CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 5, 6, 7, 8, 9, 10, 13 and 14

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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Comments submitted by the European Union

Agenda Item 5: Maximum levels for lead in certain food categories (at Steps 4 and 7)

European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work on the maximum levels (MLs) for lead by the electronic Working Group chaired by Brazil.

For **brown sugar, raw cane sugar and non-centrifuged sugars** the EU can support the proposed ML of 0.15 mg/kg.

For **ready-to-eat meals for infants and young children,** the EU considers that, because children are a more vulnerable consumer group, ingredients of these foods should be selected, to ensure that the lead content is as low as reasonably achievable. Therefore, a rejection rate above 5.3% for this category would be acceptable, because once the ML is established, through the appropriate sourcing of ingredients, the rejection rate will become lower than 5%. Because at CCCF15 an ML of 0.02 mg/kg was agreed for cereal-based foods for infant and young children, this shows that it is possible to achieve concentrations of lead below 0.020 mg/kg in cereals used for foods for infants and young children. Therefore, it would not be appropriate to establish a higher ML for ready-to-eat meals for infant and young children, containing cereals or to establish a higher ML for all ready-to-eat meals for infants and young children, in order to ensure a higher compliance rate for the cereal-based ones. On the basis of the available LOQ corrected data for the entire group of ready-to-eat meals for infants and young children, an ML of 0.020 mg/kg would result in a rejection rate of 5.3%, which would be acceptable. Therefore, the EU supports a lower ML of 0.02 mg/kg in order protect children, which are a vulnerable consumer group.

Agenda Item 6: Code of Practice for prevention and reduction of mycotoxin contamination in cassava and cassava-based products (at Step 7)

Mixed Competence
Member States Vote

The European Union and its Member States (EUMS) welcome and appreciate the work done by Nigeria as chair and Ghana as co-chair of the Electronic Working Group to prepare document CX/CF 23/16/6 related to the draft Code of Practice for prevention and reduction of mycotoxin contamination in cassava and cassava-based products.

The EUMS wish to make the following comment:

§ 32: it is proposed to replace the last sentence “Fermentation typically takes place, 2-5 days fermentation” by “Fermentation typically takes place over 2-5 days”.

The EUMS have not identified key issues which would need further consideration and can therefore agree to advance this draft Code of Practice for final adoption by the Codex Alimentarius Commission (CAC46, 2023).

Agenda Item 7: Sampling plans for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children (At Step 4)

European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work done by Brazil as chair and India as co-chair of the Electronic Working Group to prepare the document CX/CF 23/16/7 related to sampling plan for total aflatoxins in certain cereal and cereal-based products including foods for infants and young children. The development of the sampling plan should take into account the possibility to harmonize the sampling plans for maize grain, flour, meal, semolina and flakes with the sampling plan for deoxynivalenol (DON) and fumonisins and the sampling plan for cereal-based foods for infants and young children with the sampling plan for DON.

The EU wishes to make the following comments:

In line with its reply to CL 2022/46-CF, the EU can in principle agree with the sampling plan for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children as provided in Appendix I to CX/CF 23/16/7 on the condition that following comments are taken into account:

- For the sampling plan for total aflatoxin in maize grain, destined for further processing:
    - Given that the aggregate sample will in most cases be 10 kg, and a laboratory sample size of 10 kg versus 5 kg significantly reduces the sampling variance, it is proposed as laboratory sample size to have ≥ 5 kg instead of 5 kg. Furthermore, given that the sample preparation variance is significantly reduced with a test portion size of 50 g compared to 25 g, 50 grams is proposed as test portion size (see table 2 in Appendix II)
- For the sampling plan for total aflatoxin in flour meal, semolina and flakes derived from maize:
    - In the line of test portion, the second mentioning of test portion is superfluous
    - In the decision rule, the level for acceptance/rejection of the lot has to be aligned with the maximum level i.e. 10 µg/kg
- For the sampling plan for total aflatoxin in husked rice:
    - Given that the aggregate sample will in most cases be 10 kg, the possibility to use the complete aggregate sample as laboratory sample should be provided and therefore it is proposed as laboratory sample size to have ≥ 5 kg instead of 5 kg
    - In the decision rule, the level for acceptance/rejection of the lot has to be aligned with the maximum level i.e. 20 µg/kg
- For the sampling plan for total aflatoxin in polished rice
    - Given that the aggregate sample will in most cases be 10 kg, the possibility to use the complete aggregate sample as laboratory sample should be provided and therefore it is proposed as laboratory sample size to have ≥ 5 kg instead of 5 kg
    - In the decision rule, the level for acceptance/rejection of the lot has to be aligned with the maximum level i.e. 5 µg/kg
- For the sampling plan for total aflatoxin in sorghum
    - Given that the aggregate sample will in most cases be 10 kg, the possibility to use the complete aggregate sample as laboratory sample should be provided and therefore it is proposed as laboratory sample size to have ≥ 5 kg instead of 5 kg
    - In the sampling plans for maize grain, husked rice and polished rice reference is made to lot mass while for sorghum reference is made to lot size. Terminology should be consistent throughout the document.
    - In the decision rule, the level for acceptance/rejection of the lot has to be aligned with the maximum level i.e. 10 µg/kg

- For the sampling plan for total aflatoxin in cereal-based food for infants and young children
    - In the decision rule, the level for acceptance/rejection of the lot has to be aligned with the maximum level i.e. 5 µg/kg
- For the sampling plan for total aflatoxin in cereal-based food for infants and young children destined for food aid programs
    - In the decision rule, the level for acceptance/rejection of the lot has to be aligned with the maximum level i.e. 10 µg/kg

As regards the method criteria for aflatoxins in cereals (table 5 of Appendix I):

The four single aflatoxins (aflatoxin B1, B2, G1 and G2) are analysed with the same method of analysis and aflatoxin B1 is among the four aflatoxins not the most challenging compound for achieving a certain low limit of quantification.

Therefore, the EU is of the opinion that the LOD and LOQ requirement for the single aflatoxins should not depend on the assumed ratio of the concentration of the single aflatoxin in relation to the concentration of the sum of aflatoxins. Furthermore, the factor between the limit of detection (LOD) and limit of quantification (LOQ) is usually 3 and not 2.

The EU proposes therefore a single criterion for the LOQ, e.g. LOQ is ≤ 0.5*ML. In case the ML applies to a sum of toxins, then the LOQ of the individual toxins is ≤ 0.5*ML/n, with n being the number of toxins included in the ML definition.

This means that the LOQ performance criterion for total aflatoxins is ≤ ML/2 and for the single aflatoxins ≤ ML/8 and the LOD (taking a factor of 3 instead of 2 between LOQ and LOD) the performance criterion for total aflatoxins is ≤ ML/6 and for the single aflatoxins ≤ ML/24.

Agenda Item 8: Maximum level for total aflatoxins in ready-to-eat peanuts and associated sampling plan (at Step 4)

European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work done by India as chair and Senegal as co-chair of the Electronic Working Group to prepare document CX/CF 23/16/8 related to a maximum level for total aflatoxins in ready-to-eat peanuts and associated sampling plan.

The EU wishes to make the following comments as regards the recommendations outlined in §7 of CX/CF 23/16/8:

- The EU shall provide the available analytical results for aflatoxin total in peanuts RTE, sampled from the year 2019 onwards. These analytical results are from peanuts imported into the EU for placing on the EU market. These occurrence data are from peanuts from the different important peanut producing countries in the world and the country of origin (in addition to the country of sampling) of the peanuts of the individual samples shall be reported with the analytical results.
- All EU data submitted/to be submitted for peanuts RTE are obtained with a method of analysis with LOQ ≤ 2 µg/kg
- In recommendation (iii) of §7, “below” has to be replaced by “above”.

Agenda Item 9: Maximum levels for total aflatoxins and Ochratoxin A in nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans (at Step 4)

European Union Competence
European Union Vote

The European Union (EU) welcomes and appreciates the work done by India as chair of the Electronic Working Group to prepare the document CX/CF 23/16/10 related to maximum levels for total aflatoxins and ochratoxin A in nutmeg, dried chilli and paprika, ginger, pepper and turmeric and associated sampling plans.

The EU wishes to make the following comments:

Proposed corrections/ requests for explanation

- on § 20: it is mentioned that 64.2 % of the data for total aflatoxins and 70.8 % of the data for ochratoxin A was from EURO region. It is correct that these occurrence data have been submitted by the EU for the European region related to samples of lots imported into the EU or placed on the EU market. These occurrence data are for a significant part from spices from different important spice producing countries in the world, outside the EU and are therefore not to be classified as originating from the European region.
- On table 4b, it is observed that the expected percentage rejection is for
    - pepper chilli, dried whole and for paprika higher for a hypothetical ML of ≥ 5 µg/kg higher than for lower hypothetical MLs (ND and 0.01-4.99 µg/kg)
    - pepper chilli, dried powder/crushed/ground higher for a hypothetical ML of 0.01-4.99 µg/kg than for a lower hypothetical ML (ND)
    - ginger root, powder/crushed/ground higher for a hypothetical ML of 0.01-4.99 µg/kg than for a lower hypothetical ML (ND)
    - nutmeg powder/crushed/ground higher for a hypothetical ML of ≥ 5, ≥ 10, ≥ 15, ≥ 20 and ≥ 30 than for a lower hypothetical ML (0.01-4.99 µg/kg)

  It would be appropriate to provide an explanation why in these cases higher hypothetical MLs resulted in higher rejection rates.
- On table 6: the entry nr 9 for Finland has to be deleted as Finland is part of the EU. It is to be noted that Norway (entry nr 21) as part of the European Economic Area (EEA) has the same legislation on contaminants, including mycotoxins, as the EU.

As regards the proposed maximum levels (Appendix I, part I maximum levels)

Total aflatoxins

- the EU cannot agree on the proposed maximum level of 20 µg/kg for total aflatoxins in dried chilli pepper and nutmeg.
- The EU proposes to better describe "dried chilli pepper" and proposes following description of the food: "*Capsicum spp.* (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne or paprika)"
- The EU notes that no Codex maximum levels are proposed for total aflatoxins in ginger, black and white pepper and turmeric and the EU has no objection to this but does not agree that it is "redundant" to fix any MLs for aflatoxin total for these spices.

Ochratoxin A

- The EU agrees with the proposed maximum level of 20 µg/kg for ochratoxin A in dried chilli pepper.
- The EU proposes to better describe "dried chilli pepper" and proposes following description of the food: "*Capsicum spp.* (dried fruits thereof, whole or ground, including chillies, chilli powder, cayenne or paprika)"
- The EU cannot agree with the proposed maximum level of 20 µg/kg for ochratoxin A in nutmeg. For nutmeg a hypothetical maximum level of ochratoxin A lower than 20 µg/kg, e.g. 15 µg/kg, do not increase significantly the rejection rate. Given the health concern related to the presence of ochratoxin A in food, a maximum level of 15 µg/kg for nutmeg is proposed.
- The EU notes that no Codex maximum levels are proposed for ochratoxin A in ginger, black and white pepper and turmeric and the EU has no objection to this but does not agree that it is "redundant" to fix any MLs for ochratoxin A for these spices.

As regards the proposed sampling plan (Appendix I, part II Sampling plan)

The EU agrees with the sampling plan for spices for the control of the presence of total aflatoxins and ochratoxin A as proposed in Appendix I part II of CX/CF 23/16/9.

The EU has only one minor comment as regards the note to Table 1 *"(*) the number of incremental samples of 100 g to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100"*. The 100 g needs to be replaced by 200 g to reach an aggregate sample weight of 20 kg in case 100 incremental samples are taken. Therefore, the note to Table 1 should read *"(*) the number of incremental samples of 200 g to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100"*.

Agenda Item 10: Discussion paper on the prevention or reduction of ciguatera poisoning

Mixed Competence
European Union Vote

The European Union as co-chair and its Member States (EUMS) welcome and appreciate the work done by the United States of America as chair of the Electronic Working Group (EWG) to prepare the discussion paper CX/CF 23/16/10.

The EUMS support the proposal for a new work on a Code of Practice for the prevention or reduction of ciguatera poisoning based on the discussion paper CX/CF 23/16/10 developed by the EWG.

The EUMS wish to make the following comments, suggestions (mostly suggestions for other wording, additional information) to the document CX/CF 23/16/10:

GENERAL

It is observed that certain terms are wrongly translated into French and the Codex secretariat will be informed of these wrong translations.

INTRODUCTION

- Paragraph 1: it is proposed to replace "*shellfish*" by "*filter feeders or scavengers marine invertebrates*"

APPENDIX I

- Paragraph 4: it is proposed to replace in the 5th line "*are not well understood*" by "*for which the mode of action remains unknown*" and in the last sentence to replace "*symptoms can be managed*" by "*a systematic treatment is possible*"

- Paragraph 7: it is proposed to replace "*Neuroblastoma assay (N2A) : uses cell lines to measure a composite cytotoxicity*" by "*Cellular-based assay on neuroblastoma (CBA-N2A) : measures cell lines viability N2A exposed to a biological extract contaminated with CTX and enables to evaluate its concentration of ciguatoxins*"

- Paragraph 9: it is proposed to replace in the second sentence "*collected*" by "*isolated*" and "*shellfish*" by "*marine invertebrates*"

- Paragraph 11: it is proposed to insert the word "*incidence*" before "*rate of illness*".

- Paragraph 12: in order to clarify the presentation of the EU project EuroCigua, it is proposed to replace the second bullet by "*The EuroCigua project in the European Union (EU)/Economic European Area (EEA). The main objective of this project is to characterise the risk in the UE with several objectives : determine the incidence of ciguatera cases in Europe and epidemiological characteristics ; evaluate the presence of ciguatoxins in fish and fishery products and in EU waters ; and elaborate and validate detection, quantitative and confirmatory methods for CTX analysis*

  See www.aesan.gob.es/AECOSAN/web/ciguatera/home/aecosan_home_ciguatera.htm"

- Paragraph 14: it is proposed to replace "*take advantage of different aspects*" by "*are based on biological and structural properties*" and to replace "*health advisory levels*" by "*safety limits defined by competent authorities / public health agencies*"

- Paragraph 15: it is proposed to replace "*toxin congeners*" by "*toxin analogues*" and to replace "*source location*" by "*geographical origin*"

- Paragraph 16: it is proposed to replace "*vary with the season*" by "*vary from one location to another*"

- Paragraph 22: it is proposed to insert in the second sentence after "*Passive sampling*" "*of toxins in the water column*"

- Paragraph 23: it is proposed to replace "*N2A*" by "*CBA-N2A*", to replace "*using quantitative method such as LC-MS*" by "*using an analytical method such as LC-MS/MS that enables to identify well-known toxins and determine CTX content*." and to replace "*to test fish to a sufficient degree*" by "*to test systematically fish*"

- Paragraphs 24 and 31: it is proposed to replace "*regulators/government officials*" by "*competent authorities*".

- Paragraph 27, second bullet: it is proposed to replace the second bullet "*The Government of Canary Islands (Spain) has developed a protocol for management of wild-caught (non-aquaculture) fishery products susceptible to CP at the first point of sale[2]"* by "*The Government of Canary Islands (Spain) has developed a protocol for management for all the wild-caught (non-aquaculture) fishery products obtained at the first point of sale [2], and that are considered risk specimens to vehicular CTX to the consumer, by detection of ciguatoxin in a 100 g muscle sample, obtained from the dorso-caudal area. The method consists of a previous extraction procedure, and detection of toxicity is determined by Neuro-2a-MTT assay. The evaluation is carried out on specimens individually, and the risk level of each one is included in the official control protocol, considering the species of fish to which it belongs and the weight of each specimen. The specimens in which CTX is not detected are released for consumption, while those with traces of CTX are disposed as animal by-products."* (footnote 2 remains unchanged).

- Paragraph 27, 5th bullet: it is proposed to replace the 5th bullet "*The Ciguawatch platform (referred to in the previous section) includes information on management options, fish advisories, and sampling strategy*" by "*In French Polynesia, even if no management measures is implemented since the strategy is based on an integrated risk based approach, it can be noted that the Ciguawatch platform (referred to in the previous section) includes information on management options, fish species at risk and advisories on sampling strategy"*

- Paragraph 37 (ii): "*Appendix I*" should be replaced by "*Appendix II*"

- Paragraph 37 (iii): "*Appendix II*" should be replaced by "*Appendix III*"

APPENDIX II

- Point 3): it is proposed to replace "*government officials*" by "*competent authorities*" and to replace "*fish harvesters and producers*" by "*fish sector operators*"

- Point 4(a): it is proposed to delete the first sentence as it is reflected in the second sentence and therefore superfluous and to replace "*fish harvesters and producers*" by "*fish sector operators*".

- Point 4(d): it is proposed to add "*and public health agencies*" after "*international organisations*"

APPENDIX III

- Point 2. 3rd bullet: it is proposed to replace "*government officials*" by "*competent authorities*" and to replace "*local area*" by "*different harvesting areas*".

- Point 2. 4th bullet: it is proposed to replace for the definition of "outbreak" *"(e.g. at least one person ill)"* by "*(e.g. at least two persons ill)"*

- Point 2. 5th bullet: it is proposed to add "*and/or considered as being at risk*" after "*closed to harvesting*"

- Point 2. 6th bullet: it is proposed to replace "*Government officials could develop policies related to CP and request that producers adhere to HACCP principles*." by "Competent authorities *could develop policies related to CP and request that operators take this risk into account in the HACCP plan"*

- Point 4. Title: it is proposed to replace "*producers*" by "*fish sector operators*"

- Point 4. 1st bullet: it is proposed to replace the first bullet by "*Firms should consider adding CP to the FSMS plans, **to include CP risk into the HACCP plan**, to reduce the likelihood of CTX-contaminated fish entering the marketplace. These could include inspection **by the competent authorities** of fish processing plants **regarding this hazard**, testing of commodities, and establishing criteria for rejecting shipments." (**bold parts changed or added**)*

- Point 4. 2nd bullet: it is proposed to replace "*primary seafood processors*" by "*fish sector operators*" and to replace the last sentence by "***Fish sector operators** should avoid purchasing fish species **harvested in areas established or at risk for ciguatoxins**"*

- Point 6 2nd bullet: it is proposed to replace "*restricted*" by "*known to be at risk*"

APPENDIX IV

- It is important to clarify if the list of species listed in appendix taken from the "Report of the expert meeting on ciguatera poisoning" is aimed to be a comprehensive list (including the locations and the references to scientific papers) or not.

In case it is aimed to be a comprehensive list, then

- "French Polynesia (Gaboriau et al 2014)" has to be added to the entry "Blacksaddled coral grouper, *Plectropomus laevis"* and
- "Rapa island (Chinain et al 2020)" has to be added to the entry "Blue sea chub (omnivorous), *Kyphosus cinerascens".*

Agenda Item 13: Forward work-plan for CCCF: Review of staple food-contaminant combinations for future work of CCCF

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) welcome and appreciate the work done by the Host Country, JECFA and Codex secretariat to prepare the discussion document CX/CF 23/16/13 on the review of staple food-contaminant combinations for future work of CCCF.

The EUMS support the option 1 for follow-up, i.e. to continue this work through an EWG, using the same methodology.

The work within this EWG should address from the sections referred to in §14 of CX/CF 23/16/13 only section I "*Finding relevant staple food -contamination combinations (SFC) for compilation of a list of interest"*, section II "*Compiling a list of interest SFC for further exploration*" and section III "*Selecting combinations from the list of interest for possible exploration in discussion paper CCCF*".

Section IV "*Decision for developing discussion paper depending on available discussion time in total workload of CCCF*", section V "*Development of a discussion paper on the selected SFC*", section VI "*Decision on starting new work on SCF in step procedure*" and section VII "*Development of new CCCF standard*" are sections that should not be addressed by the EWG as discussions and decisions on these sections fall under the remit of the Plenary Session of CCCF.

Agenda Item 14: Review of Codex standards for contaminants

Mixed Competence
European Union Vote

The European Union and its Member States (EUMS) welcome and appreciate the work done by Canada on a structured approach to review the Codex standards and related texts for contaminants in feed and food and wishes to provide following comments:

The EUMS agree with the prioritisation criteria and the process for the revision of Codex Standards and related texts for contaminants. As regards the highest priority list for the evaluation of Codex Standards and related texts in that list, the EU would like to share the following considerations on the topics as listed in Annex II of CL 2022/85-CF that the EU wishes to maintain on the overall highest priority list.

Concerning the topics which are not mentioned in this position paper, the EU is of the opinion that there is no need to keep these topics on the overall highest priority list for re-evaluation of Codex Standards and Related Texts for Contaminants in Feed and Food

- ML acetylated deoxynivalenol derivatives**.** Given that the acetylated deoxynivalenol derivatives have the same toxicological potency as the parent compound and that the presence of acetylated deoxynivalenol derivatives compared to the parent compound can it is appropriate to consider as moderate to high priority to consider the inclusion of the acetylated deoxynivalenol derivatives into the ML for deoxynivalenol.
- ML aflatoxin M1 in milk: due to the potential safety concerns (genotoxic carcinogen) and the newly available occurrence data, the EUMS consider the revision of this ML as a moderate to high priority. In connection with the review of the ML, it might be appropriate to simultaneously discuss the need to update of the Code of Practice "Raw Materials and Supplemental Feedingstuffs for Milk-Producing Animals (CXC 45-1997)" – new occurrence data available, technological advances and developments to reduce presence of aflatoxin M1 in milk.
- aflatoxin B1 CoP on raw materials and supplemental feedingstuffs for milk producing animals: see comments aflatoxin M1

- ML inorganic arsenic in husked rice: due to the potential safety concerns (genotoxic carcinogen) and the newly available occurrence data, the EUMS consider the revision of this ML as a moderate to high priority. This work should be combined with work on the revision of the CoP on arsenic in rice.

- CoP arsenic in rice: the EUMS are in favour of a revision of this Code of Practice, as new information on mitigation measures is available.

- ML total arsenic in salt**:** the EUMS are of the opinion that it would would be good to check whether on the basis of the most recent data, there is margin to lower the ML for total arsenic in salt.

- MLs cadmium in salt, legume vegetables, pulses, wheat, cephalopods, marine bivalve molluscs and polished rice: the EUMS are of the opinion that, as new maximum levels should reflect concentrations in crops, which were produced taking into account good practices for the mitigation of cadmium, it could be considered to first draft a general code of practice for the mitigation of cadmium in agricultural crops, followed by a data collection on products to which these good practices were applied. Those data could then be used at a later stage for a possible review of the MLs. Priority could be given for a review of the MLs for legume vegetables, pulses, wheat, cephalopods, marine bivalve molluscs and rice, polished

- ML lead in cereal grains: the EUMS could support a revision of the ML for lead cereal grains on the basis of newly available occurrence data and because cereal grains are a staple food. It should be checked whether for specific cereal grains the ML could be lowered. As in the EU new occurrence data are available, this work could be listed as priority 1

- ML mercury in salt: the EUMS are of the opinion that it would be good to check whether on the basis of the most recent data, there is margin to lower the ML for total methylmercury in salt.

- ML methylmercury in tuna: the EUMS are of the opinion that due to potential safety concerns and the availability of new occurrence data, it would be good to check whether the current Codex ML can be lowered. This work aligns with ongoing CCCF work on the development of a sampling plan for mercury in fish.

- ML tin in total in cured chopped meat, cured ham, cured pork shoulder, corned beef and luncheon meat: the EUMS can support to start work on these tin MLs. As the MLs for tin in canned foods and canned beverages are in List A2 since 2023, also these MLs should be revised together with the meat MLs.

- CoP tin inorganic in canned foods: in case work is started on the tin MLs, The EUMS are of the opinion that also work on the Code of Practice should be taken along.

The EUMS have no further suggestions for standards to be added to the highest priority list for the evaluation of Codex Standards and related texts.