

BRAZIL

Brazil supports to forward the body of the standard to Step 5.