CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/CAC 10/33/4-Add.1**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty-third Session,
Geneva, Switzerland, 5 - 9 July 2010

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

(Comments submitted by 31 May 2010)

CODEX COMMITTEE ON FRESH FRUITS AND VEGETABLES
COMITÉ DU CODEX SUR LES FRUITS ET LEGUMES FRAIS
COMITÉ DEL CODEX SOBRE FRUTAS Y HORTALIZAS FRESCAS

Proposed Draft Revision to the Standard for Avocado (CODEX STAN 197-1995) (N19-2008) (ALINORM 10/33/35, APPENDIX IV)

Comments of Australia, Brazil

AUSTRALIA

Australia is pleased to submit the following comments in response to CL 2009/31-FFV, Part A (points 3 & 4).

General comments

Australia considers that the proposed draft revision of the Standard for Avocado, and all other fruit and vegetable standards, should be developed recognising:

- the requirement of the Codex Strategic Framework that "although quality provisions are fundamentally driven by the market, the CAC has an important role in ensuring that provisions relating to quality are sound and based on the criteria of essentiality and do not constitute disguised barriers to trade;" and
- the Codex Strategic Plan 2008–2013 which requires CAC to "ensure that texts for food quality are generic in nature and whilst maintaining inclusiveness, reflect global variations and focus on essential characteristics so as to avoid being overly prescriptive and not more trade restrictive than necessary."

Australia believes that restrictive provisions going beyond 'criteria of essentiality' are likely to stifle product innovation and trade and hence to be detrimental to consumption of fresh fruit and vegetables, with negative flow-on consequences for consumer health and wellbeing. Australia notes that the WHO Global Strategy on Diet, Physical Activity and Health recommends Codex takes action to increase consumption of fruits and vegetables.

Australia believes that certain provisions in the draft Standard for Avocado do not meet the requirement that Codex standards should only cover those provisions that "protect health of consumers and ensure fair practices in food trade" (Article 1 – Statutes of Codex Alimentarius Commission).

Specific Comments

1 Definition of produce: Australia supports the Committee's decision to remove the reference to race, as the inclusion of race gave potential for confusion as to which race some varieties belonged and avocadoes are rarely classified this way during trade and marketing.

2.1 Minimum Requirements

2.1.1: Australia supports removal of the text in the first square brackets that requires that fruit must have been carefully picked as it can be difficult to determine whether or not fruit has been carefully picked. The requirement for fruit to arrive in satisfactory condition at the place of destination should be adequate.

Australia supports retaining the text in square brackets "and/or commercial type".

2.1.2 Maturity requirements: Australia supports the proposed values for minimum dry matter content.

3 Provisions concerning sizing: Australia supports the text in square brackets, allowing Hass avocadoes to have a minimum size of 80 grams. Small Hass fruit occupy an important market niche which assists generally in increasing the consumption of fresh fruits and vegetables.

4.2 Size tolerances: The provision that "the difference between the smallest and largest fruit within a package should not be more that 25g" is likely to be difficult to achieve with the larger sized fruit, especially in developing countries. Australia recommends a more achievable tolerance, if tolerances are needed.

5 Provisions concerning presentation

5.1 Uniformity: Setting parameters for uniformity does not have an impact on eating quality but can be misused to manipulate the marketing and trade of the prescribed products. Australia considers that uniformity provisions should not be included in commodity standards as they place unnecessary limits on commercial trade, restrict innovation and have no bearing on health and safety, eating quality or fairness in trade.

5.2 Packaging: In section 5.2.1 Description of containers, the requirement that packages (or lot for produce presented in bulk) must be free of all foreign smell is a requirement under *2.1 Minimum Requirements*, therefore is not necessary in this section.

6. Marking or labelling

6.2.3 Origin of produce: The origin of produce, or country of origin labelling, should not be a mandatory requirement in Codex standards except where its omission would mislead or deceive consumers. Country of origin labelling for non-retail containers is covered through certification and is part of normal documentation accompanying shipments in international trade (i.e. Bill of Lading).

Australia proposes the following wording for this provision to align with provisions for origin of produce set out in clause 4.5 of the Codex General Standard for the Labelling of Pre-packaged Foods:

"Country of origin and, optionally, district where grown, or national, regional or local place name, where its omission would mislead or deceive the purchaser"

6.2.4 Commercial identification: As variety need not be labelled on consumer packages, it should not be mandatory to be labelled on non-retail containers.

BRAZIL

Item 2.1.1

- [haberse recolectado cuidadosamente. Su desarollo deverá]:

Brasil propuso la eliminación del texto entre corchetes, porque entiende que no es necesario, ya que es un procedimiento inherente a cualquier vegetal. Además, es un requisito que no se puede comprobar en el destino.

- [y/o tipo comercial]:

Brasil cree que puede mantener el texto.

Item 2.1.2 e Item 3 (a):

No hay comentario sobre este tema.

Item 5.1

- [excepto para los calibres y variedades mezcladas]:

Brasil propuso la eliminación del texto entre corchetes. Sin embargo, si se mantiene, sugiere que el asunto se trata en otros artículos vinculados a al etiquetado, ya que el tema en cuestión a la toma de muestras.

Proposed Draft Standard for Tree Tomatoes (N18-2008) (ALINORM 10/33/35, APPENDIX VI)

Comments of Australia

AUSTRALIA

Australia is pleased to submit the following comments in response to CL 2009/31-FFV, Part A (points 3 & 4).

General comments

Australia considers that the proposed Codex standard for tree tomatoes, and all other fresh fruit and vegetable standards, should be developed recognising:

- the requirement of the Codex Strategic Framework that "although quality provisions are fundamentally driven by the market, the CAC has an important role in ensuring that provisions relating to quality are sound, based on the criteria of essentiality and do not constitute disguised barriers to trade;" and
- the Codex Strategic Plan 2008–2013 which requires CAC to "ensure that texts for food quality are generic in nature and whilst maintaining inclusiveness, reflect global variations and focus on essential characteristics so as to avoid being overly prescriptive and not more trade restrictive than necessary."

Australia believes that restrictive provisions going beyond 'criteria of essentiality' are likely to stifle product innovation and trade and hence to be detrimental to consumption of fresh fruit and vegetables, with negative flow-on consequences for consumer health and wellbeing. Australia notes that the WHO Global Strategy on Diet, Physical Activity and Health recommends Codex takes action to increase consumption of fruits and vegetables.

Australia believes that certain provisions in the draft Standard for Tree Tomatoes do not meet the requirement that Codex standards should only cover those provisions that "protect health of consumers and ensure fair practices in food trade" (Article 1 – Statutes of Codex Alimentarius Commission).

Specific Comments

3. Provisions Concerning Sizing:

Provisions for sizing are unnecessary as fruit size does not affect eating quality and such restrictions may be misused to manipulate the marketing and trade of tree tomatoes. In any case, size is easily determined by consumers and retailers, thus sizing codes are unnecessary.

4. Provisions Concerning Tolerances:

4.2 Size Tolerances: If section 3 *Provision concerning Sizing* is removed, tolerances for size are unnecessary.

5. Provisions concerning presentation

5.1 Uniformity: Setting parameters for uniformity does not have an impact on eating quality but can be misused to manipulate the marketing and trade of the prescribed products. Australia considers that uniformity provisions should not be included in commodity standards as they place unnecessary limits on commercial trade, restrict innovation and have no bearing on health and safety, eating quality or fairness in trade.

5.2 Packaging: In section 5.2.1 Description of containers the requirement that packages (or lot for produce presented in bulk) must be free of all foreign smell is a requirement under *2.1 Minimum Requirements,* therefore is not necessary in this section.

6. Marking or labelling

6.2.3 Origin of produce: The origin of produce, or country of origin labelling, should not be a mandatory requirement in Codex standards except where its omission would mislead or deceive consumers. Country of origin labelling for non-retail containers is covered through certification and is part of normal documentation accompanying shipments in international trade (i.e. Bill of Lading).

Australia proposes the following wording for this provision to align with provisions for origin of produce set out in clause 4.5 of the Codex General Standard for the Labelling of Pre-packaged Foods:

> *"Country of origin and, optionally, district where grown, or national, regional or local place name, where its omission would mislead or deceive the purchaser"*

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

Proposed Draft Standard for Smoked-Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (ALINORM 10/33/18, APPENDIX VI)

Comments of Egypt, Libya, Philippines and United States of America

EGYPT

Egypt approves the proposed draft Standard for Smoked-Fish, Smoke-Flavoured Fish and Smoke-Dried Fish.

LIBYA

6.6 Histamine

The product shall not contain histamine that exceeds 20 mg/100 g fish flesh. This applies only to susceptible species.

The Libyan national committee for fish & fishery products doesn't see any reason to have two levels of histamine in the same standard & suggest to omit the histamine level indicated in section 3.4 Decomposition.

Section 3.4 could be restated as following:

3.4 Decomposition.

The product of susceptible species shall not contain more than 10 mg of histamine per 100g fish flesh based on the average of the sample unit tested and all products in this Standard shall be free from persistent and objectionable odors and flavors characteristic of decomposition

3.4 Decomposition.

The product shall be free from persistent and objectionable odours and flavours characteristic of decomposition & histamine level shall not exceed the level stated in section 6.6 of this standard.

PHILIPPINES

The Philippines supports the elaboration of the said draft standard and recommends the following:

1. Rewrite bullets 3 and 4 of Section 2.2.2 for brevity:

• "Packaging" a process in which smoke-flavoured fish is put in a container, either aerobically or under reduced oxygen conditions, including under vacuum or in a modified atmosphere.	• "Packaging" **as defined in Sec. 2.1.2**
• "Storage" is a process in which smoke-flavoured fish is kept refrigerated or frozen to assure product safety and quality in conformity with Sections 3 and 6.	• "Storage" **as defined in Sec. 2.1.2**

2. Rewrite bullets 2, 3, 4 and 5 of Section 2.3.2 for brevity:

• "Drying" is a process in which the moisture	• "Drying" **as defined in Sec. 2.1.2**

content in the fish flesh is decreased by exposing the fish to circulating air.	
• "Salting" is a process of treating fish with salt of food grade quality to lower water activity in fish flesh and to enhance flavour by any appropriate salting technology (e.g. dry salting, brining, injection salting).	• "Salting" **as defined in Sec. 2.1.2**
• "Packaging" is a process in which smoke-dried fish is put in a container to avoid contamination and prevent rehydration.	• "Packaging" **as defined in Sec. 2.1.2**
• "Storage" is a process in which smoke-dried fish is typically kept at ambient temperature in a way to assure its safety and quality in conformity with Sections 3 and 6.	• "Storage" **as defined in Sec. 2.1.2**

3. Clarification as to the rejection level for histamine as this varies in Sections 3.4, 6.6 and 10.iii, to wit:

3.4 Decomposition The product of susceptible species shall not contain more than 10 mg of histamine per 100g fish flesh based on the average of the sample unit tested and all products in this Standard shall be free from persistent and objectionable odours and flavours characteristic of decomposition	Shall not contain more than **10 mg of histamine per 100 g**
6.6 Histamine The product shall not contain histamine that exceeds 20 mg/100g fish flesh. This applies only to susceptible species	The product shall not contain histamine that exceeds **20 mg/100 g** fish flesh.
10. LOT ACCEPTANCE A lot will be considered as meeting the requirements of this standard when: iii. The Food Additives, Contaminants, Hygiene and Handling and Labelling requirements of Sections 4, 5, 6 and 7 are met. For histamine no sample unit shall exceed 20mg/100g of fish flesh as per the sampling plan chosen. (Ref. Section 8.3).	For histamine no sample unit shall exceed **20 mg/100 g** of fish flesh as per the sampling plan chosen. (Ref. Section 8.3).

4. Edits for Section 6.1 to read as:

6.1 General provisions The products covered by the provisions of this standard shall be prepared and handled in accordance with the appropriate sections of the recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) and other relevant Codex texts such as codes of practice and codes of hygienic practice, such as the Code of Practice for Fish and Fishery Products (CAC/RCP 52- 2003).	The products covered by the provisions of this standard shall be prepared and handled in accordance with the appropriate sections of the recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) and other relevant Codex texts such as **Code** of **P**ractice and **Code** of **H**ygienic **P**ractice, **as well as** the Code of Practice for Fish and Fishery Products (CAC/RCP 52- 2003).

5. Clarification as to the basis of the inclusion of paragraph 2 in Section 6.5 as this statement was not originally part of the original draft deliberated during the committee meeting.

Countries where the products are to be consumed may allow these products in an uneviscerated state or may require evisceration, either before or after processing,

in such a way as to minimise the risk of Clostridium botulinum.

6. Edit for the symbol degree Celsius in bullets 1, 2 and 3 **of Annex 1** and to insert the phrase ***"and storage at the same temperature for at least "***to indicate that the required thermal temperature should be achieved as quickly as possible.

Examples of freezing processes that may be sufficient to kill some or all parasites are: • Freezing at –20Cº at the thermal centre of the product for 24 hours (for *Anisakis* species and *Pseudoterranova decipiens* only); • Freezing at –35Cº at the thermal centre of the product for 15 hours (all parasites)1-4; • Freezing at –20Cº at the thermal centre of the product for 168 hours (7 days) 1-4 (all parasites).	Examples of freezing processes that may be sufficient to kill some or all parasites are: • Freezing at –20ºC at the thermal centre of the product ***and storage at the same temperature for at least*** 24 hours (for *Anisakis* species and *Pseudoterranova decipiens* only); • Freezing at –35ºC at the thermal centre of the product ***and storage at the same temperature for at least*** 15 hours (all parasites)1-4; • Freezing at –20ºC at the thermal centre of the product ***and storage at the same temperature for at least*** 168 hours (7 days) 1-4 (all parasites).

UNITED STATES OF AMERICA

In response to CL 2009/29-FFP the United States respectfully submits the following comments on the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (at Step 5 of the Procedure). Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

2.1.2 Process Definitions, 2nd bullet, "Smoking by regenerated smoke". Revise the last sentence as follows:

"Smoke condensates are products obtained by controlled thermal degradation of wood in a limited supply of oxygen (pyrolysis), subsequent condensation of the resultant smoke vapours, and fractionation of the resulting liquid products **to remove polycyclic aromatic hydrocarbons (PAHs)**."

Reason: To ensure that fractionation does not remove the antimicrobials that are present.

2.1.2 Process definitions, 4th bullet, "Cold smoking". Revise as follows:

"Cold smoking is a process of treating fish with smoke using a time/temperature combination that will not cause significant coagulation of the proteins in the fish flesh **and will not harm naturally occurring spoilage bacteria,** but that will cause some reduction of the water activity."

Reason: Live natural spoilage bacteria should be present for product safety. When shelf life expires, or proper holding temperature is exceeded, natural spoilage bacteria compete with and help slow growth of harmful bacteria such as *Clostridium botulinum.* Off-odors produced by natural spoilage bacteria may also deter consumption of potentially harmful product.

2.2 SMOKE FLAVORED FISH

2.2.1 Product definition. Revise as follows:

"Smoke flavoured fish is prepared from fish that has been treated with smoke flavours, without undergoing a smoking process as described in 2.1, **and may undergo a salting and/or drying process**. The end product must have a smoked taste.

Reason: Salting and drying processes may be used as with smoked fish and smoke-dried fish.

2.2.2 Process definition. Add the following two bullets:

• "Salting" is a process of treating fish with salt of food grade quality to lower water activity in fish flesh and to enhance flavour by any appropriate salting technology (e.g. dry salting, brining,

injection salting).

• "Drying" is a process in which the moisture content in the fish flesh is decreased by exposing the fish to circulating air.

Reason: Added the salting and drying definitions to be consistent with the suggested change for Section 2.2.1 (Product definition) above.

3.4 Decomposition. Add an 's' to the word 'unit' as follows:

"The product shall not contain more than 10 mg of histamine per 100g fish flesh based on the average of the sample unit**s** tested."

Reason: The singular implies that a single sample unit will be tested multiple times.

4. FOOD ADDITIVES. Add the following:

"Colours, preservatives, flavor enhancers and antioxidants used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category 9.2.5 (Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms) are acceptable for use in foods conforming to this standard."

Reason: The U.S. proposes standard language appropriate to this product.

6.3 Parasites. Revise as follows:

"Products covered by this Standard shall not contain living parasites and particular attention needs to be paid to cold smoked or smoke flavoured products, which should be frozen before or after smoking if a parasite hazard is present (see Annex 1). Viability of nematodes, ~~and~~ cestodes and trematodes shall be is examined according to Section 8.9 ~~and/or 8.10~~."

Reason: The U.S. is proposing a revision to Section 8.9 that would incorporate a viability testing method that can be used during determination of visibility of parasites (Section 8.10).

6.5 *Clostridium botulinum.* 1st paragraph. Revise as follows:

"Toxins of *Clostridium botulinum* are not allowed in smoked fish, smoke-flavoured fish, and smoke-dried fish products. The formation of *Clostridium botulinum* toxin can be controlled through an application of science-based options such as packaging type, **smoking temperature,** storage temperature, and water activity, e.g. by use of salt in the water phase. Examples are shown in the Table in Annex 2, which addresses these control options."

Reason: Processing temperature controls are important to maintain secondary barriers to botulinum toxin formation (heat damage of *Clostridium botulinum* spores in hot smoked, and low heat to allow survival and competition by natural spoilage bacteria in cold smoked).

6.6 Histamine. Revise as follows:

"**No sample unit** ~~The product~~ shall ~~not~~ contain histamine that exceeds 20 mg/100g fish flesh. This applies only to susceptible species."

Reason: This limit appears to allow averaging. Averaging histamine from multiple subsamples, as applied for decomposition (Section 3.4), is inappropriate for a safety limit. This revision reverts the wording back to the previous wording (Alinorm 08/31/18 Appendix VII) and wording found in other Codex seafood standards.

7.3 Storage Instructions. Revise as follows:

"7.3 Storage **and Handling** Instructions

The label shall declare storage **and handling** instructions appropriate for the product. **For example, the label on a frozen reduced oxygen package states 'keep frozen until use, thaw under refrigeration, and use immediately after thawing'**."

Reason: Storage and handling instructions are essential for preventing death from botulinum toxin.

8. Sampling, Examination and Analysis. Add new section titles as placeholders:

"8.11 Determination of water activity

8.12 Determination of water phase salt"

Reason: There are provisions for water activity and water phase salt in the standard. The U.S. intends to propose methods for water activity and water phase salt.

8.1 Sampling. 3rd paragraph. Delete the following line:

"~~The number of samples to be taken for the determination of the levels of histamine in a lot, shall be determined by the Competent Authority having jurisdiction~~."

Reason: We do not understand why this wording is applied only to histamine sampling. And, it is not needed because the competent authority already decides the number of samples for all examinations. Should this sentence be retained we would suggest moving the words "in a lot" to the position directly after the words "to be taken".

8.2 Sensory and Physical Examination. Revise as follows:

"Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in **this section** ~~Sections 8.4 through 8.7~~ and the 'Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories (CAC/GL 31-1999)'."

Reason: Section numbers are incorrect, and candling for parasites is excluded.

8.4 Determination of Gelatinous Conditions. Delete this section.

Reason: This method is used for the flesh abnormalities defect in Section 9.4, and we suggest removing section 9.4 because we are not aware that this is a common abnormality.

8.5 Determination of Net Weight. Revise as follows:

"The net weight is determined as the weight of the product, exclusive of **the dried** packaging material, interleaving material, etc."

Reason: Results may vary substantially if excess moisture is not removed, particularly from interleaving sheets in thinly sliced cold smoked fish.

8.9 Determination of the viability of parasites. Revise as follows:

"Methods used for **extracting and** testing the viability of parasites could include the method set out in Annex I for nematodes in the Standard for Salted Herring and Sprats or other ~~validated~~ methods for parasites acceptable to the competent authority having jurisdiction.

Parasites found during determination of visible parasites (Section 8.10) may be carefully removed and put into physiological saline for observation of spontaneous movement that indicates viability. Parasites from salted product may exhibit apparent movement with this procedure because of water absorption, in which case, three hours of equilibration time in saline should be allowed before observation."

Reasons:

- The salted herring and sprat method is primarily a pepsin digestion to extract parasites from the fish flesh followed by observation of extracted worms for spontaneous movement.
- The U.S. is not aware of any validated (collaborative) methods for parasite extraction or viability.
- A simple method to determine viability during the examination for visible parasites was added (Section 8.10).

[9.4 Flesh abnormalities]. Delete this section.

Reason: The U.S. is not aware that this is a common abnormality in smoked fish.

ANNEX 1, Procedures sufficient to kill parasites. Revise as follows:

"~~Any~~ **A** method **that is acceptable to the competent authority having jurisdiction shall be** used to kill parasites ~~shall be acceptable to the competent authority having jurisdiction~~."

Reason: Grammatical correction. It could be interpreted that the competent authority must accept any method.

ANNEX 2, Examples of combinations of product attributes that minimise the likelihood of *Clostridium botulinum* toxin formation.

Revise the introductory text as follows (see "Reasons" for details):

"Countries where the products are to be consumed can be expected to make their science-based risk management choices with the assistance of this framework, e.g., select some options and exclude others, based on conditions within the country (e.g., nature and enforcement of refrigeration and shelf life controls; transportation times and conditions; variability in amount of salt in the aqueous phase that could occur despite best efforts to achieve a required percentage, etc.), and the level of protection that the country chooses for itself for this particular risk.

This table applies to smoked fish and smoke flavoured fish where the smoke flavor is provided by smoke condensates. If the smoke flavour is imparted by artificial flavor blends, then 5% aqueous phase salt would be required in order to provide complete protection at ~~any temperature over~~ **temperatures between** 3°C **and 10°C**. This table does not apply to smoke-dried fish because the required water activity of 0.85 or below inhibits the growth of all foodborne pathogens so that refrigeration is not required.

As an alternative to aqueous phase salt, certain ~~time/~~temperature **or water activity** parameters can minimise the likelihood that *C. botulinum* will grow in the product. *C. botulinum* cannot grow and produce toxin at or below 3ºC or below a water activity of 0.85. Other time/temperature combinations exist that similarly control the formation of toxin. **(Skinner, G.E. and Larkin, J.W., Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods. *Journal of Food Protection*, 1998; 61, 1154-1160)**.

Where enforcement of shelf life as well as consumer acceptance of shelf life are norms, the country may select a system that relies on the combination of existing storage temperature conditions (i.e. during transport, retail storage, and consumer storage) and shelf life limitations.

However, in countries where consumer acceptance and regulatory enforcement of shelf life are not norms, continuous monitoring, such as that provided by time/temperature integrators on consumer packages can be an important adjunct to shelf-life monitoring in the country where the product will be consumed. The necessity for time/temperature integrators exists because, unlike freezing, temperature control through refrigeration is not a visual condition and cannot be determined without an additional monitoring control.

Reasons:

- The first paragraph was split into two paragraphs for clarity.
- In the second paragraph, an upper temperature of 10°C was added because proteolytic *C. botulinum* can grow at temperatures above 10°C in 5% salt.
- In the third paragraph, "time/temperature" was replaced by "temperature or water activity" because these are what are discussed in the next sentence.
- In the third paragraph, editorial corrections were made to the Skinner and Larkin reference.

Revise table in Annex 2 as follows (see "Reasons" for details):

Product Temperature **d**uring Storage	Packaging	Water Activity controlled by Aqueous Phase Salt (NaCl)	Comments
Frozen (≤ minus 18º C)	Reduced Oxygen*****	No maximum water activity needed.	*C. botulinum* toxin cannot form when product is frozen. In the absence of adequate aqueous phase salt, toxin production can occur after thawing so, labelling information about the need for the consumer to keep the product frozen, to thaw it under refrigeration, and to use it immediately after thawing, is important. The

			country where the product is consumed may require temperature monitoring for each package to ensure that the time temperature combination does not permit the production of ***Clostridium botulinum*** toxin after thawing.
0° C to 3° C	Reduced Oxygen*****	No maximum water activity is needed.	*C. botulinum* toxin cannot form below 3° C. Temperature monitoring is needed for each package, e.g.**,** time temperature integrators, to ensure that the temperature does not exceed 3ºC. The country where the product is consumed may require temperature monitoring for each package to ensure that the time-temperature combination does not permit the production of ***Clostridium botulinum*** toxin.
>3° C to 5° C	Reduced Oxygen*****	Aqueous phase salt at minimum level of between 3% & 3.5% may be selected by the country where the product is to be consumed.	Aqueous phase salt at a minimum level of between 3 and 3.5% (w/w) (aqueous phase salt) in combination with chilling will significantly delay (or prevent) toxin formation. For that reason, the country where the product is consumed may require 3.5% aqueous phase salt as a barrier to growth of non-proteolytic strains of *C. botulinum* if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.
>5° C to 10° C	Reduced Oxygen*****	5% Aqueous Phase Salt provides complete protection	At these temperatures or higher non-proteolytics (*C. botulinum*) are controlled when aqueous phase salt is 5%. Proteolytic strains of *C. botulinum* start growing above 10ºC**. However, it** should be noted that the temperature range of >5ºC to 10ºC is not recommended for smoked fish products because of the possibility of growth of other microorganisms. It is included in this Annex solely to provide information about attributes affecting *C. botulinum* toxin formation when packaging is reduced oxygen.
>3° C to 5° C	Aerobically Packaged	No maximum water activity is needed. Nonetheless, where there is a **reasonable** possibility of severe time/temperature abuse, the country where the product is being consumed might choose an aqueous phase salt barrier of at least 3% to 3.5% as an additional barrier.	When these products are packaged aerobically, 5ºC is the maximum recommended storage temperature for the control of pathogens generally and for quality. In air-packaged products, aerobic spoilage organisms provide sensory signs of spoilage before the formation of toxin by *C. botulinum.* However, even in air packaging it is possible for anaerobic micro-environments to exist and toxin may form if the product is subject to severe time/temperature abuse. For that reason, the country where the product is consumed may still require aqueous phase salt as a barrier to growth of non-proteolytic strains of *C. botulinum* if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.

***Including vacuum packaging and modified atmosphere Packaging. (As new technologies are developed, e.g. modified atmosphere with high oxygen, new controls may be defined).**

Reasons:

- Rearranged order of rows to sort in sequence of increasing holding temperature and packaging for clarity.
- Italicized *Clostridium botulinum* species names.
- Removed unnecessary brackets and parentheses from temperature ranges in "Product Temperature during Storage" column, and clarified "< or = -18°C".
- Moved parenthetical information below "Reduced Oxygen" in the "Packaging column" to the footnote for clarity
- Removed a dash in "reason-able"

Grammatical correction for "however" junction in comments for ">5° C to 10° C

Proposed Draft Standard for Fish Sauce (ALINORM 10/33/18, APPENDIX IX)

Comments of Egypt, Japan, Libya, Philippines and United States of America

EGYPT

Egypt approves the proposed draft Standard for Fish Sauce

JAPAN

The Government of Japan appreciates the efforts of the CCFFP in elaboration of the proposed draft standard for fish sauce, which is presented in Appendix IX of ALINORM 10/33/18. Japan supports the adoption of the document at Step 5.

In the mean time, Japan would like to submit the following comments on the text for consideration at the next session of the CCFFP:

3.4 Chemical properties

Third dash point - pH: The pH shall not be more than 6.5

Japan would like to suggest deleting the pH provision.

Rational: Japan believes that there is no clear reason to set the current provision of pH value (not more than 6.5). Japan is of the opinion that the value should be evaluated based on scientific data for food safety and technical justification for food quality.

5. Contaminants

Japan would like to suggest that new subsections 5.2 and 5.3 should be included after current Section 5, Contaminants (as underlined).

5.2. Raw material fish for fish sauce shall not contain biotoxin (e.g. Ciguatoxin, Tetrodotoxin and PSP) in such amount that may present a risk to human health.

Rational: No scientific evidence is available to indicate that Ciguatera toxin, Tetrodotoxin and PSP contents in fish decrease through the fermentation process. Therefore it is important that raw material fish shall not contain these marine biotoxins in such amount that may present a risk to human health.

5.3 Products made using fish from aquaculture shall comply with the maximum residues limits for pesticides and/or veterinary drugs established by the CAC.

Rational: Since aquaculture is spreading fast world-wide, fish may be used for production of fish sauce more often in the future. Therefore it is important the control of pesticide and/or veterinary drugs should be concerned and be included in this section.

LIBYA

8.1 Name of the product

The name of the product shall be "fish sauce" or other names, in accordance with the law and custom of the country in which the product is sold, and in a manner not to mislead the consumer. The name of the product ~~**may**~~ shall be preceded or followed by the common or usual name of the fish. If during fermentation process, fish is mixed with salt or brine only, the fish sauce may be declared on

the label as "natural fermentation".

N.B : in case of using mixed species, the number of the species should not be more than three .

Justification:

1- Common names or species should be indicated to protect the consumers who are allergic to certain fish species .

2- Limiting the number of mixed species to three in order to avoid using trash fish in such kinds of product.

PHILIPPINES

The Philippines supports the elaboration of the proposed standard with the following changes:

1. Modify sentence 2 in Section 2.2 and to insert the phrase "succeeding extractions" to begin another sentence. This statement would already take into account the practice of extracting the remaining protein fish flavor for at least 2 to 3 times as is being done in the Philippines and possibly in other countries.

2.2 PROCESS DEFINITION The product is prepared by mixing fish with salt and is put in covered containers or tanks. Generally, the fermentation process takes not less than 6 months and may follow by adding brine to extract the remaining protein fish flavor and odour until the liquid is obtained. The product shall meet the requirements of section 3.3. Other ingredients may be added to assist the fermentation process.	**2.2 PROCESS DEFINITION** The product is prepared by mixing fish with salt and is put in covered containers or tanks. **Generally, the fermentation process takes not less than 6 months. Succeeding extractions may follow by adding brine to extract the remaining protein fish flavor and odour until the liquid is obtained**. The product shall meet the requirements of section 3.3. Other ingredients may be added to assist the fermentation process.

2. Insert in Section 3.5 "must be of food-grade and" which is a requirement for packaging materials used in any food products:

3.5 Final product The product shall meet the requirements of this standard when lots examined in accordance with Section 10 comply with the provisions set out in Section 10. The products shall be examined by the methods given in Section 9. The packaging for the final product shall be free from any integrity defects, such as cracks, leakage, or loose pieces of the packaging units.	**3.5 Final product** The product shall meet the requirements of this standard when lots examined in accordance with Section 10 comply with the provisions set out in Section 10. The products shall be examined by the methods given in Section 9. The packaging for the final product **must be of food grade and** shall be free from any integrity defects, such as cracks, leakage, or loose pieces of the packaging units.

3. *Omit redundant word – sampling and to spell out liter as 1 and l look almost the same in* Section 9.1:

9. SAMPLING, EXAMINATION AND ANALYSIS **9.1** Sampling Sampling of lots for examination of the final product shall be in accordance with the Codex General Guidelines on Sampling (CAC/GL 50-2004). A sample unit is the individually packed product (bottle) or a 1l portion from bulk containers.	**9. SAMPLING, EXAMINATION AND ANALYSIS** **9.1** Sampling of lots for examination of the final product shall be in accordance with the Codex General Guidelines on Sampling (CAC/GL 50-2004). A sample unit is the individually packed product (bottle) or a 1**liter** portion from bulk containers.

4. Renumber Bullet 4 of Section 9.2 as another section as the test category does not fall under Sensory and Physical Examinations. Likewise, the succeeding chemical tests should be renumbered accordingly:

• Test methods for chemical properties Determination of total nitrogen: AOAC 940.25 **9.3** Determination of pH: The pH shall be measured in a sample of fish sauce diluted with water to 1:10 using a pH meter. The dilution of fish sauce is necessary because of the high ionic strength in the undiluted sauce. **9.3** Determination of amino acid nitrogen by determining formaldehyde nitrogen (AOAC 2.066) and subtracting by ammoniacal nitrogen (AOAC 2.065) **9. 4** Determination of sodium chloride: FAO 1981, Technical Paper 219 See AOAC 937.13 or 976.18 or 976.19. **9.5** Determination of Histamine: See AOAC 977.13.	**9.3 Test methods for chemical properties** **9.3.1** Determination of total nitrogen: AOAC 940.25 **9.3.2** Determination of pH: The pH shall be measured in a sample of fish sauce diluted with water to 1:10 using a pH meter. The dilution of fish sauce is necessary because of the high ionic strength in the undiluted sauce. **9.3.3** Determination of amino acid nitrogen by determining formaldehyde nitrogen (AOAC 2.066) and subtracting the ammoniacal nitrogen (AOAC 2.065) **9.3.4** Determination of sodium chloride: FAO 1981, Technical Paper 219 See AOAC 937.13 or 976.18 or 976.19. **9.3.5** Determination of Histamine: See AOAC 977.13.

UNITED STATES OF AMERICA

In response to CL 2009/29-FFP the United States respectfully submits the following comments on the Proposed Draft Standard for Fish Sauce (at Step 5 of the Procedure). Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

1. SCOPE. Revise as follows:

"This standard applies to fish sauce produced by means of fermentation **by mixing fish and salt** and may include other ingredients added to assist the fermentation process."

Reason: The words "by mixing fish and salt" were in CRD 36 and should have been retained with the revision about added ingredients. See paragraph #138 in the Report of the 30th Session of CCFFP. The sentence does not make sense otherwise.

2.2 PROCESS DEFINITION. Revise as follows:

"The product is prepared by mixing fish with salt~~,~~ and **fermenting** ~~is put~~ in covered containers or tanks **at temperatures below 45° C**. Generally, the fermentation process takes not less than 6 months and may **be** follow**ed** by adding brine to extract the remaining protein**,** fish flavor and odour ~~until the liquid is obtained~~. The product shall meet the requirements of section 3.3. Other ingredients may be added to assist the fermentation process."

Reason: We recommend a maximum temperature limit to prevent the production of a cooked rather than fermented product. Above 40-45° C fermentation is stopped. Other edits for clarity.

3.1.1 Fish. Add the following:

"Certain fish from some geographical areas have been found to accumulate biotoxins. It is up to the competent authority in the producing country to determine whether this risk exists in any geographical areas under their control and if so, put in the necessary mechanisms to ensure that fish parts used comply with the following requirements:

Name of biotoxin	**Maximum level in parts used**
Saxitoxin (STX) group	**≤0.8 milligrams/kg (2HCL) STX equivalents**
Domoic acid (DA)	**≤20 milligrams/kg DA**
Okadaic acid (OA) group	**≤0.16 milligrams/kg OA equivalents**
Brevetoxin (BTX) group	**≤200 mouse units or 0.8 milligrams/kg brevetoxin-2 equivalents**
Azaspiracid (AZP) group	**≤0.16 milligrams/kg AZP equivalents**
Ciguatoxin (CFP) group	**≤0.01 micrograms/kg CFP equivalents for Pacific ciguatoxin and ≤0.1 micrograms/kg CFP equivalents for Caribbean ciguatoxin**
Tetrodotoxin (TTX)	**Fish that contain tetrodotoxin (usually order tetraodontiformes) shall not be used for fish sauce."**

Reason: Biotoxins have been found in fish, and we have no evidence that these toxins are destroyed by the fermentation process. Fish sauce may be produced from any species from any location.

3.2 Other ingredients. Revise as follows:

"~~All~~ **Any** other ingredients used **to assist the fermentation process** shall be of food grade quality and conform to all applicable Codex standards."

Reason: The 30th Session of the CCFFP decided that only other ingredients used to assist the fermentation process are allowed (See Scope, and paragraph #138 in the Report of the 30th Session of CCFFP)

5. Contaminants. Revise as follows:

"**5.1** The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods and Feed (CODEX/STAN 193-1995).

5.2 Products made using aquacultured fish shall comply with the maximum residue limits for pesticides and/or veterinary drugs established by the CAC.

5.3 The product shall not contain any other substance in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission."

Reasons:

5.2: Aquacultured fish are studied for use in fish sauce, they are not prohibited, and may be used extensively in the future, and therefore control of veterinary drugs should be listed for aquacultured fish.

5.3: This line is found in other codex fisheries standards and may be important for other hazards.

6. Hygiene and Handling, Section 6.4 (histamine)

Comment:

The US questions the use 40 mg histamine/100 g fish sauce instead of 20 mg/100 g. Not necessarily because of the histamine poisoning hazard, but because the higher level is not in agreement with the use of sound and wholesome raw material, and because there is an increased risk for *Clostridium botulinum* toxin formation in uneviscerated fish that are not held chilled or salted on harvest vessels prior to the fermentation process. The US is also aware that fish of low economic value are commonly used or diverted to fish sauce production and that these fish may be temperature abused before the start of the fermentation process. Studies conclude that levels of histamine in fish sauce are high only when the raw material used has been improperly handled prior to fermentation.

Brillantes et al. (2002) reflect that "Sato and others (1995) hypothesized that the high histamine levels that were found in the final product were already produced prior to the salting process." Brillantes et al. (2002) conclude from their own study that "It is thus reasonable to conclude that preserving the freshness of the raw

material can control histamine levels in the final products. This can be achieved by proper icing of fish, maintaining them at low temperatures, and/or by immediate and proper mixing of fish with salt."

Yongsawatdigul et al (2004) conclude that "Histamine, cadaverine, putrescine, and tyramine were major biogenic amines found in fish sauce prepared from temperature-abused anchovy (16h). Changes of biogenic amines during fish sauce fermentation were subtle, suggesting that raw material, rather than a fermentation process, was a major source of biogenic amines."

These studies show that high histamine contents in fish sauce are indicative of the use of mishandled raw material, and are not the result of the fermentation process. Immediate icing, or salting, of small uneviscerated fish on the harvest vessel is required to control the formation of botulism toxin. The US is concerned that levels of histamine near 40 mg/100g in fish sauce are suggestive of raw material that was not properly iced, or salted, and which may contain *C. botulinum* toxin, if the toxin is not destroyed by a secondary process (e.g., boiling).

Brillantes S, Paknoi S, Totakien A. 2002. Histamine formation in fish sauce production. *J. of Food Science* 67(6):2090-2094.

Yongsawatdigul J, Choi YJ, Udomporn S. 2004. Biogenic amines formation in fish sauce prepared from fresh and temperature-abused Indian anchovy (*Stolephorus indicus*). *J of Food Science* 69 (4) (Published on Web 4/28/2004)

7. WEIGHTS AND MEASURES

7.1.1. "Minimum Fill Containers should be filled as full as commercially practicable"

Comment:

The US does not think that minimum container fill is an acceptable replacement for net weight or net volume (see suggested revision for Section 7.1.3 below).

7.1.3 Lot acceptance. Revise as follows:

"A lot shall be considered as meeting the requirement of section 7.1.1 when the number of 'defectives' as defined in Section 7.1.2, does not exceed the acceptance number (c) of the appropriate sampling plan with an AQL 6.5**. In addition, the average net weight or net volume shall be greater than or equal to the declared net weight or net volume."**

Reason: Variance is allowed, however the average net weight should never be less than the declared net weight.

8.1 Name of the Product. Revise as follows:

"If during fermentation process, fish is mixed with salt or brine only**, and no additives are used,** the fish sauce may be declared on the label as 'natural fermentation'."

Reason: To clarify that the restriction applies to additives.

9. SAMPLING, EXAMINATION AND ANALYSIS.

Sections 9.2, 9.3 (number used twice)**, 9.4,** and **9.5.** Revise by combining last bullet of 9.2 and other subsections into new Section 9.3 as follows:

"**9.3 Test methods for chemical properties**

9.3.1 Determination of total nitrogen: AOAC 940.25

9.3.2 Determination of pH: The pH shall be measured in a sample of fish sauce diluted with water to 1:10 using a pH meter. The dilution of fish sauce is necessary because of the high ionic strength in the undiluted sauce.

9.3.3 Determination of amino acid nitrogen by determining formaldehyde nitrogen (AOAC 2.066) and subtracting by ammoniacal nitrogen (AOAC 2.065)

9.3.4 Determination of sodium chloride: FAO 1981, Technical Paper 219 See AOAC 937.13 or 976.18 or 976.19.

9.3.5 Determination of Histamine: See AOAC 977.13."

Reason: Clarity

11. LOT ACCEPTANCE. Revise as follows:

"A lot shall be considered as meeting the requirements of this standard when:

(i) the total number of defective sample units as classified according to Section 10 does not exceed the acceptance number (c) of the appropriate sampling plan in Section 9; and

(ii) the **essential composition and quality factors,** food additives, contaminants, hygiene and **handling, weights and measures, and** labelling requirements of Sections **3,** 4, 5, 6, **7,** 8 are met."

Reason: Important lot acceptance criteria are absent (e.g., Section 3.4, Chemical Properties).

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE
GROUPE INTERGOUVERNEMENT SPECIAL DU CODEX SUR LA RESISTANCE AUX ANTIMICROBIENS
GRUPO DE ACCION INTERGUBERNAMENTAL ESPECIAL DEL CODEX SOBRE LA RESISTENCIA A LOS ANTIMICROBIANOS

Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008) (ALINORM 10/33/42, APPENDIX II)

Comments of Argentina, Brazil, Canada, Colombia, Egypt, European Union, Japan, Mexico, IFAH, WVA

ARGENTINA

Argentina agradece la posibilidad de realizar los siguientes comentarios:

INTRODUCCIÓN

2. De acuerdo con los principios del Codex, el análisis de riesgos es una herramienta esencial para evaluar los riesgos generales para la salud humana que entrañan los microorganismos resistentes a los antimicrobianos transmitidos por los alimentos, y para determinar las estrategias ~~**de mitigación**~~ apropiadas a fin de controlar **y mitigar** tales riesgos. […]

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

4. La fase inicial […]. Las etapas posteriores del marco de análisis de riesgos comprenden la identificación, evaluación, selección y ejecución de las medidas adecuadas de gestión del riesgo con el fin de reducir al mínimo (si es necesario) y ~~**contener**~~ **delimitar** los riesgos señalados para la salud humana. Los gestores de riesgos tienen la responsabilidad de verificar que las

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano. El término "contener", pese a que se encuentra bien ubicado en el contexto de la frase, no es el correcto, ya que, a partir de la interpretación del texto en inglés, el uso de éste es el de poner un límite definido y circunscribir a los riesgos.

DEFINICIONES

Párrafo 9

Antimicrobiano- Cualquier sustancia de origen natural, semisintético o sintético que en

concentraciones in vivo mata microorganismos o inhibe su crecimiento al interactuar con un ~~**objeto**~~ **objetivo** específico (FAO/OIE/OMS, 2008).

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Comensal: microorganismo que participa en una relación simbiótica en la que una especie obtiene alguna ventaja mientras la otra no es afectada. En general, los microorganismos comensales se consideran no patógenos en su hábitat normal pero, en caso de estar presentes, en determinadas circunstancias pueden transformarse en patógenos oportunistas **o transmitir factores de resistencia**.

Comentario Argentina: Se considera que la inclusión de la posibilidad de transmitir factores de resistencia puede ser más oportuna, abarcando los alcances del documento.

Criterios interpretativos: se trata de valores específicos tales como las concentraciones mínimas inhibidoras o el diámetro de la zona de inhibición, ~~**con arreglo a**~~ **en base a los cuales** los cuales las bacterias pueden clasificarse como "susceptibles", "intermedias" o "resistentes".

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Uso no previsto o distinto del indicado en la etiqueta: el uso de un agente antimicrobiano ~~**que no se ajusta a las indicaciones de la**~~ **por fuera de las indicaciones de uso aprobadas para éste, tal como conste en su** etiqueta aprobada ~~**del producto**~~. Ciertas normas nacionales pueden permitir este tipo de usos.

Comentario Argentina: Debe tenerse en cuenta que las reglamentaciones aplicables para la aprobación de productos veterinarios consideran la evaluación de la información técnica necesaria para la autorización de comercialización, siendo la etiqueta un breve resumen de las características del producto, en concordancia con las condiciones bajo las cuales el producto fuera autorizado.

MARCO PARA EL ANÁLISIS DEL RIESGO DE RAM TRANSMITIDA POR LOS ALIMENTOS

Figura 1

El cuadro que contiene al texto identificado como "gestion del riesgo" debe centrarse

Elaboración de un perfil del riesgo de resistencia a los antimicrobianos (Apéndice 1)

Parrafo 15

Viñeta Nº 6

- Identificación de las ~~**lagunas de**~~ **principales carencias en el** conocimiento ~~**principales**~~.

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Caracterización del peligro

35. La etapa de caracterización del peligro considera las características del peligro, de la matriz **alimentaria** y del huésped a fin de determinar la probabilidad de que sobrevenga una enfermedad luego de la exposición a dicho peligro. […]

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41. Otros elementos por considerar […]

Viñeta 1

- ~~**Subpoblaciones sensibles**~~ **Poblaciones susceptibles** (es decir, las poblaciones humanas con vulnerabilidad especial) y si se caracterizaron de forma adecuada los riesgos, la exposición o los efectos potenciales para la salud.

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

Viñeta 4

- Análisis de sensibilidad e incertidumbre. Se prefiere el análisis de incertidumbre cuantitativo~~**; no obstante, se puede llegar a él subjetivamente**~~. En el contexto […]

Comentario Argentina: Se considera que, en el marco del análisis de incertidumbre, el llegar a un modelo cuantitativo a partir de datos subjetivos puede ser una solución de compromiso ante las deficiencias en la información disponible, pero en ningún caso podrá sustituirlo. En el caso de aplicarse un modelo cuantitativo a partir de datos cualitativos, esto deberá ser adecuadamente documentado y fundamentado.

Viñeta 6

- Ventajas y deficiencias / limitaciones de la evaluación de riesgos – […]. Se deberían especificar claramente las ~~lagunas~~ **faltas puntuales de datos** relacionadas con el número limitado de especies microbianas consideradas o para las que se dispone de datos sobre resistencia.

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Viñeta 8

- Principales conclusiones respecto de las ~~**lagunas importantes**~~ **deficiencias importantes** en los datos y las necesidades de investigación.

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GESTIÓN DE RIESGOS DE RAM TRANSMITIDA POR LOS ALIMENTOS

Parrafo 47 – cuarto renglón

Debe corregirse el término “deberá aplica**r**se”

[APÉNDICE 1. ELEMENTOS PROPUESTOS PARA SU INCLUSIÓN EN UN PERFIL DEL RIESGO DE RAM TRANSMITIDA POR LOS ALIMENTOS]

2. Información sobre el producto alimenticio

- • ¿Cómo y cuándo entra en ~~**el suministro alimentario**~~ **la cadena alimentaria** el microorganismo/determinante de resistencia a los antimicrobianos identificado?

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

3. Información sobre el microorganismo/determinante de resistencia a los antimicrobianos

- ¿Cuáles son las características de la resistencia expresada por el microorganismo (por ejemplo, espectro de resistencia, corresistencia o resistencia cruzada, ~~**transferibilidad**~~ **capacidad de transferencia**)?

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

6. Otra información pertinente

Comentario Argentina: la frase que aparece en la 3º viñeta es la continuación de la que aparece en la 2º viñeta.

APÉNDICE 2. ELEMENTOS PROPUESTOS PARA SU CONSIDERACIÓN EN UNA EVALUACIÓN DE RIESGO DE RAM TRANSMITIDA POR LOS ALIMENTOS

2. Evaluación de la exposición

2.1. Factores previos a la recolección que afectan la prevalencia del peligro en las fincas

- Presión selectiva de la resistencia:
  - Atributos del uso individual de antimicrobianos
    - Tiempo transcurrido entre la **última** administración del antimicrobiano y la recolección **o la faena**

Comentario Argentina: Dado que este punto refiere a la aplicación de períodos de restricción, corresponde ajustar el texto a las definiciones usualmente aplicadas.

3**. Caracterización del peligro**

3.1. Huésped humano y efectos adversos para la salud

- Patrón epidemiológico (brote o ~~carácter~~ **caso** esporádico)

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

3.2. ~~**Facotres**~~ **Factores** relacionados con la matriz alimentaria […]

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

4. Caracterización del riesgo

4.1. Factores en la estimación del riesgo

Viñeta 6

- Importancia de la patología causada por los microorganismos ~~**objetivo**~~ **que son objeto del análisis**

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

4.3. Análisis de sensibilidad

- ~~**Solidez**~~ **Robustez** de los resultados del modelo ~~**(producto)**~~

Comentario Argentina: Corrección de traducción y estilo únicamente para la versión en castellano

BRAZIL

Brazil would like to thank for the opportunity to submit its comments to the **Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008).**

Brazilian delegation also registers the excellent work of all delegations participants of Task Force to the great effort to obtain the **Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (N01-2008, N02-2008, N03-2008).**

General Comments – Appendix II

Brazilian delegation understands that the present document is more readable; in line to *Codex Alimentarius* language and represents the best approach to *Codex Alimentarius* or national/regional authorities in conducting risk analysis activities related to foodborne antimicrobial resistance.

We observe that in some paragraphs (e.g. 3, 12 and 24) the Task Force should harmonize the language by always using the acronym AMR microorganisms and AMR determinants.

Specific Comments – Appendix II

PARAGRAPH 16: at the end of paragraph add the sentence: **"Decision and its motivation should be timely communicated to all interested parties, as well possible results obtained from risk assessment."**

The paragraph would read: "Consideration of the information given in the risk profile may result in options leading to a range of initial decisions, such as determining that no further action is needed, commissioning a foodborne AMR - risk assessment, establishing additional information gathering pathways or implementing immediate risk mitigation measures. **Decision and its motivation should be timely communicated to all interested parties, as well possible results obtained from risk assessment".**

Rationale: to be consistent with it is showed at Figure 1.

FIGURE 1: include the sentence **"establishment of broad risk management goals"** at the Figure 1 between "ranking of the hazard for risk" and "establishment of risk assessment"

Rationale: to complete the framework for foodborne AMR-risk analysis and be compatible with paragraph 20.

PARAGRAPH 69: delete the last phrase of paragraph: **"The level of detail of data collection could be implemented according to the resources available."**

The paragraph would read: "Surveillance programmes on the use of antimicrobial agents and prevalence of foodborne AMR provide information including baseline data that is useful for all parts of the risk analysis process. Data can be used to explore potential relationships between antimicrobial use and the prevalence of AMR microorganisms in food producing animals, crops, food, feed, feed ingredients and biosolids, manure and other natural fertilisers, as input for risk profiling and risk assessment, to measure the effect of interventions and to identify trends. ~~**The level of detail of data collection could be implemented according to the resources available**~~".

Rationale: Brazilian delegation understands that it is not compatible with the context of this document and with the *Codex Alimentarius* mandate.

PARAGRAPH 70: replace "between countries" at the first sentence of paragraph by the text: **"taking into account references of international organisms".**

The paragraph would read: "Methodology of surveillance programmes should be harmonized ~~between countries~~ **taking into account references of international organisms**. The use of standardized and

validated antimicrobial susceptibility testing methods and harmonised interpretive criteria are essential to the ability to use information from such programs".

Rationale: the harmonization would be more feasible and the obtained information more consistent and standardized.

PARAGRAPH 26 – merge bullets 8 and 11 or delete bullet 8, if words "use" and "usage" have the same meaning in English.

PARAGRAPH 26 – insert the word **"sound**" at the last bullet point.

The bullet point would read: "Science-based and **sound** expert opinions".

Rationale: to be consistent with it was previously defined by Task Force (ALINORM 10/33/42, paragraph 71, page 8).

PARAGRAPH 33 – insert the word **"suggested"** before "pre-harvest factors".

The paragraph would read: "Section 2.1 of Appendix 2 includes **suggested** pre- harvest factors for estimating the likelihood of selection and dissemination of resistance within animal or plant populations. A possible output from the pre-harvest component of exposure assessment is an estimate or probability of the influence of the use of antimicrobial agents on the prevalence of resistance microorganisms in the target animals or crops. Section 2.2 of Appendix 2 considers possible post-harvest factors related to the human exposure to food containing AMR microorganisms and/or antimicrobial resistance determinants. A possible output from the post-harvest component of exposure assessment is an estimate of the likelihood and level of contamination of the food product with resistant microorganisms at the time of consumption".

Rationale: to be consistent with Appendix 2 ("Suggested elements for consideration in foodborne AMR-risk assessment").

FIGURE 2: represent Figure 2 in a more readable format.

PARAGRAPH 55: change the last sentence of paragraph to **"minimize the exposure to food containing AMR microorganisms and AMR determinants".**

The paragraph would read: "Table 1 provides examples of RMOs for the control of foodborne AMR risks, inclusive but not exhaustive of existing Codex Codes of Practice, and RMOs specific to foodborne AMR. The table is divided into pre-harvest RMOs, which include measures to reduce the risk related to the selection and dissemination of foodborne AMR microorganisms, and post-harvest RMOs, which include measures to minimize the **exposure to food containing** ~~**contamination of food by**~~ AMR microorganisms and **AMR** ~~**antimicrobial resistance**~~ determinants".

Rationale: to be in accordance with the examples of post-harvest options presented at Table 1.

TABLE 1 – Food crop production: delete the words **"as supplements"** as previously agreed by Task Force and indicated at paragraph 90.

The sentence would read: "Evaluate the safety of viable microorganisms used ~~**as supplements**~~ in food and feed crop production for their potential to introduce and spread AMR".

Rationale: to be in accordance with it was previously defined by Task Force (ALINORM 10/33/42, paragraph 90, page 9).

PARAGRAPH 80 – amend the first sentence of paragraph to include the words **"and plant"** (**"animal and plant derived food"**).

The paragraph would read: "Training should be undertaken to ensure the safety to the consumer of animal **and plant** derived food and, therefore, the protection of public health. Training should involve all the relevant professional organizations, regulatory authorities, the pharmaceutical industry, veterinary schools, research institutes, professional associations and other approved users".

Rationale:to obtain consistency with other parts of the document.

CANADA

Canada strongly supports the adoption of the "Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance" at Step 5 of the Codex adoption process. Canada believes that substantial progress has been made at the last session of the Task Force and there is general agreement amongst the members on

the main elements of the guidelines. While some editorial revisions would improve the clarity of the text, it is Canada's opinion that no substantive changes need to be made to the document at the next session of the Task Force and, therefore, Canada supports the progress of these draft guidelines to the next step of the Codex adoption process (i.e. Step 5).

According to the decisions made at the last session of the Task Force, a physical working group will be established and will meet immediately prior to the 4th session (October 2010). This working group will provide the opportunity to address these editorial modifications. Canada looks forward to active participation from member countries and observers at the working group meeting as well as the next session of the Task Force in order to finalize the guidelines.

COLOMBIA

Colombia tiene el agrado de presentar los siguientes comentarios al documento **"Anteproyecto de directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos"** en el trámite 5 del procedimiento, enviado por el Secretariado de la Comisión del Codex Alimentarius**.**

En adelante tomamos como referencia el documento Anexo al CX/AMR 10/33/42 apéndice II en versión en español.

I. Párrafo 4- Introducción

Para que exista una buena comunicación entre los evaluadores y gestores del riesgo y las partes interesadas es necesario establecer puntos de acopio.

Por ello se recomienda adicionar al final del párrafo 9 del documento lo siguiente: …,"estableciendo un punto de acopio para el intercambio eficiente de información entre los actores."

II. Párrafo 6- Introducción

Para complementar los documentos de lectura necesarios para el desarrollo de estas directrices, se sugiere adicionar el relacionado con la "Aplicación del Sistema de Análisis de Riesgos y de los Puntos Críticos de Control (HACCP)", en razón a que el Código de Prácticas de Higiene de la Carne y la Leche los menciona más no los desarrolla. Quedando de la siguiente manera:

Este documento se debería leer conjuntamente con los Principios prácticos sobre el análisis de riesgos para la inocuidad de los alimentos para su aplicación por los gobiernos (CAC/GL 62-2007), los Principios y directrices para la aplicación de la evaluación de riesgos microbiológicos (CAC/GL 30-1999),

los Principios y directrices para la aplicación de la gestión de riesgos microbiológicos (CAC/GL 63-2007), el Código de prácticas del Codex para reducir al mínimo y contener la resistencia a los antimicrobianos (CAC/RCP 61-2005**),** *Directrices para la Aplicación del Sistema de Análisis de Riesgos y de los Puntos Críticos de Control (HACCP))*, el Código de prácticas de higiene para la carne (CAC/RCP 58-2005), el Código de prácticas de higiene para la leche y los productos lácteos (CAC/RCP 57-2004)……

III. Párrafo 7- Ámbito de aplicación

Como ajuste a la traducción del documento se recomienda cambiar la frase ~~*se relaciona con el suministro de*~~ por la palabra *proporciona,* ya que no se puede hablar de suministro de orientación mas bien establecer o dar un lineamiento o similar

IV. Párrafo 8- Ámbito de aplicación

En concordancia con el Principio 4 y 7, no debería excluirse *¨los residuos de agentes antimicrobianos en alimentos"* del ámbito de aplicación de las directrices porque son la mayoría de los antibióticos no son absorbidos al 100% por los animales que son tratados ya sea por razones terapéuticas o preventivas. En la literatura científica ha sido reportado que más del 60% del antibiótico es eliminado por la orina y por la materia fecal al medio ambiente.

Se sabe también que algunos cultivos son irrigados con soluciones que contienen antibióticos para prevenir el ataque de microorganismos patógenos.

Por consiguiente se propone adicionar al final del párrafo 7 "y *los residuos de agentes antimicrobianos en alimentos"* ya que allí se contempla los riesgos asociados en sus diferentes campos.

V. Párrafo 9- Definiciones – Determinantes de resistencia antimicrobiana

Se sugiere cambiar el título de esta definición no es acorde con la definición, ya que el texto hace referencia a mecanismos genéticos de resistencia. Por lo tanto el título para esta definición se recomienda que sea: *Mecanismos genéticos de resistencia a los antimicrobianos*

VI. Párrafo 9- Definiciones – Efecto adverso para la salud

Como ajuste a la traducción del documento se recomienda eliminar la frase ~~o captados a través de alimentos~~, debido a que es reiterado dentro del párrafo.

VII. Párrafo 9- Pie de página – Clase de antimicrobianos

Incluir dentro de las definiciones contempladas en el párrafo 9 la definición: "Clase de antimicrobianos" ya que se considera importante en la comprensión del documento

Clase de antimicrobianos: agentes antimicrobianos con estructuras moleculares afines, a menudo con modalidades de acción similares porque interactúan con un objeto parecido y por tanto están sujetos a un mecanismo análogo de resistencia. Las variaciones en las propiedades de los antimicrobianos de una misma clase suelen ser el resultado de la presencia de distintas sustituciones moleculares, que confieren diversas actividades intrínsecas o diversos patrones de propiedades farmacocinéticas y farmacodinámicas

VIII. Párrafo 9- Pie de página – Agente antimicrobiano

Esta definición se refiere a agentes antimicrobianos *in vivo*, los cuales son suministrados a hospederos. Sin embargo no se hace referencia a agentes antimicrobianos *in vitro,* los cuales son usados para aplicar externamente en organismos o superficies. Se sabe que estos últimos también pueden producir resistencia en microorganismos.

Se considera necesario adicionar el tèmino in Vitro a la definición:

Agente antimicrobiano: cualquier sustancia de origen natural, semisintético o sintético que en concentraciones determinadas *in vivo o in Vitro*, inhibe o mata el crecimiento microbiano

IX. Párrafo 10- Principios generales para el análisis de riesgos de RAM transmitida por alimentos – Principio 2

Con el fin de complementar el alcance del principio se sugiere incluir la palabra primaria.

Principio 2: El análisis del riesgo de RAM transmitida por los alimentos debería considerar la selección y diseminación de esta a lo largo de la cadena que va desde la producción *primaria* hasta el consumo de Alimentos

X. Párrafo 12- Actividades preliminares de gestión del riesgo de RAM transmitidas por los alimentos

Como ajuste a la traducción del documento se recomienda eliminar las frases ~~de gestión de riesgos, que comienza~~; ~~comenzar las actividades de gestión del riesgo señalado.~~ Igualmente cambiar la palabra ~~evaluar~~ por determinar para que no hayan confusiones con la evaluación de riesgo. Quedando el párrafo de la siguiente manera:

El gestor de riesgos inicia el proceso con actividades preliminares dirigidas a determinar el ámbito y la magnitud del problema de inocuidad de los alimentos y, según corresponda, comienza las actividades de gestión del riesgo a que haya lugar

XI. Párrafo 18- Clasificación de los problemas de inocuidad alimentaria y determinación de prioridades para evaluación y gestión de riesgo.

Como ajuste al párrafo por duplicidad se recomienda eliminar la palabra ~~opciones~~, debido a que es reiterado dentro del párrafo.

XII. Párrafo 19- Clasificación de los problemas de inocuidad alimentaria y determinación de prioridades para evaluación y gestión de riesgo.

Se sugiere que sería importante incluir en el documento, un anexo que describa cómo se realiza la clasificación o determinación de prioridades diferentes a un perfil de riesgos.

XIII. Párrafo 24- Evaluación del riesgo

Como ajuste a la traducción del documento se recomienda cambiar la palabra ~~cubra~~ por contemple ~~o captados a través de alimentos~~.

XIV. Párrafo 26- Fuentes posibles de información

Por precisión es necesario corregir los numerales ~~83-60~~ por 69-72 según lo relacionado en el documento.

XV. Párrafo 47 - Gestión de riesgo de RAM transmitida por los alimentos

Para unificar criterios con el documento de Codex de Principios Generales se sugiere reemplazar la palabra ~~"legales"~~ por "competentes"

XVI. Párrafo 48 - Gestión de riesgo de RAM transmitida por los alimentos

Como ajuste al párrafo por duplicidad se recomienda reemplazar la palabra ~~"adoptado~~", por "tomado".

XVII. Párrafo 52 – Determinación de las opciones de gestión del riesgo de RAM

Por precisión es necesario corregir los numerales de los párrafos ~~54 y 55~~ por 49 y 50 según lo relacionado en el documento.

EGYPT

Egypts comments are as follows:

It is important to take into consideration the foodborne antimicrobial resistance through crops: feed ingredients and biosolids manure fertilizers input of risk assessment.

We agree on the proposed draft guidelines for risk analysis of foodborne antimicrobials resistance at Step 5.

EUROPEAN UNION

The European Union strongly supports the adoption of the proposed draft Guidelines for the Risk Analysis of foodborne Antimicrobial Resistance at Step 5.

The European Union will submit specific comments on the draft Guidelines once the Codex document is circulated for comments at Step 6.

JAPAN

Recognizing the usefulness of the "Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (Appendix 2, CL 2009/30-AMR)" in controlling the risks to human health associated with foodborne antimicrobial resistant microorganisms and determinants, Japan supports their adoption at Step 5 and advancement to Step 6 at the 33rd Session of the Commission.

Japan believes that when the Task Force considers the Draft Guidelines at Step 7, it should try to make the text as consistent as possible with that of the "Working Principles for Risk Analysis for Food Safety for Application by Government (CAC/GL 62-2007)". We will provide comments on the draft in due course.

MEXICO

México agradece la oportunidad de presentar comentarios. Adicionalmente expresa algunas observaciones a fin de dar claridad en la idea a transmitir con el documento:

En la definición de determinante de resistencia a antimicrobianos, se sugiere especificar que" están ubicados en **el** cromosoma", en virtud de que las células procarióticas solo tienen un cromosoma.

Definiciones. "Criterios interpretativos: se trata de valores específicos tales como las concentraciones mínimas inhibidoras o el diámetro de la zona de inhibición, con arreglo a los cuales las bacterias pueden clasificarse como "susceptibles", "intermedias" o "resistentes".

Se sugiere modificar para referir: "Criterio interpretativo para Resistencia de antibióticos". Ello deriva de la recomendación de emplear una base para definir resistencia en estas guías, con la finalidad de evitar conclusiones inapropiadas respecto a los riesgos para la salud en el ser humano, amén de que dicho concepto se ha utilizado en algunos documentos relativos a la materia sobre el uso de antibióticos.

Cuadro 1. Ejemplos de opciones de gestión de riesgos de RAM transmitida por los alimentos. Sección titulada "Producción de Alimentos de origen Animal", controles reglamentarios sobre las condiciones de uso de medicamentos veterinarios antimicrobianos y aditivos, respecto al párrafo: "Mejorar la precisión del

diagnostico microbiológico en la elaboración, la divulgación y el uso de normas internacionales para: cultivos bacterianos y pruebas de sensibilidad a los antimicrobianos y criterios interpretativos". Se sugiere incluir que dichas pruebas de diagnostico se encuentren disponibles, o bien, especificar en qué sitio podrían encontrarse, ello ayudaría a dar rapidez a las acciones a desarrollar.

INTERNATIONAL FEDERATION FOR ANIMAL HEALTH (IFAH)

In response to CL 2009/30-AMR, the International Federation for Animal Health (IFAH) recommends adoption of the Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (called the Guidelines in this document) at Step 5. IFAH agrees with many of the positions taken by the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance (called the Task Force in this document) and generally supports the draft Guidelines. However, IFAH notes that several content areas would profit from amendment for clarity and technical improvement.

1. Clarification and tightening of the risk profile definitions in harmony with previous Codex texts and FAO/OIE/FAO recommendations is still needed, both for Appendix 1 bracketed text, Figures and paragraphs 14-17. The proposed Canadian-led Working Group scheduled to meet prior to the 4th Task Force meeting will be critical to achievement of this goal.
2. Clinical resistance breakpoints are necessary for defining food borne antimicrobial resistance in the Guidelines because the use of other endpoints may lead to inappropriate conclusions as to the true human health risks outlined in the risk assessment section.
3. The Guidelines should be useful for all countries, and therefore should be made clear and understandable for all readers. In spite of the fact that progress has been accomplished towards these goals in the first 3 sessions of the Task Force, some further clarification and streamlining is still necessary. In this respect, IFAH recommends that the consistency of the Figures 1 and 2 with the explanation provided in the text and Appendices should be ensured. Clear and defined terminology should be used throughout the document.

IFAH is grateful for the opportunity to provide its support for the draft Guidelines and looks forward to providing constructive comments on the draft at Step 5. More in depth comments on the points made above will be made available to the 4th session of the TFAMR and the physical working group preceding it.

WORLD VETERINARY ASSOCIATION (WVA)

The World Veterinary Association (WVA) - representing the veterinary profession at global level - has followed the discussions of the Codex Alimentarius ad hoc Task Force on Antimicrobial Resistance with great interest. We believe that the Task Force has made good progress in the development of the draft guidelines.

Without doubt antimicrobial resistance can pose serious risks towards the protection of the health of people and animals and international agreements on the development of AMR risk profiles, AMR risk assessment and AMR risk management options are indispensable.

The WVA much welcomes the addition of “Principle 8” regarding to the inclusion of animal health aspects relevant to food safety.

With regard to page 35, paragraph 17, concerning provisional decisions, we believe that it would be more appropriate to place this paragraph in the chapter on AMR-risk management than under the heading of development of AMR-risk profile. Furthermore we believe that it should be stated that such provisional decisions should be objectively justifiable, and proportional to the related risk. We also believe that the provisional decision should be limited in time and that possible prolongation should be justified in the light of the evidence further obtained.

With regard to the RMOs mentioned in table 1, for Food animal production, we wish to inform you know that several of the options listed here are part of the WVA policy on the prudent use of antibiotics, since many years. One of the principles of the WVA policy is: “Antibiotics shall be used under the supervision of a veterinarian. Regular close veterinary involvement is essential for informed advice concerning the use of antibiotics. Regardless of the distribution system available, the use of antibiotics should be subject to appropriate professional advice, including by a veterinarian”. Although we are aware of the fact that RMOs in table 1 are examples and that the list is not exhaustive, we recommend including this point of the WVA policy in the table.

Finally we would like to draw your attention to paragraph 7 under Scope where we believe an error is made in the wording of the second sentence. “The intent of the guidelines is to assess the risks to human health associated with the presence in food and feed…by developing advice…” In our opinion the word “by” should be replaced by “and”.

WVA appreciates the opportunity to provide input into the proposed draft guidelines and wishes to thank you for your consideration of our remarks.

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
COMITE DU CODEX SUR LA NUTRITION ET LES ALIMENTS DIETETIQUES OU DE REGIME
COMITE DEL CODEX SOBRE NUTRICION Y ALIMENTOS PARA REGIMENES ESPECIALES

General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Populations (N06-2008) (ALINORM 10/33/26, APPENDIX III)

Comments of Argentina, Brazil, Colombia, Egypt, Mexico, Republic of Korea and United States of America

ARGENTINA

Argentina appreciates the opportunity to provide these comments.

References
Bold text: Commented text in the document
Text in italics: *Justification*

2. DEFINITIONS

2.1. **Individual Nutrient Level** 98 (INL98)1 is the daily nutrient intake value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.

As regards this item, Argentina believes the definition should include the term “intake” as the phrase “Individual Nutrient Level” does not seem to be the most appropriate one; it is misleading in that the definition refers to the requirement of 98 percent of the population.

It should read as follows:

2.1. Individual Nutrient Intake 98 (INL98)1 is the daily nutrient intake value that is estimated to meet the nutrient requirement of 98 percent of the apparently healthy individuals in a specific life stage and sex group.

2.2. Upper level of intake (UL)2 is the maximum level of **habitual** intake from all sources of a nutrient judged to be unlikely to lead to adverse health effects in humans.

With respect to this item, Argentina believes the term “habitual” is misleading. Care needs to be taken with this definition, and it should be noted that it is not the habitual intake, but the intake proven to lead to adverse effects.

Footnote 1

1 Different countries may use other terms for this concept, for example, Recommended Dietary Allowance (RDA), Recommended Daily Allowance (RDA), Reference Nutrient Intake (RNI), or Population Reference Intake (PRI).

2 Different countries may use other terms for this concept, for example, Tolerable Upper Nutrient Intake Level (UL), or upper end of safe intake range.

*Argentina believes it is advisable to translate the English acronyms into Spanish in order to harmonize the language among Spanish-speaking countries and in texts edited in Spanish, for example, the upper end of safe intake range (*nivel máximo del intervalo de ingesta seguro*).*

Argentina supports the rest of the document and agree with its contents, taking into account the provisions of its current standards.

BRAZIL

Brazil supports advancing the document to step 5.

COLOMBIA

Este apéndice III contiene los principios generales que deben seguir los países para determinar los VR de nutrientes para la población en general. Estamos de acuerdo con la propuesta y no encontramos inconveniente ya que se trata de principios generales donde se establecen las fuentes de las cuales se deben tomar los VR (FAO/OMS) y otras distintas reconocidas internacionalmente, y además, dan libertad a los países para fijar valores según condiciones especificas. Para Colombia, se tienen en cuenta los valores reconocidos por la FAO/OMS y se adoptaron a través de las Recomendaciones de Ingestas de Energía y Nutrientes para la población en Colombiana.

EGYPT

Egypt approves the Proposed Draft Standard at Step 5 of General Principles for Establishing Nutrient Reference Values of Vitamins and Minerals for General Population (Appendix III).

MEXICO

MODIFICACIONES SUGERIDAS	JUSTIFICACIÓN
1. PREÁMBULO	
Estos principios se aplican al establecimiento de los valores de referencia de nutrientes del Codex para fines de etiquetado (VRN) relativos a las vitaminas y los minerales para la población general, definida como los individuos mayores de 36 meses. Estos valores pueden utilizarse para ayudar a los consumidores 1) a la hora de calcular la contribución relativa de los diferentes productos a la ~~ingesta dietética total sana~~ ingesta total recomendada y 2) como una de las formas de comparar el contenido de nutrientes entre productos.	Se sugiere eliminar las palabras diétetica y sana (healthful), en función de que las ingestas dietéticas diarias de una población no son clasificables.
Además, los Gobiernos pueden establecer valores de referencia de nutrientes para el etiquetado de alimentos que tengan en cuenta factores específicos del país o la región y que afecten a la absorción de nutrientes o al uso que se haga de los mismos. Los Gobiernos también podrían decidir establecer valores de referencia de nutrientes independientes para el etiquetado de alimentos para segmentos específicos de la población general, como las mujeres embarazadas y las mujeres ~~lactantes~~ en período de lactancia.	La traducción de la palabra lactancy women al español no corresponde a los términos que se utilizan en el idioma.
2. DEFINICIONES	
2.3. Valores nutrimentales de referencia.- conjunto de cifras que sirven como guía para valorar y planificar la ingestión de nutrimentos de poblaciones sanas y bien nutridas, ésta incluye la Ingesta Diaria Recomendada (IDR) e Ingesta Diaria Sugerida (IDS).	México propone integrar en el documento una definición pata Valores nutrimentales de referencia.
3. PRINCIPIOS GENERALES PARA EL ESTABLECIMIENTO DE VRN DE LAS VITAMINAS Y LOS MINERALES	
A. Selección de las fuentes de datos adecuadas para establecer VRN A la hora de establecer los VRN, se deben tener en cuenta los valores de referencia de la ingesta diaria pertinentes y recientes proporcionados por la FAO/OMS. También se podrían tener en cuenta valores pertinentes y recientes que reflejen evaluaciones independientes de los datos científicos y que procedan de organismos científicos gubernamentales o no gubernamentales competentes, reconocidos y distintos de la FAO/OMS.	México considera que cada país cuenta con instituciones educativas y de investigación gubernamentales y no gubernamentales con experiencia relevante al tema.
Los VRN para la población general deben determinarse mediante el cálculo del valor o los valores medios de un grupo de población de referencia elegido mayor de 36 meses. Los valores	La traducción de la palabra lactancy women al español no corresponde a los términos que se

de referencia de nutrientes extraídos por el CCNFSDU se basan en valores para hombres adultos (19 a 65 años) y mujeres adultas (19 a 50 años).**]** A efectos de establecer esos VRN, se deben excluir a las mujeres embarazadas y a las mujeres ~~lactantes~~ en período de lactancia.	utilizan en el idioma.
PIE DE PÁGINA	
1 Otros países pueden utilizar distintos términos para este concepto: ingesta dietética recomendada (RDA, del inglés Recommended Dietary Allowance), ingesta diaria recomendada (RDA, del inglés Recommended Daily Allowance), ingesta de referencia de nutrientes (RNI, del inglés Reference Nutrient Intake) o ingesta de referencia para la población (PRI, del inglés Population Reference Intake), VNR (Valor Nutrimental de Referencia) por citar algunos ejemplos. 2 Otros países pueden utilizar otros términos para este concepto: nivel máximo de ingesta de nutrientes tolerable (UL, del inglés Tolerable Upper Nutrient Intake Level) o nivel máximo del intervalo de ingesta seguro (upper end of safe intake range), por citar algunos ejemplos.	Se propone la adición del término VNR, de acuerdo con la propuesta sugerida en las definiciones.

REPUBLIC OF KOREA

A. Selection of suitable data sources to establish NRVs

We agree this principle because the objective of this agenda 4 is to establish principles for the legibility of NRVs about Vitamins and Minerals. We think that the FAO/WHO is one of the most scientific sources in establishing NRVs. Also, we support that relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than FAO/WHO could also be taken into consideration.

B. Selection of the appropriate basis

We support above principle. The NRVs should be based on Individual Nutrient Level 98 (INL98). We think INL98 could cover the needs of as much of the population as possible.

In Korea, KDRI (Dietary Reference Intakes for Koreans, KDRIs, 2005) is determined by calculating the mean values for a chosen reference population group older than 48 months.

We agree choosing reference population group older than 36 months is scientific selection of establishing NRVs for as much of the population as possible.

For the purpose of establishing these NRVs, the values for pregnant and lactating women should be excluded because these are most likely to exceed the recommended maximum intake of some of the target group.(ex, iron content)

C. Consideration of upper level of intake

We agree this principle. In Korea, KDRI is taking into account upper level of intake established by recognized authoritative scientific bodies.

UNITED STATES OF AMERICA

The United States supports the preliminary adoption of the above draft principles.

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
COMITE DU CODEX SUR LES METHODES D'ANALYSE ET D'ECHANTILLONNAGE
COMITE DEL CODEX SOBRE MÉTODOS DE ANÁLISIS Y TOMA DE MUESTRAS

Proposed Draft Revised Guidelines for Measurement Uncertainty (N10-2008) (ALINORM 10/33/23, APPENDIX IV)

Comments of Brazil, Malaysia

BRAZIL

Brazil thanks the United Kingdom for the preparation of this document and proposes new wording to:

General amendment of the document: eliminating the structure based on of questions and answers and using the following titles for the items:

In the item 1 substituting [1. What is Measurement Uncertainty?] by 1. The meaning of Measurement Uncertainty

In the item 2 substituting [2. Does the Measurement Uncertainty have to be Estimated in Codex?] by 2. Why the Measurement Uncertainty should be estimated and excluding the word [Yes,] starting the sentence "One of the requirements of….".

In the item 3 deleting [3. Does Measurement Uncertainty Arise From both Sampling and Analysis?] in addition, moving the text "Measurement uncertainty applies to the whole measurement process. However, this guidance only considers analytical measurement uncertainty." to the beginning to become it the first sentence of the document.

In the item 4 substituting [4. What is the Relationship between Measurement Uncertainty, the Analytical Result and the Method Used to Obtain the Result?] by 4. Relationship between Measurement Uncertainty, the Analytical Result and the Method Used to Obtain the Result

The other titles are appropriate.

In the item 1, 1st. paragraph: excluding the text [It is not always appreciated that analytical results are variable, and just how large that variability may be, particularly when low concentrations of a measurand (i.e. ppb levels) are being determined. As stated in the Guidelines,] and starts the paragraph – "Measurement uncertainty applies to the whole measurement process. However, this guidance only considers analytical measurement uncertainty."

Substituting ["most quantitative analytical results take the form of "a ± 2u" or "a ± U" where "a" is the best estimate of the true value of the concentration of the measurand (the analytical result) and "u" is the standard uncertainty to 68% level of confidence and "U" (equal to 2u) is the expanded uncertainty to 95% level of confidence. The range "a ± 2u" represents a 95% level of confidence in which the true value would be found. The value of "U" or "2u" is the value, which is normally used and reported by analysts, normally referred to as "measurement uncertainty" and may be estimated in a number of different ways.] by "Most quantitative analytical results take the form of "a ± ku or a ± U" where "a" is the best estimate of the true value of the concentration of the measurand (the analytical result), "k" a coverage factor and "u" is the standard uncertainty and "U" (equal to ku) is the expanded uncertainty. The range "a ± ku" (where k = 2) represents a 95% level of confidence where the true value would be found (in other cases can be increased as k = 3 for 99% level of confidence). The value of "U" or "ku" is the value which is normally used and reported by analysts and is hereafter referred to as "measurement uncertainty" and may be estimated in a number of different ways."

In the i**tem 8.1 Measurement Uncertainty**

Use the following title for diagram on page 72.

"Assessment of compliance with and Upper Limit"

MALAYSIA

Malaysia supports the adoption of the Proposed Draft Guidelines for Measurement Uncertainty at Step 5 by the 33rd Session of the Codex Alimentarius Commission.