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CODEX ALIMENTARIUS COMMISSION

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COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED TO THE COMMISSION FOR ADOPTION

(Comments submitted by 15 June 2011)

CODEX COMMITTEE ON PESTICIDE RESIDUES

COMITÉ DU CODEX SUR LES RÉSIDUS DE PESTICIDES

COMITÉ DEL CODEX SOBRE RESIDUOS DE PLAGUICIDAS

Draft and Proposed Draft MRLs for pesticides at Step 8 and 5/8 (REP 11/PR, paras 31 - 81 and Appendix II).

Comments of EU

EUROPEAN UNION

The EU supports the adoption at Step 8 of all the draft MRLs in Appendix II of REP 11/PR with the exception of the Draft MRLs for the substances/commodities below:

HALOXIFOP (194): The EU does not support the adoption of the draft MRLs at Step 8 due to chronic dietary intake concerns. The EU has already forwarded a concern form to the Codex Secretariat and JMPR.

The ADI and ARfD values derived by JMPR are in the same range as the EU toxicological reference values (EU ADI 0.00065 mg/kg bw/day, JMPR ADI 0.0007 mg/kg bw/day, both based on the same chronic study in mice, SF 100; EU ARfD 0.075 mg/kg bw, JMPR ARfD 0.08 mg/kg bw, both based on the developmental toxicity NOAEL in rabbits, SF 100). In the Risk assessment is used the EFSA PRIMo rev. 2. The exposure related to the CXL proposals amounts of up to 219 % of the ADI and is mainly driven by the CXL for milk (using the STMR in the exposure assessment). The ADI is exceeded for FR toddler, UK infant, NL child, UK toddler and FR infant.

FLUOPICOLIDE (235): The EU and Switzerland already expressed their concerns due to acute intake concerns at the 42nd session of the CCPR. Therefore, the EU does not support the adoption at Step 8 of the draft MRLs.

The EU has set a lower ARfD (0.18 mg/kg bw) than JMPR (0.6 mg/kg bw). Using EU endpoints and risk assessment methodologies, there are intake problems for head cabbage, scarole, kale, celery Chinese cabbage, witloof, lettuce; spinach, purslane. There is a problem even with the variability factor of 5. Even when using JMPR endpoints there are also intake problems for scarole, kale, celery and Chinese cabbage.

The EU supports the adoption at Step 5/8 of all the Proposed Draft MRLs in Appendix III of REP 11/PR with the exception of the Proposed Draft MRLs for the substances/commodities below:

CHLOROTHALONIL (81):

-Cucumber, gherkin and summer squash (3 mg/kg): The proposed draft MRL for cucumber is not acceptable. The database is too small 5 trials outdoor in the US and 1 trial indoor in NL in cucumber. Extrapolation to gherkin and summer squash is also not acceptable

- Root and tuber vegetables (0.3 mg/kg): Extrapolation to the whole group of root and tuber vegetables requires in the EU also trials in sugar beet. Also the residue levels in carrots are higher than the residue levels found in potatoes. Therefore, extrapolation to the whole group of root and tuber vegetables is not acceptable.

- Brussels sprouts (6 mg/kg): Using the OECD calculator the MRL should be 5 mg/kg.

BIFENTHRIN (178):

- **For brassica (cole or cabbage) vegetables, Head cabbages, flowerhead brassicas**, due to extrapolation problems, as the group of brassica contains crops with different morphology. According to Maclachlane et al. the normalised residue at day 0 after the last application are significantly different for crops belonging to this group, resulting from different surface texture and wettability, shape of the edible part of the crops and surface/weight ratio.

- **For pulses** due to the trials for the individual crops (beans, peas and soybeans) would allow setting of specific MRLs.

- **For hops, tea, green and black**, due to insufficient number of trials

NOVALURON (217):

- **Stone fruits**: The CXL proposal was derived by extrapolating results from cherries to the whole group of stone fruits (except prunes). The group of stone fruit contains crops with different plant morphology, surface texture, wettability and surface/weight ratio (cherries vs. peaches). Therefore, the extrapolation from cherries to the whole group of stone fruit is scientifically not valid. This fact is also substantiated by the findings of Maclachlane et al., that the normalised residue concentrations on day 0 are significantly different for the different stone fruit crops.

- **Brassica vegetables (except leafy brassica)**: The group of brassica contains crops with different morphology. According to Maclachlane et al. the normalised residue at day 0 after the last application are significantly different for crops belonging to this group, resulting from different surface texture and wettability, shape of the edible part of the crops and surface/weight ratio. Thus, the extrapolation to the whole crop group is scientifically not valid.

- **Fruiting vegetables, cucurbits**: At EU level an extrapolation is not possible between cucurbits with edible peel and inedible peel because of differences regarding the surface textures and the surface/weight ratios. It is noted that according to Maclachlan et al. these differences are confirmed.

- **Fruiting vegetables other than cucurbits (except sweet corn)**: It is noted that the residue trials on peppers and tomatoes belong to the same population (Kurskal-Wallis H Test). Since a GAP was notified for the whole crop group of fruiting vegetables, an extrapolation would be acceptable. However, it should be clarified if the GAP is relevant also for fungi.

BIFENAZATE (219):

- **Legume vegetables** (7 mg/kg): The residue levels found on shelled beans (up to 0.15 mg/kg) and peas (up to 0.17 mg/kg) are much lower than the residues found on podded beans (up to 1.8 mg/kg) and peas (up to 3.7 mg/kg). The morphology of beans and peas with pods is not comparable with shelled beans and peas. There are sufficient trials data which would allow establishing MRLs for beans and peas in pods and succulent shelled beans and peas. The commodity group legume vegetable is too inhomogeneous to justify the setting of a group tolerance

BOSCALID (221):

- **Leafy vegetables** (i.e., leafy brassica, lettuce and other salad plants, spinach and similar leaves, water cress, chervil) as the proposed draft MRL was derived by extrapolating results from lamb's lettuce to the whole group of leafy vegetables. This extrapolation is not foreseen at EU level. Specific residue levels for lamb's lettuce, lettuce and red mustard could be derived.

- **Stalk and stem vegetables, witloof (except fennel, leek)**: The proposed draft MRL was derived by extrapolating results from celery to the whole group of stalk and stem vegetables. This extrapolation is not foreseen at EU level.

CHLORANTRANILIPROLE (230):

- **Brassica**: due to disagreement with the extrapolation used by the JMPR

CLOTHIANIDIN (238):

- **Stone fruit**: There are sufficient trials data which would allow establishing separate MRL for plums, peaches and cherries resulting from the use of thiamethoxam. These data confirm the findings of Maclachlan et al. which postulate that for plums a lower MRL. For plums a MRL of 0.02 mg/kg would be sufficient. For cherries a MRL of 0.1 mg/kg is appropriate. For peaches and apricots the MRL of 0.2 mg/kg are proposed (the results from peaches could be extrapolated to apricots.).

- **Berries and other small fruits except grapes**: The morphology of various berries within the group is not comparable. There are residue data which would allow establishing separate MRLs for strawberries, blueberries, raspberries, blackberries, boysenberries, cranberries. There are no GAPs reported on other berries. Scientific studies indicate that initial residue deposits at 0 d PHI vary significantly between various berries (Maclachlan, 2010) thus introducing additional uncertainty to the extrapolation.

- **Brassica vegetables (flowering, head brassica and kohlrabi)**: Residue trials were available for broccoli and head cabbage. The results from cabbage were extrapolated to the whole group.

- **Root and tuber vegetables (including sugar beet roots)**: GAPs were reported for carrots, potatoes, radishes and sugar beet. (in addition, GAPs for clothianidin were reported for carrots, chicory roots, tuberous and corm vegetable and sugar beet, but they were less critical than the use of thiamentoxam.) The GAPs were not comparable: seed treatment for sugar beets, foliar application for the other crops, different application rate for carrots and radishes compared with potatoes.

FLUBENDIAMIDE (242):

- **Stone fruits**: Extrapolation of residue data from cherries to the whole group of stone fruit is not acceptable in EU. There are sufficient trials data which would allow establishing separate MRLs for peaches/nectarines, plums and cherries. Scientific studies indicate that initial residue deposits at 0 d PHI vary significantly between stone fruits (cherries/plums) (Maclachlan, 2010). Thus the extrapolation is scientifically not valid.

- **Fruiting Vegetables**: Both tomatoes and peppers are considered major crops in the EU, eight residue trials would be required in each crop for MRL calculation. The data sets on which the proposed draft MRL is based are insufficient.

- **Cucurbits (edible and inedible peel)**: There are sufficient trials data which would allow establishing MRL for courgettes, cucumbers (6 trials) and melons (6 trials) Residues in cucurbits-edible peel would allow deriving lower MRL proposal than in cucurbits-inedible peel, maybe due to differences in surface texture. Residue extrapolation from cucurbits-inedible peel to cucurbits-edible peel (or vice-versa) are not acceptable at EU level due to different surface/weight ratios of the crops (gherkins vs. water melons) as well due to variations of the surface texture between various species of cucurbits (rough and smooth surfaces). Furthermore, since both melons and cucumbers are considered major in the EU, eight residue trials would be required in each crop for MRL calculation.

- **Brassica**: There are sufficient trials data which would allow establishing separate MRLs for head cabbage, Brussels sprouts, broccoli and cauliflower. Scientific studies indicate that initial residue deposits at 0 d PHI vary significantly between Brassica vegetables (Brussels sprouts/ broccoli) (Maclachlan, 2010). Thus the extrapolation is scientifically not valid.

- **Legume vegetables**: Extrapolation of residue data from peas with pods to the whole group of legume vegetables is not acceptable in the EU. The morphology of beans and peas with pods is not comparable with shelled beans and peas. Extrapolation not compliant with regard to “one GAP” principle (FAO, 2009). There are sufficient trials data which would allow establishing separate MRLs for beans (with pods), peas (with pods) and beans (without pods).

- **Tea**: is considered major in the EU, and thus eight residue trials would be required

THIAMETHOXAM (245):

- **Citrus fruits** (only valid for oranges)

- **Stone fruits** (only valid for cherries): The group of stone fruit contains crops with different plant morphology, surface texture, wettability and surface/weight ratio (cherries vs. peaches). Therefore, the extrapolation from cherries to the whole group of stone fruit is scientifically not valid. This fact is also substantiated by the findings of Maclachlan et al., that the normalised residue concentrations on day 0 are significantly different for the different stone fruit crops. There are sufficient data available which allow the setting of MRLs for plums, peaches and cherries. For apricots, the data from peaches could be extrapolated.

- **Berries and other small fruits** (only valid for strawberries): The group of berries and other small fruit contains crops with different plant morphology, surface texture, wettability and surface/weight ratio (e.g. grapes, strawberries, raspberries). The data published by Maclachlan demonstrate that the initial residue deposit is expected to be significantly different. Extrapolation from strawberries to the whole group is therefore scientifically not valid.

- **Brassica vegetables** (only valid for head cabbage): The group of brassica contains crops with different morphology. According to Maclachlan et al. the normalised residue at day 0 after the last application are significantly different for crops belonging to this group, resulting from different surface texture and wettability, shape of the edible part of the crops and surface/weight ratio. Thus, the extrapolation to the whole crop group is scientifically not valid.

- **Cucurbits** (only valid for those of edible peel): At EU level an extrapolation is not possible between cucurbits with edible peel and inedible peel because of differences regarding the surface textures and the surface/weight ratios. It is noted that according to Maclachlan et al. these differences are confirmed.

- **Fruiting vegetables other than cucurbits** (only valid for peppers): No GAPs were notified for fruiting vegetables other than peppers. Therefore, the setting of a group tolerance is not justified.

- **Leafy vegetables** (only valid for lettuce and/or spinach): Residue trials were available for leafy lettuce, head lettuce, spinach and mustard greens. The group tolerance is based on the trials on leaf lettuce where the highest residues were

observed. For the other crops lower MRLs could be derived. The fact that on lettuce lower residues are expected can be explained by the crop morphology.

- Root and tuber vegetables (only valid for potatoes): Taking into account that the GAPs are not comparable (see also clothianidin) an extrapolation from potatoes to the whole group is not acceptable. There are sufficient data to set individual MRLs for carrots, potatoes, radishes, sugar beet. It is not clear if for other crops belonging to the group GAPs were notified and whether the setting of MRLs is necessary.

Proposed Draft Revision to the Guidelines on the Estimation of Uncertainty of Results for the Determination of Pesticide Residues (Annex to CAC/GL 59-2006) at Step 5/8 (REP 11/PR, para. 121 and Appendix X).

Comments of EU

EUROPEAN UNION

Editorial comment:

The European Union would like to propose the deletion of the reference numbers (1), (2) and (3) in Appendix X of the CCPR Report (page 101 and 102) as the respective references are not included in the final Codex text.

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

Draft Standard for Fish Sauce at Step 8 (REP 11/FFP para.36 and Appendix III)

Comments of EU, Philippines

EUROPEAN UNION

Section 4: Food Additives

INS No. for Benzoates: 210-213

INS No. for Sorbates: 200-203

Section 9: Sampling, examination and analysis

9.3.3 Total nitrogen: AOAC 940.25 is included in this section for the second time (already listed under Section 9.3.1. Determination of total nitrogen) and should be deleted. The numbering should be adjusted accordingly.

PHILIPPINES

The Philippines supports the decision of the Committee to advance to Step 8 the draft Standard for Fish Sauce for adoption by the 34th meetin

g of the CAC with the following recommendations and/or minor edits:

1. On Sec. 3.4 Chemical Properties

To insert the phrase “flavour profile” to indicate that the lower level of TN is only on account of the flavour preferences. The section will read as follows:

- Total nitrogen content: no ~~be~~ less than 10g/l. As total nitrogen is responsible for the flavour profile, competent authorities may also specify a lower level of ~~total nitrogen~~ if it is the preference of that country.

2. On Sec.4. Food Additives

The Philippines supports the Committee decision to include the list of food additives as part of the standard that will be forwarded to the relevant committee for endorsement. However, the country would like to propose the inclusion of **sodium metabisulfite** in the said list which is listed in the GSFA under Food Category 12.6, INS 223 (Codex Stan 192-1995, rev. 2010).

The details for inclusion in the list of food additives are as follows:

Functional Class	INS number	Additive	Maximum Level
Preservatives/antioxidants	223	Sodium metabisulfite	300mg/kg

3. On sec. 5.2

To restate the paragraph for clarity.

5.2 Raw material fish for fish sauce shall **not be harvested from areas found to contain marine biotoxins** ~~not contain marine biotoxins (e.g. Ciguatoin, Tetrodotoxin and PSP) in amounts which could present a risk to human health.~~

Proposed Draft Code of Practice for Fish and Fishery Products (section on smoked fish and relevant definitions)
at Step 5/8 (REP 11/FFP para. 70 and Appendix V)

Comments of EU, Philippines

EUROPEAN UNION

Section 12.1: Processing of smoked fish

Flow Chart: "Hot smoking, Cold Smoking and Smoking by Regenerated Smoke"

For the production stage "Reception of ingredients" the right reference should be Section 8.5.1 and for "Storage of ingredients" the reference Section 8.5.2.

Section 12.3: Smoke-dried fish

Flow chart: "Smoked dried fish preparation line":

The production stage "Ingredient: Sugar spices, herbs, food additives" should be adjusted accordingly: "Reception and Storage of Ingredients: Sugar spices, herbs, food additive Section 8.5.1 and 8.5.2".

PHILIPPINES

The Philippines supports the Committee's decision to advance to Step 5/8 the draft Code of Practice for Fish and Fishery Products (section on smoked fish and relevant definitions) with the following recommendations and/or edits:

1. On Sec. 2.9 Definitions

To merge the two definitions on packaging for clarity, to read:

Packaging is a process in which the smoked fish product is placed in a container, either aerobically or under reduced oxygen conditions, including under vacuum or in a modified atmosphere to prevent contamination and rehydration.

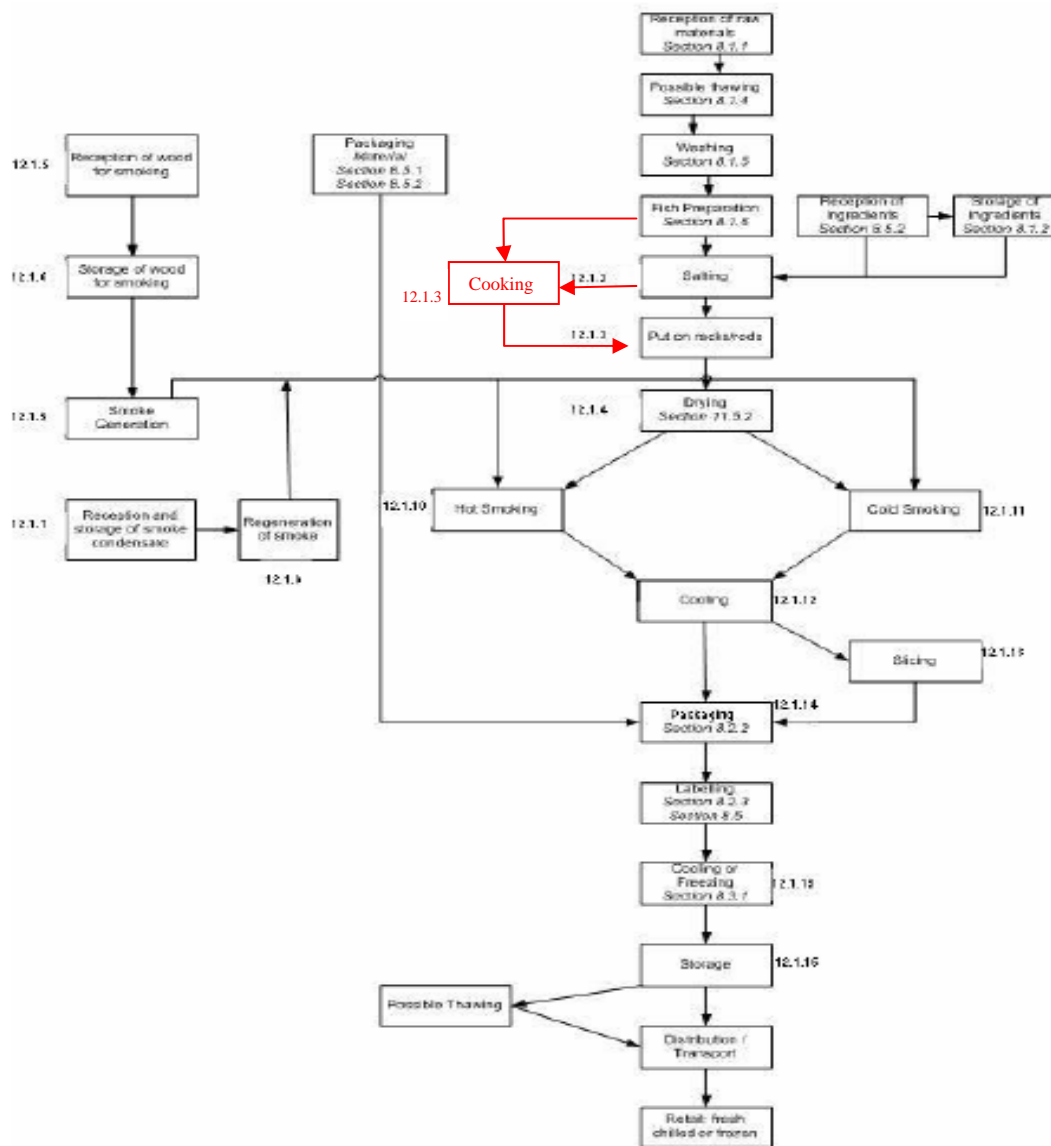
2. On Sec. 12.1 Processing of smoked fish

To delete the last two sentences in the last paragraph as these pertain to GMP. For simplicity, the paragraph is suggested to read as –

Hot smoked products and some cold smoked products, such as smoked salmon are ready to eat without a further cooking preparation stage **and therefore strict compliance to GMP must be observed.** ~~For these products it is necessary to introduce high care practices during the processing, which would include employment of trained staff who handle products in segregated areas, using dedicated equipment. For instance non smoked and smoked fish must be kept separate to avoid cross contamination.~~

3. On the process flow chart

a. To insert **cooking** after fish preparation. The rationale being that there are traditionally prepared smoked fish products in the Philippines (or possibly in some other countries) that undergo "cooking" of fish prior to smoking. The revised portion of the flowchart is shown below:



b. Also, to insert a new subsection under technical considerations to cover the proposed addition, to read as follows:

12.1.3 Cooking

Potential hazards: microbiological

Potential defects: physical damage, undesirable texture,

Technical Guidance

1. **Cooking may be applied prior to smoking to ensure the destruction of microorganisms in addition to improving the flavour and texture of fish**
2. **To ensure complete cooking, a minimum internal temperature of 65 degrees C should be reached.**

4. On Sec. 12.1.1 Salting

To replace the term undesired with undesirable –

1. *Potential Defects: Decomposition, physical contamination, ~~undesired~~ **undesirable** texture, physical damage*

Edits for bullets under Technical Guidance:

a. Strikeout ~~salt~~ before the term brine for clarity

- Typically fish for hot smoking are salted only a short time for enhancing flavour using a low to medium strength ~~salt~~ brine.

- Fish for cold smoking are dry salted, wet salted, combined salted or salted by brine injection of a medium strength ~~salt~~ brine to enhance flavour and for safety purposes.

b. Insert the **size of the fish** at the end of the last bullet as this also affects the duration of salting.

- xxx The equilibration time should be adapted to the salting technique used to the temperature (8-12°C) and depending on ~~the~~ fish species **and size**.

c. Replace the term *selected* with **appropriate** for clarity and to transfer the term potable before the term water, also for clarity:

Salting time and temperature and fish temperature should be ~~selected~~ **appropriate** so as to control the development of histamine, where fish of susceptible species are concerned (e.g. *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryphaenidae*, *Pomatomidae*, *Scomberesocidae*). Brine should be prepared from food grade salt and **potable** water of ~~potable quality~~.

d. Strike-out ~~ed~~ in cooled in bullet 5 to read –

The brine should be kept ~~cooled~~ and the temperature should be monitored.

e. To insert the term **brine** to describe injected fish, for clarity

Brine-injected fish products should be checked for broken needles and metal inclusion.

5. On Sec. 12.1.3 Hanging and racking

a. To insert the terms **arranged** and to correct the tense of the word ~~hung~~ for clarity.

Fish should be ~~hung~~ **hanged or arranged in** racks in a way that ensures that pieces are completely separated from each other allowing an adequate flow of air/smoke.

b. To delete ~~post-brining~~ for clarity

As *Staphylococcus aureus* has been given a competitive advantage via brining, a strict adherence to time/temperature and hygiene/sanitation controls should be followed at all steps ~~post-brining~~ (excluding the smoking and refrigeration/freezing steps) to minimise risk of contamination of the product and subsequent microbiological growth.

6. On Sec. 12.1.4 Drying

To delete **fungal contamination** under potential defects considering that the duration for surface drying is not sufficient to allow fungal growth to occur. Also, to replace the term ~~contamination~~ with **damage** for clarity.

Potential defects: *Decomposition*, ~~fungal contamination~~, physical ~~contamination~~ **damage**

7. On Sec. 12.1.10 Hot smoking

To replace the term ~~damage~~ with **destroy** for clarity.

Time and temperature combination should be controlled, monitored and recorded to ensure effective control of *Listeria monocytogenes* and to ~~damage~~ **destroy** spores of non-proteolytic *Clostridium botulinum*. xxx

8. On Sec. 12.3.1 Pre-drying

To insert the word **in** between **help** and **providing** in bullet 1 for clarity

- Fish for smoke drying should be exposed to sun, air or mechanical drying for a period of time in order to reduce the water content of the skin and flesh which should help **in** providing uniform distribution of smoke over product surfaces.

9. On Sec. 12.3.2 Smoke drying

Editorial comments for bullet 5:

- If smoke drying is carried out in a smoking chamber, smoking and drying are done simultaneously ~~in the smoking chamber~~. Temperature in the chamber should gradually increase from 50°C to 70°C. The smoking and drying process are continued until the finished product is completely dried with the final moisture content **of not more** than 10% or the water activity ~~should be less~~ **of not more** than 0.75.

NORWAY

We appreciate this opportunity to comment upon the **Proposed Draft Code of Practice for Fish and Fishery Products (section on smoked fish and relevant definitions) (para. 70, Appendix V); step 5/8**

We would like to suggest some minor changes for the sake of consistency.

Chapter 6 **Hygiene and Handling** only sets specific criteria for *Listeria monocytogenes* and *Clostridium botulinum* in addition to any microbiological criteria established in accordance with CAC/RCP 21-1997. Therefore specific guidance with regard to microbiological contamination in the Code of Practice should mainly focus on these pathogens, as other contamination in general should be controlled by the implementation of the prerequisite program. We therefore propose the following minor changes to more clearly distinguish between the importance of *Listeria monocytogenes* and *Clostridium botulinum* and other microbiological contamination.

12.1.3. Hanging and racking

Third bullet point insert “**other pathogens i.e.**” after the first word in the first sentence, so that it would read:

As “**other pathogens i.e.**” *Staphylococcus aureus* has been given....

12.1.16 Storage

Third bullet point, insert “*other pathogens i.e.*” before *S. aureus* and change the order in which the pathogens are mentioned, so that it would read:

The maintenance of proper storage temperature (chilled or frozen) for both cold and hot smoked products is of critical importance in controlling microbiological growth, in particular growth of *Listeria monocytogenes*, *Clostridium botulinum* and “**other pathogens i.e.**” *Staphylococcus aureus*.

We also propose a minor change to the technical guidance on hot smoking to more clearly distinguish between the time/temperature to control *Listeria monocytogenes* and

Clostridium botulinum and the time/temperature for coagulation of proteins, since the second bullet deals with both issues.

12.1.10 Hot smoking

Technical guidance, second bullet point, split the bullet point after the second sentence, to make the last sentence become a new bullet point.

To read:

- Time and temperature combination should be controlled, monitored and recorded to ensure effective control of *Listeria monocytogenes* and to damage spores of non-proteolytic *Clostridium botulinum*. Listericidal processes should be validated to ensure that the treatments are effective and can be applied consistently. **(Split bullet)**
- An appropriate time/temperature combination must be used for complete coagulation of proteins (a typical example of hot smoking temperature reaches 65°C in the thermal center of the product).

Proposed Draft Amendment to Section 3.4.5.1 Water of the Code of Practice for Fish and Fishery Products at Step 5/8 (REP 11/FFP para. 75 and Appendix VI)

*Comments of Philippines***PHILIPPINES**

The Philippines poses no objection to the proposed amendment.

Proposed Draft Amendment to the Standard for Quick Frozen Fish Sticks at Step 5/8 (REP 11/FFP para. 155 and Appendix XI)

*Comments of Philippines***PHILIPPINES**

The Philippines acknowledges Thailand and Malaysia for their comprehensive studies on the nitrogen factor of tilapia in their respective countries. However, as a Codex or international food standard the country reiterates the need to gather additional data from other countries for consideration before establishing the average N factor for tilapia. Likewise, it is also recommended that nitrogen factors for other tropical fish used in the production of fish sticks be considered.

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

Draft Standard for Tree Tomatoes at Step 8 (REP 11/FFV, para. 70, Appendix III)

Comments of Colombia

COLOMBIA

Colombia tiene el agrado de presentar el siguiente comentario al documento “**PROYECTO DE NORMA CODEX PARA EL TOMATE DE ARBOL**” en el trámite 8 del procedimiento, anexo al reporte de la 16ª Reunión del Comité del Codex sobre Frutas y hortalizas frescas.

I. Numeral 3. DISPOSICIONES RELATIVAS A LA CLASIFICACIÓN POR CALIBRES

Literal A)

En la tabla de clasificación por diámetro, en el calibre E, se debe invertir la presentación del rango de tamaño, el cual debe ser de mayor tamaño a menor tamaño, como se contempla en los demás rangos de calibre en esta tabla.

Por lo tanto lo correcto es 45 a 35.

**CODEX COMMITTEE ON FOOD LABELLING
COMITÉ DU CODEX SUR L'ÉTIQUETAGE DES DENRÉES ALIMENTAIRES
COMITE DEL CODEX SOBRE ETIQUETADO DE LOS ALIMENTOS**

Proposed Draft Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology at Step 5/8 (REP 11/FL, para. 156, Appendix III)

Comments of European Union, Norway

EUROPEAN UNION

The EU strongly supports the final adoption of the proposed draft compilation of Codex texts relevant to labelling of foods derived from modern biotechnology.

The EU suggests to clarify footnote 1: “See the Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003)” as follows: “**For the definition of modern biotechnology**, see the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003)”.

Rationale:

The EU proposes to clarify the wording of footnote 1 as a simple reference to the document without pointing to the definition of “Modern Biotechnology” is helpless for the reader, especially taking into account that this document is already referred to in the text itself.

NORWAY

Norway is very pleased that the Codex Committee on Food Labelling at its 39th session in 2011 agreed on the text in the document on “*Recommendations for the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering*”, having discussed this issue for more than 16 years. We strongly support the text which can be found in Annex III to REP 11/FL and that this text be advanced to the Commission for adoption at steps 5/8 as a standalone document.

**CODEX COMMITTEE ON FOOD HYGIENE
COMITÉ DU CODEX SUR L'HYGIÈNE ALIMENTAIRE
COMITÉ DEL CODEX SOBRE HIGIENE DE LOS ALIMENTOS**

Proposed Draft Guideline for the Control of *Campylobacter* and *Salmonella* spp in Chicken Meat at Step 5/8 (REP 11/FH, para 63 and Appendix III)

Comments of Egypt

EGYPT

Egypt agrees on the Proposed Draft Guidelines at Steps 5/8 of the CAC Procedure, that they are well scientifically designed, with some comments.

Since these Guidelines apply a risk management framework (RMF) Approach as supported in the Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CAC/GL 63-2007), and “Preliminary Risk Management Activities” and “Identification and Selection of Risk Management Options” are represented by the guidance developed for control measures at each step in the food chain,

Comments, group I:

- 1- Egypt agrees that these two bacteria are very important and Campylobacteriosis and salmonellosis are the two most frequently reported food borne diseases worldwide. The burden of the diseases and the cost of control measures are highly significant in many countries, and contamination with zoonotic *Campylobacter* and *Salmonella* has the potential to severely disrupt the locally circulating foods and trade between countries.
- 2- However, these Proposed Guidelines will be very difficult to apply in countries like EGYPT, particularly on the national level or even on individual industries.
- 3- In addition, the RMF approach is primarily considered a country-wise activity, needs Planning, Application, Implementation and Monitoring of all the components of the RMF along with the Food Chain of Poultry Industry and Food Serving. The RMF, and in general, the usage of Risk Analysis Methodology, in the Food Safety in EGYPT is not yet completely structured.
- 4- On the other hand, the characteristics of the Food Chain of Poultry Industry and Food Serving in Egypt seem to be different from those illustrated in the Flow Diagrams of the Proposed Draft Guidelines, that major parts of the Poultry industry in Egypt are private ownership and fragmented (not in the form of Integrated Industry or Systems, Primary production to Consumption).
- 5- In view of the above mentioned circumstances, it will be very difficult to apply these Proposed Guidelines in EGYPT, particularly on the national level.
- 6- However, in Egypt, there are some Companies or Groups have their Integrated Poultry Industry Systems, (Primary production to Consumption, or from Farm to Table approach), can experience these Proposed Guidelines to produce safe products with minimum incidence of foodborne diseases particularly with a level of control of *Campylobacter* and *Salmonella* in chicken meat that is required to meet public health goals.

Comments, group II:

Since these Guidelines have been built on most general food hygiene provisions already established in the Codex system, mainly:

- a) Good hygienic practice (GHP) – based Control Measures,
- b) Hazard-based Control Measures for control of *Campylobacter* and *Salmonella* in chicken meat,
- c) Incorporation of hazard-based control measures and risk assessment (risk-based control measures) (application of a risk management framework (RMF), and
- d) the web-based decision tool, the following comments are important:

1- Mixing of all these control measures, Qualitative and Quantitative, to control only two bacteria (*Campylobacter* and *Salmonella*) in the poultry Food Chain seems to be complicated, and need empirical scientific knowledge and experience, even if the producers use the HACCP System or even ISO 22000 to control these two hazards.

2- Other complications may arise from that to apply these proposed Guidelines we should apply other Codex Guidelines, Code of Practices or Technical Reports, etc., as prerequisites "*The Guidelines are supplementary to and should be used in conjunction with the Recommended International other Code of Practices*" and these general and overarching provisions are referenced as appropriate in the Guidelines and their content is not duplicated in these Guidelines".

These other Code of Practices Approaches and Guidelines such as:

- 1- *Recommended International Code of Practice –General Principles of Food Hygiene* (CAC/RCP 1 – 1969), and later revisions.
- 2- *Code of Practice on Good Animal Feeding* CAC/RCP 54-2004.
- 3- *Code of Hygienic Practice for Meat* CAC/RCP 58-2005
- 4- *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69 -2008)
- 5- *International Code of Practice for the Processing and Handling of Quick Frozen Foods* (CAC/RCP 8-1976)
- 6- *Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering* (CAC/RCP 39-1993).
- 7- *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985)
- 8- *General Standard for Irradiated Foods* (CODEX STAN 106-1983)
- 9- *Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003).
- 10- FAO/WHO, 2009. Technical Meeting on *Salmonella* and *Campylobacter* in chicken meat. 4-8 May 2009, Rome, Italy.
- 11- JEMRA, 2002. Risk Assessments of *Salmonella* in Eggs and Broiler Chickens.
- 12- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CAC/GL 63-2007).
- 13- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999)
- 14- FAO/WHO Microbial Risk Assessment Series No. 2. Joint FAO/WHO Expert Committee for Microbial Risk Assessment. JEMRA, 2009. Risk Assessment of *Campylobacter* spp in Broiler Chickens, Technical Report. FAO/WHO Microbial Risk Assessment Series No. 12 Joint FAO/WHO Expert Committee for Microbial Risk Assessment
- 15- OIE Terrestrial Animal Health Code19 (applies to *Salmonella* only):
- 16- Hazard Analysis and Critical Control Point (HACCP) System, CAC, 1997

3- Although these guidelines are very important, there will be some difficulties facing the application of these guidelines in Egypt on national level.

4- We still need simple Control Measures for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat, easy to promote and enhance the producers to apply and produce safe products, and also easy to be validated, controlled and monitored by the regulatory authorities and their officers.

Proposed Draft Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) at Step 5/8 (REP 11/FH, para 116 and Appendix V)

Comments of Egypt and Iran

EGYPT

Egypt agrees on the Proposed Draft Revision at Steps 5/8 of the CAC Procedure, they are well scientifically designed.

IRAN

Appreciating the draft for standard no.REP 11/FH APPENDIX V (at step 5/8) we hereby inform you that National Natural Mineral Water Committee of Iran, considered the draft contents, compared it with relative standard documentations no.CAC/RCP 33-1985 and extracted altered or added items, hereby propose some recommendations and amendments to some paragraphs under draft document no.REP 11/FH APPENDIX V as following:

1. On page 93 under the relative paragraph for “Containers”, recovery and refilling of mineral water bottles with other types of water by unauthorized producers, we recommend the term “With properly labeled and intended for sale” to be added to the end of related sentence.

2. On page 93, under the relative paragraph for “Groundwater” whereas under groundwaters having the three following specifications are included by United States of America Environment Protection Agency in surface water group to which surface water regulations are applied, below particulars are better to be added to the said definition:

- a) Extracted from the depth of 10 meter or less
- b) Temperature fluctuations complying with changes in ambient temperature
- c) Containing high quantities of iron and magnesium

3. On page 93, under paragraph 3-1-1, "Authorization", as the competent authority for approval of natural mineral water should be legally competent and specialized in the field (natural mineral water), we recommend the term "For this region", as given under paragraph 3-1 in CAC/RCP 33-1985, to be considered in the new definition.
4. We recommend the following term to be added as a subparagraph to page 94, paragraph 3-1-4, section 16:
"Considering further plans for land and water utility in the area:"
5. On page 95, under paragraph 3-2-4, section 25, as World Health Organization has defined measurement of turbidity factor as important scale in evaluation of the water quality from the basin to consumer side while on the other hand, according to different scientific studies, the relationship between turbidity and water microbial contamination are totally proved. So, we recommend measurement of turbidity to be added to physical factors section.
6. On page 96, paragraph 4-3, section 39, as there are Must and Must not for user is standard document, the paragraph is not in harmony with the standard soul and unnecessary to be given, We recommend section 40 to be omitted.
7. To direct the user correctly for easy access to the relative subject, paragraphs 4-4-3 to 4-4-7, 52 (section 5), 5-2, 5-2-4, 5-5 to 5-8, 80 (section 6), 6-2, 6-4, 6-5, 90 (section 7), 91 (section 8), 94 and 96 (sections 9, 10) in referring "Recommended International Code of Practice-General Principles of Food Hygiene", related paragraph(s) number should be given clearly.
8. On page 97, paragraph 4-4-8, under the chapter for "Storage" we recommend other paragraph to be given regarding "How to store materials, accessories and general equipments" in addition to paragraph 50 and 51 governing material and packing devices for water (materials and equipments directly used in production line). The new paragraph is a summary of paragraphs 5-7-2 and 5-7-1 related to CAC/RCP 33-1985 document on the subject. Meantime we recommend paragraph 5-4 to be omitted and the relative text to be given under "Storage" chapter as a single subparagraph titled "Consumer materials Warehouse in Packing"
9. On page 99, paragraph 5-2-2-2, as the premier condition for water hygiene, including bottled natural mineral water for drinking purpose, is being microbe free, relative description should be given clearly in a separate paragraph for disinfection methods and permitted disinfectants.
10. Where no bottle is recovered and reused, we recommend necessary descriptions to be given on the subject in a single paragraph. Meantime, the three icons at the top of third column in the flow chard are better to be omitted.
11. On page 101, section 8, for storage of filled bottles, the term should be given that Filled bottles should not be under direct sun light.