

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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DRAFT REP21/CF

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

44<sup>th</sup> Session

Geneva, Switzerland

8 - 13 November 2021

### DRAFT REPORT OF THE 14<sup>th</sup> SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

(virtual)

3-7 and 13 May 2021

## INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 14th Session virtually, from 3 to 7 and 13 May 2021, at the kind invitation of the Government the Netherlands. The session was chaired by Dr. Sally Hoffer, Manager, Food Safety and Sustainable Food, Directorate Plant Agro Food Chains, Ministry of Agriculture, Nature and Food Quality, The Netherlands. The session was attended by XX member countries, one Member Organization, and XX observer organizations. The list of participants is contained in Appendix I.

## OPENING OF THE SESSION

2. The Session was opened by Ms Marije Beens, the Director General for Agriculture and Food Quality of the Ministry of Agriculture, Nature and Food Quality in the Netherlands. Mr Steve Wearne, the vice-Chair of the Codex Alimentarius Commission, also addressed the meeting.

### Division of Competence<sup>1</sup>

3. CCCF noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission.

## ADOPTION OF THE AGENDA (Agenda Item 1)<sup>2</sup>

4. CCCF:
  - noted that Agenda Items 17 and 19 would be discussed subject to availability of time and that no issues would be considered under Agenda Item 21.
  - adopted the provisional agenda as its Agenda for the Session.

## MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMITTEE AND/OR ITS SUBSIDIARY BODIES (Agenda Item 2)<sup>3</sup>

5. CCCF noted that some matters were for information only, and that the certain issues would be considered under the relevant agenda items as follows:
  - cadmium (Agenda Item 5 and 6);
  - ciguatera toxins (Agenda Items 3 and 20);
  - periodic review of Codex standards for contaminants (Agenda Item 18); and
  - scopoletin (Agenda Item 20).

## Executive Committee of the Codex Alimentarius Commission (CCEXEC78)

### *Timeliness of Codex working documents*

6. CCCF noted that the Codex Secretariat would continue to work closely with the Chair of CCCF, Chairs of EWGs and the Host Country Secretariat on ways to improve work management of the Committee.

## Committee on Methods of Analysis and Sampling (CCMAS40)

### *Review of methods in the General Standard for Methods of Analysis and Sampling (CXS 234-1999)*

7. A delegation noted that conversion to performance criteria was already contained in the *Guidelines for Establishing Numeric Values for Method Criteria* in the Procedural Manual but that some examples might need updating. The Codex Secretariat confirmed that the Guidelines in the PM should be followed, and if there was any need for amendments, this should be brought to the attention of CCMAS for their consideration.

## Conclusion

8. CCCF acknowledged the *General Standard for Methods of Analysis and Sampling* (CXS 234-1999) as the single reference point for methods of analysis and sampling under the remit of CCMAS.
9. CCCF agreed:
  - i) to review the methods in the *Standard for General Methods of Analysis for Contaminants* (CXS 228-2001) with the view to transfer them to the *General Standard for Methods of Analysis and Sampling* (CXS 234-1999) if applicable and subsequent revocation of *Standard for General Methods of Analysis for Contaminants* (CXS 228-2001); and

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<sup>1</sup> CRD01

<sup>2</sup> CX/CF 21/14/1

<sup>3</sup> CX/CF 21/14/2

- ii) that Brazil with the assistance of the United States of America (USA) and Japan would review the methods in the *General Standard for Methods of Analysis for Contaminants* (CXS 228-2001) with the aim of assessing their appropriateness or replacement by other more appropriate methods and possible conversion to performance criteria for consideration by CCCF15. The work would focus only on those methods that related to compounds in CXS 228-2001 that fall within the definition of contaminant.

#### **MATTERS OF INTEREST ARISING FROM FAO AND WHO (INCLUDING JECFA) (Agenda Item 3)<sup>4</sup>**

10. The Representative of FAO summarized the information in the working document and highlighted the activities by JECFA90 (2020) and 91 (2021), including the evaluation of some mycotoxins such as trichothecenes and ergot alkaloids, a group of substances evaluated for their potential presence in oils and fats when transported as a previous cargo as well as exposure assessment of cadmium. He further highlighted expert meetings convened by FAO and WHO that aimed to provide scientific advice on tropane alkaloids in food as well as ciguatera fish poisoning, and the FAO's publication on climate change that covered several food safety hazards including heavy metals, mycotoxins and marine toxins; he also presented other FAO's work including the recent report on food safety aspects of edible insects, as well the ongoing reviews on microplastics and seaweed.
11. The Representative of WHO introduced progress of the work on dioxin and dioxin-like compounds, aiming to provide refined toxic equivalency factors (TEFs) later in 2021. He further introduced microplastic issues, concerning implication on public health, stating that the report for the assessment of health risks of microplastic would be published in 2021, and drew the attention of CCCF14 to the WHO Global Strategy for Food Safety which was requested by a resolution of the World Health Assembly.
12. Several delegations expressed support for the new FAO report on edible insects<sup>5</sup>, stating that edible insects were a popular source of food in certain areas of the world. They reminded that CCASIA in the past had discussed the establishment of standards for edible insects and suggested CCCF take into consideration food safety aspects of edible insects.
13. With respect to how CCCF could consider food safety aspects of edible insects, the Codex Secretariat suggested considering it as a part of follow-up work to outcomes of FAO, WHO and JECFA under Agenda Item 20.

#### **Conclusion**

14. CCCF:
  - i) welcomed the report provided by FAO and WHO; and
  - ii) agreed that any issues around edible insects, as well as the other issues raised in the working paper, such as ciguatera fish poisoning, tropane alkaloids, etc., will be considered under Agenda Item 20.

#### **MATTERS ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 4)<sup>6</sup>**

##### **The Joint FAO/IAEA Center of Nuclear Techniques in Food and Agriculture**

15. The Representative of the Joint FAO/IAEA Center introduced the item and summarized the information provided in the working paper related to technical cooperation projects in the area of food safety and control, international research projects and research laboratories.
16. The Representative drew the attention of CCCF on the ongoing work in IAEA on radionuclides in food, feed and drinking water and the linkages with the information presented in the discussion paper for consideration by CCCF under Agenda Item 16. He mentioned that work at international level in this area is currently developing methodologies that can be used to produce criteria to assess these radionuclides in food. This work involved FAO, IAEA and WHO. An updated summary<sup>7</sup> of this is given in the aforesaid discussion paper. He further noted that it is important to verify that naturally occurring radionuclides in food, feed and water do not seem to be an issue for food safety and trade. The IAEA could also commit to producing any necessary information or documents that might be helpful to food authorities, in this regard and thanked the EWG, the Chairs of the EWG and the Codex secretariat for this excellent discussion paper.

#### **Conclusion**

17. CCCF welcomed the information provided by the Representative of the Joint FAO/IAEA Centre.

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<sup>4</sup> CX/CF 21/14/3

<sup>5</sup> Looking at edible insects from a food safety perspective. Challenges and opportunities for the sector, FAO (2021) <http://www.fao.org/3/cb4094en/cb4094en.pdf>

<sup>6</sup> CX/CF 21/14/4

<sup>7</sup> CX/CF 21/14/14, paras. 27-31

**MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES CONTAINING OR DECLARING <30% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS (Agenda Item 5)<sup>8</sup>**

18. Ecuador, as chair of the EWG, introduced the item and recalled that CCCF13 had advanced the ML to Step 5/8 for adoption by CAC42 (2019). The Commission had adopted the ML at Step 5 only, for comments at Step 6 and further consideration by CCCF14. The EWG Chair drew attention to the decision of CAC42 that the concept of proportionality as agreed by CCCF13 with respect to the adopted MLs by CAC41 (2018) should be maintained. If new additional information provided did not justify a change to the ML, CCCF14 would recommend the adoption of the ML of 0.3 mg/kg by CAC at its next session. CAC42 confirmed that upon such recommendation by CCCF14, CAC43 shall adopt the ML without further discussion.<sup>9</sup>
19. The EWG Chair further recalled that JECFA91 had performed a new exposure assessment of cadmium in all food sources and the conclusions were that the major foodstuffs that contribute to dietary cadmium exposure continue to be the same, i.e., cereals or cereal-based foodstuffs, vegetables and seafood. None of the evaluations carried out by JECFA73 (2010), JECFA77 (2013) and JECFA91 (2021) had identified cocoa products as major contributors to dietary cadmium exposure. There was also no new additional information received to justify a change to the ML proposed, given that the worldwide rejection rate for these products at that ML would be 3.2% and the rejection rate for the Latin American and Caribbean region would be 12%. The recommendation would thus be to adopt an ML of 0.3 Mg kg for chocolates that contain or declare less than 30% of total cocoa solids on a dry matter basis.
20. The JECFA Secretariat confirmed that JECFA91 had undertaken a new exposure analysis for cadmium from all food sources, taking into account all new submitted data and dietary cadmium exposure estimates from 44 national studies. JECFA91 had confirmed the conclusions of previous JECFA meetings that cadmium in cocoa does not constitute a significant source of exposure within the human diet on a global level. However, one specific exception has been noted by JECFA91, for children of the GEMS/Foods cluster G07 (mainly European countries) that consumer only cocoa sources from cluster G05 (South America) cocoa products do constitute a more significant source of exposure to cadmium. The secretariat further added that on the global level, however, the contribution of the total cadmium intake that is caused by cocoa is minor in comparison to the commodities mentioned above.
21. The Secretariat also explained that after any JECFA meeting on food contaminants, a summary is published containing the highlights on the final outcome, the final statement and brief explanation on how JECFA derived their conclusion. This is followed by the JECFA report containing more detailed information on how the key data were collected and considered and how JECFA derived its conclusion. Finally, a monograph containing detailed information on all the data submitted and assessed by JECFA is published. Recognizing the needs of CCCF14 and on an exceptional basis, for the summary report of JECFA91 a more comprehensive summary report was published containing all the information that will be part of the report, which includes the JECFA deliberations and key data elements that went into the evaluation and how the conclusions were reached in order to assist CCCF in its discussion on this item. Therefore, the publication of the report of JECFA 91 will not provide any additional information on this issue and it is unlikely that the monograph would provide further information necessary to enable conclusion on this item at a future session of CCCF.
22. The Chair also reminded CCCF that two MLs were already adopted for the chocolate categories with the higher cocoa content and according to the decision taken at CCCF13, if no consensus were reached at CCCF14, the work would be discontinued until the COP for the prevention and reduction of cadmium in cocoa was finalized and implemented. In light of the latest JECFA evaluation and the fact that no new information had been brought forward to justify a change in the ML, she proposed to advance the ML to Step 8 for adoption by CAC44.

Discussion

23. The European Union, supported by Norway, reiterated their view and reservation as also expressed at CCCF13 and CAC42<sup>10</sup>. The EU further noted that this was confirmed by the 2021 JECFA exposure assessment of cadmium from all sources, which indicated that chocolate and cocoa products with high cadmium concentrations can contribute up to 9.4% of the exposure of European children of 3-9 years old consuming only cocoa products from the one particular region, cocoa products can even be the main contributors to the cadmium exposure (39.4% of the cadmium exposure). This justified the need for a lower cadmium ML for this category of chocolates of 0.1 mg/kg.

<sup>8</sup> REP19/CF-Appendix III; CX/CF 21/14/5 (Australia, Canada, Colombia, EU, Kazakhstan, Morocco, Saint Kitts and Nevis, Switzerland, USA, ECA and FIA); CX/CF 21/1/4/5-Add.1 (Australia, Canada, Brazil, Chile, Colombia, Cuba, Ecuador, Egypt, El Salvador, EU, Malaysia, Peru, Trinidad and Tobago, Uganda, USA, ECA and ICA)

<sup>9</sup> REP19/CAC, paras 65-66

<sup>10</sup> REP19/CF, para. 53, REP19/CAC, para. 57

24. The Delegation also indicated that the concept of proportionality applicable to the two MLs adopted by CAC41 was not justified for this category of chocolates because milk chocolates are consumed by children, while dark chocolates usually are not consumed by this population group. In order to adequately protect children, a stricter ML would be more appropriate for chocolates containing or declaring less than 30% of cocoa solids, even if this ML was not proportionate to the previously agreed MLs for dark chocolates. An extensive explanation had been provided in writing in the relevant comment papers i.e. CX/CF 21/14/5, CX/CF 21/14/5-Add.1 and CRD03 in support of this reservation.
25. Egypt also expressed a reservation on the proposed ML as it enforced a lower ML of 0.1 mg/kg as more protective for consumers, especially children.

### **Conclusion**

26. CCCF agreed to advance the ML of 0.3mg/kg for chocolates containing or declaring <30% cocoa total solids to Step 8 for adoption by CAC44, noting the reservations of the European Union, Norway and Egypt to this decision.
27. The Chair reminded CCCF that all technical issues had been thoroughly discussed and urged Codex members to respect the decision made at this session and not to reopen such discussions at CAC44.

### **MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATES CONTAINING OR DECLARING ≥30% TO <50% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS AND COCOA POWDER (100% TOTAL COCOA SOLIDS ON A DRY MATTER BASIS) (Agenda Item 6)<sup>11</sup>**

#### **Chocolates containing or declaring ≥30% to <50% total cocoa solids**

28. Ecuador, as Chair of the EWG, introduced the item and focused on the conclusions and recommendations that led to the proposed MLs for consideration by CCCF. The EWG Chair recalled the decision of CCCF13 for the EWG to continue work on MLs for categories in question using a proportional approach.
29. At the time of preparing the MLs, the report of JECFA91 was not yet available, but the EWG did consider all the data available on GEMS/Food, including the data available to JECFA91 (2021), for the development of the MLs proposals for the categories under consideration.
30. For this category two scenarios were presented, one following the proportional approach and the other based on analysis of data from GEMS/Food and that based on the two considerations, this evaluation resulted in a range of MLs with some overlap namely:
  - Scenario (1) – GEMS/Food data: A range of 0.6 – 0.7 mg/kg, for which the ML of 0.6 mg/kg accounts for rejection rates of 10.39% (worldwide basis) and 13.16% (regional basis, Latin America and the Caribbean) and the ML of 0.7 mg/kg accounts for rejection rates of 5.74% (worldwide basis) and 7.33% (regional basis, Latin America and the Caribbean); and
  - Scenario (2) – Proportional approach: A range of 0.5 – 0.6 mg/kg, for which the ML of 0.5 mg/kg accounts for rejection rates of 16.23% (worldwide basis) and 20.53% (regional basis, Latin America and the Caribbean).
31. The EWG Chair reminded CCCF on the outcomes of JECFA evaluations on cadmium in cocoa grains and cocoa-based products (i.e. chocolates) as stated in previous sessions of CCCF and also under Agenda Item 5, and noted that the range of MLs proposed were all protective of consumers' health on a global basis and therefore the focus of the discussion should remain on considering an ML with a minimum negative impact on trade that could best accommodate all regions concerned.
32. The Chair reminded the Committee that an agreement had been reached on the ML for chocolates containing or declaring <30% total cocoa solids on a dry matter basis; that two MLs for chocolates containing or declaring ≥50% to <70% and ≥ 70% of total cocoa solids on a dry matter basis had been already adopted by CAC; therefore, there was a need to also agree on the remaining chocolate category. She also reminded the Committee that the EWG had shown the rejection rates for the 2 scenarios based on the proportionality approach and on GEMS/Food data and that the recommendation of the EWG was in light of the JECFA evaluations, which showed that implementing the proposed MLs would have little impact on exposure to choose an ML which has lesser impacts on trade.

### **Discussion**

33. Varying views were expressed either in support for Scenario 1, and an ML of 0.7 mg/kg, or for Scenario 2 and an ML of 0.6 or 0.5 mg/kg.

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<sup>11</sup> CL 2021/11/OCS-CF; CX/CF 21/14/6; CX/CF 21/14/6-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, El Salvador, European Union (EU), Iraq, United States of America (USA), FoodDrinkEurope, IAEA (International Atomic Energy Agency) and International Confectionery Association (ICA))

34. Delegations supporting the higher ML of 0.7 mg/kg highlighted that JECFA91 had confirmed that the presence of cadmium in chocolate was not a significant public health concern and the proposed MLs would have limited practical benefit in reducing dietary exposure to cadmium. However, it was necessary to balance the JECFA outcome with the potential adverse impact on international trade to ensure globally safe levels with minimum negative impact on trade and the level of 0.7 mg/kg would ensure a balance between globally acceptable safe levels while still promoting fair practices in trade and helping to prevent competitive advantage and unnecessary food waste. The delegations noted that these MLs had been discussed since 2013, that a pragmatic solution needed to be found and that data submitted so far to GEMS/Food had supported the outcomes of the different JECFA evaluations.
35. Delegations supporting the Option 2 (0.5 or 0.6 mg/kg) noted that this option was in line with the proportionality approach as agreed by CCCF13.
36. The European Union could not support either of the two proposals for the reasons previously expressed at CCCF13 and under Agenda Item 5, and as explained in their written comments in CX/CF 21/14/6-Add.1. The EU drew attention to the outcomes of JECFA91 evaluation, which confirmed that children are the consumer groups which undergo the highest exposure to cadmium in the EU in particular for the categories of chocolates of less than 30% and between 30-50% of cocoa solids. As already commented under Agenda Item 5, the EU did not agree to apply the proportional approach for the MLs in chocolates containing less than 50% of cocoa solids, as these products are regularly consumed by children, while the darker chocolates are not, due to their bitter taste. Furthermore, the EU noted that the conclusions taken for the worldwide data were driven by a large proportion of data from the LAC region and that data from other cocoa producing regions such as Africa and Asia were much underrepresented. It was also not clear whether the data originated from recent years and whether mitigation practices were applied to limit the cadmium concentrations in the crops. This justified the need for a lower cadmium ML for this category of chocolates of 0.3 mg/kg.
37. The EU, supported by Switzerland and Norway expressed its reservation to setting the MLs at any of the levels proposed.
38. Egypt also expressed reservation on the proposed ML as they enforced a lower ML of 0.3 mg/kg as more protective for consumers, especially children.

#### **Conclusion**

39. CCCCF agreed to advance the ML of 0.7mg/kg for chocolates containing or declaring >30% to <50% cocoa total solids to Step 5/8 for adoption by CAC44, noting the reservations of the European Union, Switzerland, Norway and Egypt.
40. The Chair reminded CCCF that all technical issues had been thoroughly discussed and urged Codex members to respect the decision made at this session and not to reopen such discussions at CAC44.

#### **Cocoa powder containing or declaring 100% total cocoa solids ready for consumption**

41. The EWG Chair explained that the category had been agreed by CCCF, but when analysing the data in the GEMS/Food database it wasn't always clear if the cocoa powder was (i) 100% total cocoa solids, (ii) natural cocoa powder, or (iii) pure cocoa powder and no information was provided on the intended use of the product (e.g. final consumption). The EWG had therefore decided to use all data to propose an ML.
42. Two scenarios were presented similar to the approach for chocolates containing or declaring ≥30% to <50% total cocoa solids on a dry matter basis namely:
  - Scenario (1) – GEMS/Food data: A range of 2.0 – 3.0 mg/kg, for which the ML of 2.0 mg/kg accounts for rejection rates of 5.39% (worldwide basis) and 13.42% (regional basis, Latin America and the Caribbean) and the ML of 3.0 mg/kg accounts for rejection rates of 2.49% (worldwide basis) and 6.33% (regional basis, Latin America and the Caribbean); and
  - Scenario (2) – Proportional approach: A range of 1.3 – 1.5 mg/kg, for which the ML of 1.3 mg/kg accounts for rejection rates of 11.48% (worldwide basis) and 27.64% (regional basis, Latin America and the Caribbean) and the ML of 1.5 mg/kg accounts for rejection rates of 8.26% (worldwide basis) and 20.37% (regional basis, Latin America and the Caribbean).
43. The EWG Chair however also noted that since more than 80% of the available data in GEMS/Food did not show the declared percentage of cocoa in the analysed samples, neither did they indicate whether they were the intermediate product or final product, CCCF should consider changing the name of the category to better reflect the products especially since all available data were considered to determine the proposals for MLs under the two scenarios.

#### **Renaming the category**

44. CCCF considered firstly whether to rename the category as follows:
  - There was little support to rename the category as it accurately reflected the product in question.
  - Most delegations agreed that it was appropriate to incorporate all GEMS/Food data for cocoa powder into the analysis irrespective of whether or not the declared percent of total cocoa solids was given, or whether or not they were intermediate or final products.

*MLs for cocoa powder*

45. CCCF proceeded to consider the two scenarios and noted the following:
- Varying views were expressed in support of either Scenario 1 or Scenario 2 for the same reasons expressed for the category of chocolates containing or declaring >30% and >30% to <50% total cocoa solids on a dry matter basis. In addition, it was noted that this category was not usually consumed directly as food but as an ingredient.
  - The decision on the ML could await implementation of the COP and to assess its impact on cadmium levels, and to allow further generation and submission of data to GEMS/Food.
  - There was limited data from the Africa region for the analysis and derivation of the proposed MLs which also support further generation and submission of data to GEMS/Food in order to increase better representability of data at the global level.
  - If there was no global ML, that default non-science-based levels were being taken up by other countries in the absence of having a Codex standard. It was therefore very important to have a Codex maximum level set for this category.
46. Similarly to the points raised on the previous categories of chocolates, the European Union, supported by Norway and Switzerland, expressed their preference for a lower ML of 0.60 mg/kg in order to sufficiently protect the younger and more vulnerable consumer groups for the same reasons expressed previously (para. XX). Alternatively, as cocoa powder was a commodity which is of lesser significance for international trade, these delegations could also support to not set an ML for this commodity.
47. Egypt could not support the proposed MLs in both scenarios as it enforced a lower ML of 0.6 mg/kg as more protective for consumers, especially children.
48. An Observer highlighted a technical issue regarding Scenario 2. He explained that there was a big difference between chocolates and 100% cocoa powder. The non-fat component was the key component that could contain cadmium and this should be used for the proportional calculation. Chocolate would typically have about 45% non-fat solids, which is where the cadmium could be present, whereas in 100% cocoa powder, typically there would be about 90% non-fat solids. This tended to be twice the ML of non-fat solids in 100% cocoa powder compared to chocolate. Therefore, it was necessary to double the allowance that could be presented in 100% cocoa powder. The proportional approach calculated in Scenario 2 did not take this into account, so if the proportional calculation was done appropriately, it would align with the GEMS/Food data scenario. He noted that further information was presented in their comments in CX/CF 21/14/6-Add.1.
49. The JECFA Secretariat, noting that members alleged several times the importance of a maximum level to protect the children, clarified that the JECFA exposure assessment / evaluation had not revealed that such a need existed on a global level. He noted the EU pointed out correctly that a subcategory of European children may face a more significant contribution from exposure to cadmium through cocoa products, and if the EU intended to protect that particular sub-segment of its children, it was their prerogative. However, at a global level, there was no health benefit gained from putting up a maximum level on any cocoa containing products.

**Conclusion**

50. CCCF agreed:
- i) to postpone discussion on the MLs by one year to allow for more data submission and proposals for ML;
  - ii) to re-establish the EWG chaired by Ecuador, and co-chaired by Ghana, working in English and Spanish to:
    - a. continue working on the ML for cocoa powder ready for consumption containing or declaring 100% total cocoa solids on a dry matter basis taking into consideration submitted written comments and comments made at this session; and to present the analysis in more detail at the next session,
    - b. collaborate closely with the EWG on data management.
  - iii) request JECFA to issue a call for data specific to cocoa powder containing or declaring 100% total cocoa solids ready for consumption;
  - iii) to encourage countries to submit data and actively participate in the EWG; and
  - iv) that if no new data is submitted, the current data set would be used to derive the ML.

## **CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF CADMIUM CONTAMINATION IN COCOA BEANS (Agenda Item 7)<sup>12</sup>**

51. Peru, as Chair of the EWG, introduced the item and recalled that the aim of the COP was to provide Codex members and other stakeholders with risk management measures to prevent/reduce cadmium contamination in cocoa beans and to support implementation of the MLs for cadmium in chocolates and cocoa products. The scope was limited to risk management measures applicable to primary production, post-harvest processing (fermentation, drying and storage) and transport. These practices had been identified as currently available and proven to be practical, cost-effective and applicable worldwide by large, medium and small-scale producers with medium- and long-term impact on containment of cadmium contamination in these products. Other measures applicable to the rest of the food chain could be included in the COP when they become available and could be part of the revision of the COP. The EWG Chair further emphasized that a comprehensive approach should be taken in order to efficiently manage cadmium contamination in the production of cocoa beans. He also encouraged Codex members and observers to continue providing internationally validated risk mitigation measures for the further development of the COP.
52. The Chair called for general comments on the format and content of the COP, and whether such comments would support the adoption of the COP at Step 5, and indicated that specific comments submitted in writing to this session would be forwarded to the EWG for their consideration in the further development of the COP.
53. CCCF noted general support for the development of the COP but that further work needed to be done in the EWG to bring the COP for finalization at the next session of the Committee.
54. Delegations provided the following general comments:
  - There is sufficient information on mitigation measures available for field production and post-harvest processes that could assist in the further development of the COP in the EWG.
  - The COP should address agricultural realities and recommend mitigation measures that are practical for all the options given in the COP as opposed to theoretical options that are currently described in the document, therefore there needs to be more work to ensure that these measures will be achievable for farmers and producers.
  - The COP should identify mitigation measures that are also applicable in the short-term and so more readily available to producers for implementation, but should also look into more medium and long-term measures.
  - While, some short-term measures could be achieved more readily, long-term mitigation measures identified in the COP might need to be looked into in more detail to avoid committing to measures that might be difficult for farmers or producers to comply with in future.
55. A delegation noted that the COP addressed mitigation measures to reduce cadmium contamination for the medium-long term as there was no practical that can be done to prevent/reduce cadmium contamination in the immediate / short-term period.
56. Ecuador, as Coordinator of CCLAC, also referred to the support of the region<sup>13</sup> to the development of this COP.

### **Conclusion**

57. CCCF agreed:
  - i) to advance the Code of Practice for the Prevention and Reduction of Cadmium in Cocoa Beans for adoption at Step 5 by CAC44, on the understanding that the COP will be further revised by the EWG as per the general comments provided by the Committee and the specific written comments submitted to this Session; and
  - ii) to re-establish the EWG, chaired by Peru and co-chaired by Ecuador and Ghana, working in English and Spanish, to work further on the COP taking into account the general comments provided by the Committee and the specific written comments submitted to this session.

## **MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES (Agenda Item 8)<sup>14</sup>**

58. Brazil, as Chair of the Electronic Working, introduced the item, and highlighted the issues which needed to be addressed, viz. data management issues and clarity on certain categories for which ML should be established; and that MLs were proposed for consideration by CCCF.

<sup>12</sup> CL 2021/12/OCS-CF; CX/CF 21/14/7; CX/CF 21/14/7-Add.1 (Australia, Canada, Cuba, Ecuador, EU, Iraq, Japan, Philippines, USA, FoodDrinkEurope, ICA)

<sup>13</sup> CX/CF 21/14/2, para. 10

<sup>14</sup> CX/CF 21/14/8; CX/CF 21/14/8-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, EU, Iraq, Japan, USA, FoodDrinkEurope, ICBA, ICA, ISDI, THIE)



59. CCCF had a short discussion on the general issues related to data management noting that these general views would be considered under Agenda Item 17; followed by a discussion on the questions raised in points (b) – (f) (CX/CF 21/14/8, paragraph 12.1) and consideration of the proposed MLs (CX/CF 21/14/8, Appendix I).

*Recommendation (a): Issues on the data analysis for the ML development*

*Rejection rates*

60. There was general support for a cut-off of 5% (ranging either from 0 – 5% or 2 – 5%), and that rejection rates should be determined on a case-by-case basis. Rejection rates would depend on the availability and amount of data, concentration and distribution of the occurrence data, consumption volumes and patterns, mitigation measures, impact on exports and trade, consumer groups, whether the ML would be set for public health or trade harmonization, amongst others, but that MLs should always be based on the ALARA principle.

*Extremes in data sets*

61. Views were expressed that attention should be paid to extremes in data and that such data should be carefully evaluated to determine whether they should be retained in or removed from the database, as there could be different reasons for such extremes in data, for example due to climatic changes in some years or adulteration. Other views were expressed, that such extremes should not be cut out of the data set *per se* if no information was available, as it would be difficult to know the reasons for these outliers. It was therefore important for submitters of data to indicate what the outliers were.

*Geographic representative data*

62. CCCF reiterated the importance of using geographically representative data for the establishment of global MLs and noted that the data used for the current proposals for MLs for lead in certain food categories did not include for example data from the Africa region, yet such data existed for commodities such as sugars, eggs, spices. Not taking into account geographically representative data could result in MLs that could be a barrier to trade.

Conclusion

63. CCCF noted the views expressed and that these issues would be further considered under Agenda Item 17.

*Recommendation (b): Establish MLs for dried culinary herbs and spices or use the already established MLs for fresh leafy, root and tuber vegetable and apply concentration factors*

64. There was general support to establish MLs for dried spices and culinary herbs as these were the commodities most widely traded and also in line with the standards being developed in the Committee on Spices and Culinary Herbs (CCSCH) and the GSCTFF which indicate that MLs should be established for food moving in international trade. However views varied on whether to establish a single ML for dried spices and culinary herbs or to establish separate MLs for the different dried spices and culinary herbs based on available data. It was noted that different factors, such as processing and storage conditions, could impact on MLs for these products.
65. However, there was also support for setting separate MLs for fresh and dried culinary herbs, as culinary herbs were either traded as fresh or in dried form, but that applying an MLI for leafy vegetables to fresh culinary herbs would not be appropriate. In case that an ML for fresh culinary herbs would be considered, the data would need to be checked carefully for the specific species of culinary herbs to ensure that the ML is appropriate for all species of fresh culinary herbs in order to avoid situations where the ML would be too low or high for certain species within the group to which the ML applies.
66. Limited support was expressed for the use of concentration factors. MLs to be set for dried culinary herbs and spices should be set on available data and not based on concentration factors apply to the corresponding fresh product.
67. While there was support to establish ML for dried spices and culinary herbs, views were expressed that this work should be postponed to allow the submission of more geographically representative data and to allow for the implementation of the newly revised *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004).

Conclusion

68. CCCF:
- supported the establishment of MLs for dried spices and culinary herbs and that consideration could be given to establishing MLs also for certain fresh culinary herbs;
  - did not support the use of concentration factors and to derive an ML for dried culinary herbs based on the ML for fresh leafy vegetables as some culinary herbs were not leafy vegetables; and
  - agreed:
    - to postpone discussion on MLs for one year to allow submission of new data to GEMS/Food;
    - that if no new data were submitted that CCCF15 would take a decision based on the current data set.

Recommendation (c): To establish an ML of 2.0 mg/kg for dried rhizomes, bulbs and roots

69. In view of the decision taken to postpone discussion on MLs for dried spices and culinary herbs, CCCF agreed to postpone the discussion on this ML, but noted the following views:
- The data used was not sufficient and did not reflect all the categories within this group for the establishment of an ML at this stage, and that data from primary producers were needed.
  - It was not appropriate to exclude turmeric data from the data set for the establishment of the ML as not all turmeric was necessarily adulterated.
  - The turmeric data should be excluded to derive the ML for this group but that the ML should also apply to turmeric.
  - The adulteration of turmeric was food fraud and such products should be eliminated from the food trade.
  - The current data set was dominated by data on turmeric and that it would be difficult to determine whether turmeric should be analyzed separately or be included with other rhizomes, bulbs and roots and the further work should consider data with and without turmeric for the establishment of an ML. This would help to determine whether the levels for turmeric were normal or due to adulteration and whether a single ML for dried rhizomes, bulbs and roots including or excluding turmeric could be set.
70. CCCF further noted there was general support to establish a single ML for dried rhizomes, bulbs and roots but there were divergent views as to the ML equal to or lower than 2.0 mg/kg.

Conclusion

71. CCCF agreed to postpone discussion by a year to allow for further data submission through GEMS/Food and that the EWG would look at MLs for this category with and without data for turmeric, and that both analysis would be presented for consideration by CCCF.

Recommendation (d): To establish an ML of 0.1 mg/kg for eggs only, in view of the lack of occurrence data for eggs products and that there is no harmonized definition for preserved eggs

72. CCCF noted the following views:
- Before a decision could be taken, consideration should be given to whether MLs should be established for fresh eggs if preserved eggs were excluded from the dataset, since the initial proposal for establishing MLs for eggs and egg products had been based on data including processed eggs and that consideration should be given to trade and health implications if an ML for eggs were established.
  - MLs should be established for fresh eggs and that consideration could be given to establishing separate MLs for chicken eggs and duck eggs, in view of the lower concentration of lead in chicken eggs compared to duck eggs and also in view of the higher consumption volume of chicken eggs.
  - A single ML should be established for fresh eggs with no further differentiation between chicken eggs and duck eggs.
73. Those delegations who supported the establishment of an ML for eggs only, also expressed support either for the ML of 0.1 mg/kg or for lower levels for chicken and duck eggs, respectively, or that more data should be obtained to derive the ML.

Conclusion

74. CCCF agreed that the EWG would consider the feasibility of establishing MLs for fresh eggs, either as a single ML or separate MLs for chicken and duck eggs, based on submission of additional data specific for fresh eggs.

Recommendation (f): To set an ML for cereal-based foods for infants and young children "as is" or "as consumed"

75. There was little support to express the ML "as consumed".
76. A proposal was made to express the ML on a "dry matter basis" similar to the ML for DON in cereal-based foods for infants and young children in the GSCTFF since these products were widely traded as dried products and for which data was available and that reconstitution would require diluent which could also be a source of lead adding to variability and lead concentrations in products on an "as consumed" basis. Other delegations supported this proposal as the closest to "as is" products and also referred to the term "as sold" as an alternative descriptor.
77. Delegations in favour of setting the ML for cereal-based foods for infants and young children "as is" indicated the following:
- "as consumed": the product "as consumed" was not appropriate and as they come in different formulations and preparation instructions which make their analysis and enforcement difficult. Therefore:

- “as is”: more practical from a regulatory point of view and easier to analyze if the ML was set on “as is” basis as it did not require the product to be prepared before being analyzed which could be difficult especially if there are no clear preparation instructions. In addition, there are also no standard procedures available for the preparation of the different cereal-based foods. Therefore, setting an ML for a product “as consumed” might lead to legal uncertainties and problems for the laboratories and law enforcement. On the contrary:
- “on a dry matter basis”: the “dry matter basis” would need adjustment of the data by correcting for the moisture content, and data available on GEMS/Food do not always report information on the moisture content of the samples.

78. It was also pointed out that it was important to be clear on how the data was analysed to determine whether to express the ML on a “dry matter basis” or “as is”.

#### Conclusion

79. CCCF agreed to consider this matter at the next session and that the EWG should consider the data and evaluate the possibilities for either expressing the ML on a “dry matter basis” or “as is”.

#### Recommendation (f): To establish an ML for lead in herbal tea specific for infant and young children or for lead in teas and herbal teas (solid, dried)

80. CCCF noted varying views expressed on this issue.

81. Delegations not supporting establishing ML for lead for herbal tea specific for infants and young children questioned whether an ML was justified due to the limited dataset; and noted information on international trade was unclear; and there was a lack of consumption data.

82. Delegations in favour of establishing an ML for lead in herbal teas for infants and young children, expressed the view that:

- Such products were traded internationally.
- It could contribute to reducing exposure of lead in infants and young children.
- If work were to proceed with an ML that it should be based on data for dried herbal teas.
- It would not be appropriate to set MLs for herbal teas and apply it to infants and young children and it was possible to achieve lower levels than the MLs proposed.
- It would not be appropriate to set MLs for herbal teas and apply it to infants but to rather set MLs for specifically for herbal teas for infants and young children because through careful sourcing of the raw material it was possible to reduce the concentrations of lead in these products which was important for reducing the exposure of the young consumer groups therefore it was possible to achieve lower levels than the MLs proposed.
- If an ML for herbal teas would be considered for infants and young children, then the data for the dried teas that are prepared by infusion or decoction should be considered apart from data for herbal teas that are sold as liquid.

83. It was also noted that herbal tea, depending on the types of herbs in the tea, may not be classified as a food product so the EWG should provide a definition and a scope of herbal tea meant for infants and children which the ML would apply to.

84. Views were also expressed to consider establishing an ML for teas and herbal teas not specifically for infants and young children, but that more data was needed for this.

#### Conclusion

85. CCCF agreed not to set an ML for lead in herbal teas specific for infants and young children at this time.

#### Other categories

##### *Sugars and sugar-based candies*

86. CCCF noted that for the MLs for white sugars that:

- It would be difficult to discuss the MLs for sugars since rejection rates up to and about 5% were not provided.
- Sugar was a major food commodity traded internationally and the proposed lower MLs were not appropriate and thus broader range of MLs should be presented with corresponding rejection rates.
- The proposed MLs were trade restrictive and more data should be requested on which to base the ML.

- If no new data was submitted, then rejection rates should be presented for higher levels to see what the most appropriate MLs would be.
- More transparency was needed on where the data originated from so that geographic representativeness could be assessed.
- Nomenclature should be aligned with the *Standard for Sugars* (CXS 212-1999).

87. Brazil expressed the view that the approach followed previously for the review of MLs for lead should be followed, if no new data was provided by producer countries the proposed ML should be approved as it showed a rejection rate of 1.1%.
88. CCCF did not consider the other commodities in this category as the approaches for the derivation of the MLs, the presentation of the MLs and their respective rejection rates were similar.
89. An observer noted that for sugar-based candies the ML should be based on data specific for this product.

#### Conclusion

90. CCCF agreed to postpone decision on MLs for a year to allow more time for submission of data to GEMS/Food for analysis by the EWG and that the EWG present data on a broader range of rejection rates, and thus a wider range of MLs. Producing countries were encouraged to submit data.

#### Food for infants and young children

##### *Fruit juices*

91. The US who led the previous work on revision of ML for lead in different food categories in GSCTFF clarified that the data for that review had included juices labelled for infants and young children.
92. The EU expressed support for a lower ML of 0.03 mg/kg which could be achieved with the global data set.
93. An observer noted that there were different MLs for fruit juices in the GSCTFF and one for fruit juices obtained exclusively from berries and other small fruits. When these levels were set, there were higher rejection rates for the fruit juices from berries. While there are steps to achieve lower levels, there were cost implications and therefore CCCF needed to be careful with establishing lower MLs.

#### Conclusion

94. CCCF agreed that the MLs for fruit juices in the GSCTFF would be extended to also cover juices for infants and young children; and noted the reservations of the EU and Norway to this decision.

##### *Ready-to-eat meals*

95. CCCF agreed to postpone decision on this category by one year to allow submission of additional data to support the establishment of an ML.

##### *Other foods*

96. CCCF confirmed that it was not feasible to set MLs for yoghurt, cheese and milk-based products as these products were complex mixtures.

#### General Conclusion

97. CCCF agreed:
- i) to extend the MLs for fruit juices in the GSCTFF to infants and young children and to advance this to CAC44 for adoption (Appendix II);
  - ii) to discontinue work on an ML for herbal teas for infants and young children, yoghurt, cheese and milk-based products at this time;
  - iii) to re-establish the EWG, chaired by Brazil, working in English to:
    - a. continue working on MLs for lead in dried spices and culinary herbs, including dried bulbs, rhizomes and roots; eggs; sugars and sugar-based candies, cereal-based products for infants and young children and ready-to-eat meals taking into account the written comments submitted, comments and decisions made at the session and new data from GEMS/Food; and to describe in more detail the data analysis and present a broader range of MLs and rejection rates;
    - b. to work in close collaboration with the EWG on data management.
  - iv) to request JECFA to issue a call for data to get more (geographically representative) data available to the EWG, with the aim to finalize the MLs next year.

98. CCCF encouraged all countries with an interest in the categories discussed to submit data on GEMS/Food and to actively participate in the EWG.

**REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF LEAD CONTAMINATION IN FOODS (CXS 56-2004) (Agenda Item 9)<sup>15</sup>**

99. The United States of America, as Chair of the EWG, introduced the item and indicated that the COP had been reviewed extensively over the past 2 years. The revised COP had been improved from the previous version by incorporating additional information on sources of lead and practices for reducing lead during agricultural production and food processing. Written comments submitted to this Session were of editorial nature for consistency with terminology used in Codex or to improve the clarity of the text and have been already incorporated in the COP to facilitate its consideration by the Committee.
100. CCCF noted general support for the final adoption of the COP with the additional revisions made by the EWG Chair as highlighted in CRD22.
101. CCCF also agreed that, besides diatomaceous earth and charcoal (activated carbon), CCCF further recommended CCFA to request JECFA to review bentonite given its importance for food processing.

**Conclusion**

102. CCCF agreed to:
- i) forward the revision of the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXS 56-2004) to CAC44 for adoption at Step 5/8; and
  - ii) recommend to CCFA to request JECFA to:
    - a. review the lead specifications for diatomaceous earth and charcoal (activated carbon) and
    - b. evaluate available data to support development of a lead specification for bentonite.

**MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (At Step 4) (Agenda Item 10a)<sup>16</sup>**

103. Brazil, as Chair of the EWG, introduced the item, and highlighted the key issues related to data management and the recommendations for MLs for the different categories of cereals and cereal-based foods.
104. CCCF noted that the data management issues (i.e. rejection rates, outliers, etc.) were similar to those discussed under Agenda Item 8 and that further discussion would be held on these issues under Agenda item 17.
105. CCCF proceeded to consider the recommendations as outlined.

**Discussion**

**Maize grain, destined for further processing**

**How should maize data be evaluated**

**Geographical representation of data**

106. More data should be requested to ensure better geographic representation and that an entry on country of origin should be included in the data submission template to better assess regional representation of the data.

**Outliers**

107. Data should be examined in more detail as regards outliers. As aflatoxins are very heterogeneously distributed in a lot, it was therefore important to consider whether the data are based on samples representative of the lot or whether they are samples from hotspots within a lot and so they can be considered as outliers.
108. If outliers do not affect the 95 percentile, there would be no need to exclude them for the consideration of the ML proposals.

**Year to year variations and geographical variations**

109. The year to year variations, due to climatic conditions, and regional variations should be further examined to assess their impact on the ability to meet the proposed ML / to come to a rejection rate acceptable for the different years and regions.

<sup>15</sup> CL 2021/14/OCS-CF; CX/CF 21/14/9; CX/CF 21/14/9-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, EU), Iraq, Japan, USA, Thailand and IUFOST)

<sup>16</sup> CX/CF 21/14/10-Part I; CX/CF 21/14/10-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, Iraq, Kazakhstan, Philippines, Thailand, Uganda, USA, Venezuela, ACF, IAEA, ISDI, MSF, UNICEF and WFP)

*Food aid / food security*

110. The current ML proposals could have a negative impact on food security and the ability to purchase and provide food aid to vulnerable populations. It was therefore important to consider higher MLs to ensure availability of food for food aid and that consideration be given to the possible impact on availability of food for food aid if lower MLs in the lower scenarios are established.

*Segregation of data: Maize destined for human consumption / animal feed*

111. There were divergent views on whether to set a single ML for maize grain for further processing (including all types of maize grains) or maize for direct consumption/ready-to-eat and whether the ML should be set on data exclusively from maize destined for human consumption or on the whole data set.
112. However, it was generally accepted that it would be difficult to segregate data for maize for human consumption from data for maize intended for animal feed, as its intended purpose was not always indicated on the lot. One delegation was of the view that higher rejection rates could be applied when considering data that does not differentiate between maize intended for food and feed.
113. Consideration should be given to establish an ML only for ready-to-eat maize based on the whole dataset. This was more suitable for human health protection especially in the Africa region where maize was a staple food and was traded as maize regardless of whether it would be going for further processing or was meant for direct human consumption. In this case, the ML for the whole category of maize should be 10 µg/kg in line with already existing standards in many African countries.
114. It would be useful to consider the impact of segregating the data or using the whole data set when proposing MLs/rejection rates for maize, as it was also important to limit aflatoxins in feed for livestock especially when there is a possibility for carry-over from feed to food (e.g. dairy cattle/milk). *The same consideration could also apply when considering other livestock situations where there is no carry over from feed to food (e.g. pig/meat) and so the impact of considering the full dataset when setting an ML for maize would be minimal.*
115. It would assist to issue another call for data that consider the points raised by delegations e.g. country of origin, whether the maize is destined for food or feed, etc. and to consult with the JECFA Secretariat on the possibility to segregate data, and if possible, to go back to the data submitters to get more details on the data uploaded onto GEMS/Food. If this would not be possible, the EWG may propose an ML based on the full data set for consideration by CCCF. Countries were encouraged to submit available data to GEMS/Food to ensure geographical distribution, if no data no new data were received, then the current data set would be used as the basis for the ML.
116. The JECFA secretariat explained that the optimal option would be to find a way to separate the data, so only data on aflatoxin in actual food commodities are used in the assessment. This would require a lot of double-checking by the data submitters and probably only help CCCF part of the way. There is, however, no way to ensure that what is intended for feed does not end up as food. One way forward for JECFA is to consider a couple of scenarios in a future assessment. One scenario is that only data on aflatoxin in clearly stated food commodities are used in the assessment. Another scenario could be that all data, also data which might refer to aflatoxin levels in commodities that might end up being used as feed are used in the assessment which then would give us a kind of upper bound.
117. Brazil indicated that further assessment of the existing and additional data would be possible but would require timely submission of the new data so that the EWG can give due consideration to the different scenarios suggested by delegations including wider ranges for MLs. Therefore, depending on how much data would be available, and when it would be available, it would be possible to have more rounds of consultation amongst the members of the EWG.

*Consideration of the MLs*

118. The following specific views were provided, ranging from:
- To support a higher ML of 20 µg/kg with a rejection rate of 4.5% or
  - To support a lower ML of 10 µg/kg for maize grain ready-to-eat / destined for direct human consumption or maize grain for further processing which would result in a similar rejection rate of 4.5% that currently apply to the proposed ML of 20 µg/kg for maize for further processing (CX/CF 21/14/10-Part I, Annex, Proposal 2).

*Conclusion*

119. CCCF agreed that the EWG would assess the data to:
- verify the outliers and whether they should be excluded or not;
  - analyse year to year and regional variations;
  - consider whether the ML would be set for maize for further processing or maize ready-to-eat; and
  - assess the impact of lower MLs on food aid/food security.

120. CCCF further agreed that the EWG should:

- try to gather more geographically representative data, including details on food and feed, request JECFA to issue a call for issue; and
- liaise with WHO JECFA Secretariat whether it would be possible to further segregate data available on GEMS/Food to differentiate between maize grain for food or feed.

*Other food categories: Flour, meal, semolina and flakes derived from maize; husked/polished rice; sorghum grain, destined for further processing; cereal-based food for infants and young children*

121. For the other categories for which MLs were proposed, CCCF noted that further work was needed by the EWG and noted general and specific views as follows:

*General comments*

122. There was general support for the categories other than maize grain but divergent views on the MLs that should apply to these categories.

123. In addition, the following was noted:

- How the considerations given for maize grain would impact on processed products e.g. geographical distribution of data, year to year variations, regional variation, treatment of outliers, etc.
- How processing could help to reduce aflatoxin contamination in processed products to allow lower MLs with acceptable rejection rates.
- MLs for processed products should be supported by data and information on the expected aflatoxin reductions due to processing.

*Specific comments*

124. Flour, meal, semolina and flakes derived from maize: wider ranges of MLs and rejection rates, up to and about 5% should be presented; and consideration should be given to processes that could reduce contamination in this category, including polished rice, similar to the considerations taken for DON in flour, meal, semolina and flakes derived from maize, and arsenic in rice, respectively.

125. For cereal-based food for infants and young children: data should be analyzed to determine if the ML should be set for the product “as is” or “on a dry matter basis”. A comment was made to set the ML on “as is” basis as the most straightforward method that would not require an adjustment of the moisture content in the products.

Conclusion

126. CCCF agreed that the EWG should further the work on these categories, with the aim to finalize the MLs at CCCF15, taking into account the comments made during this session. This would include presentation of a wider range of MLs and rejection rates, especially up to and about 5%, which would also apply to maize grain, and to include considerations on the effect of processing on the reduction of aflatoxins contamination.

*Methods*

127. CCCF noted while there were several internationally validated methods available that could be used for the MLs proposed and even for lower MLs, consideration should be given to ensure that the methods were widely available for use, that they could meet the LOQ and LOD when measuring each isomer in the sum of components, and should also include rapid field methods for rapid screening and routine use.

*JECFA dietary exposure assessment*

128. CCCF noted that there was no need for JECFA dietary exposure assessment at this point, in view of further work on the MLs and that such a request could be reconsidered at CCCF15.

General Conclusion

129. See Agenda Item 10(b).

**SAMPLING PLANS AND PERFORMANCE CRITERIA FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN (Agenda Item 10b)<sup>17</sup>**

130. Brazil introduced the item and referred to the recommendations concerning sampling plans and performance criteria for the establishment of MLs for total aflatoxins in these products.

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<sup>17</sup> CX/CF 21/1/4/10-Part II, CX/CF 21/14/10-Add.2 (Argentina, Cuba, Chile, Egypt, Iran, Kenya, Mexico, Republic of Korea, USA, AOCS and EUROCHEM)

## 131. CCCF confirmed:

- The need for sampling plans and agreed that they should be developed simultaneously as the MLs were developed to ensure that when the MLs were finalized, the corresponding sampling plans would be available to support these MLs.
- Consideration could be given to aligning with existing sampling plans in GSCTFF, but also to consider other approaches such as ISO 24333:2009.
- There was no need to request advice from CCMAS on establishment of performance criteria on “sum of components” at this time. The reply from CCMAS36 (2015) on the same question for fumonisins might be equally applicable to aflatoxins.

**General Conclusion: Agenda Items 10(a)/10(b)**

## 132. CCCF agreed:

- i) to re-establish the EWG, chaired by Brazil and co-chaired by India, working in English to:
  - a. continue working on MLs for total aflatoxins in maize grain; flour, meal, semolina and flakes derived from maize; husked and polished rice; sorghum grain destined for further processing; and cereal-based food for infants and young children, and associated sampling plans taking into account the written comments submitted, comments, conclusions and decisions made at the session and new data from GEMS/Food;
  - b. to work in close collaboration with the EWG on data management.
- ii) to request the JECFA Secretariat to issue a call for data on all the categories under discussion with a view to obtaining more geographical representative data and to include a request for country of origin and if possible to differentiate between maize for food or feed with the aim to finalize the MLs next year; and
- iii) if no data are submitted, the MLs would be finalized on the existing data set by the next session of CCCF.

## 133. CCCF urged all countries with an interest in the categories discussed to submit data onto GEMS/Food and to actively participate in the EWG.

**MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS AND ASSOCIATED SAMPLING PLAN (Agenda Item 11)<sup>18</sup>****MAXIMUM LEVELS FOR TOTAL AFLATOXINS AND OCHRATOXIN A IN NUTMEG, DRIED CHILI AND PAPRIKA, GINGER, PEPPER AND TURMERIC AND ASSOCIATED SAMPLING PLANS (Agenda Item 12)<sup>19</sup>**

## 134. The Codex Secretariat reminded CCCF that consideration of these items were suspended in 2018 to ensure implementation of the respective codes of practice for the prevention and reduction of aflatoxin contamination in peanuts and (CXC 55-2004) and mycotoxins in spices (CXC17-2017) and to resume discussion in 3 years' time to reconsider the MLs based on new / additional data submitted to GEMS/Foods. The Secretariat further recalled that the JECFA Secretariat would issue a call for data in 3 years' time to assist the work of the EWGs following their re-establishment by CCCF.

Ready-to-Eat Peanuts

## 135. Delegations emphasized the following:

- The importance of accelerating the finalization of the ML and sampling plan to ensure public health and fair practices in trade.
- The COP (CXC55) has been available for implementation by member countries for many years by now.
- The GEMS/Food should be the reference source of data to derive MLs for contaminants in Codex.
- The impact assessment conducted by JECFA83 should be taken into account when considering proposals for MLs for AFTs in ready-to-eat peanuts.
- The new dataset (data from 2018 onward) should be utilized in addition to the old dataset when considering proposals for MLs to enable identifying possible differences between the old and new ML proposals due to the implementation of the COP.
- The ML should be consistent with previous ML set for peanuts intended for further processing.

<sup>18</sup> REP18/CF, para. 115, Appendix VII; REP19/CF, paras. 16, 80; REP18/EXEC2-Rev.1, para.23;

<sup>19</sup> REP18/CF, para. 119, Appendix VIII; REP19/CF, para. 81



Certain spices: Nutmeg, dried chili and paprika, ginger, pepper and turmeric

136. Delegations generally supported to resume work on the establishment of MLs for nutmeg, dried chili and paprika, ginger, pepper and turmeric and associated sampling plans.
137. India expressed its willingness to continue chairing both EWGs.

**Conclusion**Ready-to-Eat Peanuts

138. CCCF agreed to:
- i) re-establish the EWG, chaired by India, working in English:
    - a. to consider new or additional data available on GEMS/Foods only and take into account old and new data for comparison;
    - b. to update the working paper that was last presented at CCCF12 (2018) (CX/CF 18/12/10); and
    - c. to prepare revised proposals for MLs for total aflatoxins in Ready-To-Eat Peanuts and associated sampling plan for comments and consideration by CCCF15 (2022), taking into consideration of the outcome of the impact assessment conducted by JECFA83 and the new and old datasets available on GEMS/Foods.
  - ii) request the JECFA Secretariat to issue a call for data to collect data for further consideration by the EWG.

Certain spices: Nutmeg, dried chili and paprika, ginger, pepper and turmeric

139. CCCF agreed to:
- i) re-establish the EWG, chaired by India, working in English:
    - a. to consider new or additional data available on GEMS/Foods;
    - b. to update the working paper that was last presented at CCCF12 (2018) (CX/CF 18/12/11);
    - c. to prepare revised proposals for MLs for total aflatoxins and ochratoxin A in spices: nutmeg, chili and paprika, ginger, pepper and turmeric, respectively, for comments and consideration by CCCF15 (2022) and associated sampling plans taking into account the new and old datasets available on GEMS/Foods.
  - ii) request the JECFA Secretariat to issue a call for data to collect data for further consideration by the EWG.

**METHYLMERCURY IN FISH (Agenda item 13)<sup>20</sup>**

140. New Zealand, as Chair of the EWG, introduced the item and provided key points in relation to the proposals for the establishment of MLs for methylmercury in additional fish species, sampling plans and the background to the work, summarized the process followed by the EWG, the conclusions and recommendations for consideration by CCCF.

Selection of species for ML setting

141. The EWG Chair explained the selection of species for ML setting was clear exceedance of the agreed selection criterion of 0.3 mg/kg methylmercury. He further explained that there were questions around a trade criterion to select species for ML setting. The EWG had discussed various options, but the majority view was to benchmark trade significance from species that currently have MLs and as a result, Marlin, which is the species with the lowest export volume out of the species, had been used as a reference species.
142. Setting group MLs for the different species was not supported by the EWG because of lack of or insufficient data for some of the species therein or because some of them were below the 0.3 mg/kg criterion e.g. an ML for all toothfish species grouping was not supported because there was no methylmercury data for Antarctic toothfish and also that the total mercury data was below the selection criteria for this species.
143. The three species (orange roughy, pink cusk eel and Patagonian toothfish) for which new work was proposed, had all met the selection criterion with or without consideration of trade, but that in order to proceed with developing the ML for Patagonian toothfish, more data would be needed to set a robust ML.
144. With the three species identified for ML setting and 48 taxonomic groups of fish in total reviewed (summarised in Appendix II of CX/CF 14/21/11), the review of MLs for any other additional fish species could be discontinued.

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<sup>20</sup> CX/CF 21/14/11

Sampling plans/literature review

145. The EWG Chair confirmed that there was a potential for large variation of methylmercury in fish and a lot, and this differed mainly along weight or length of fish. There was limited data on the variation of methylmercury between different tissues in an individual fish. Over one of the difficulties is then relating this back to the normal setting data sets that have been obtained from GEMS/Food because the sampling location was not generally reported in this. An initial proposal was to address these issues with species specific sampling parameters and appendices, but this approach was not favoured. Consequently, the proposed approach and format for a sampling plan is presented in Appendix IV of CX/CF 21/14/11 so that work can progress with an approach where the provisions for sampling are on different weight and value classes of the fish. This could be further refined through consideration of commercial weights for those species, for the MLs to ensure the correct weight classes, and also understanding from national sampling plans where sampling tissue is undertaken.
146. CCCF was informed that in identification of the literature around the above questions and consideration of the risk management measures, it was identified that there was not a consolidated source of advice on risk management measures for managing methylmercury in fish. It was therefore proposed to undertake a literature review to understand if there is sufficient literature available to develop such advice.

DiscussionConsideration of the MLs

147. There was general support to start new work for orange roughy and pink cusk eel, but in view of the lack of sufficient data for Patagonian toothfish, it was felt that further review was needed on the feasibility for setting an ML for this species.
148. An observer, while supporting the new work, expressed the view that when setting MLs for methylmercury, consideration should also be given to selenium content in fish as research which he had consulted had shown that selenium binds to mercury causing an increase in its toxicity.
149. The JECFA Secretariat announced that FAO/WHO would be convening another expert meeting to update the risk/benefit of fish consumption which has been done around 10 years ago, and would take into account the claims around selenium and if there were sufficient clinical evidence to support this, then it would be taken into account.

Trade criterion

150. On a question to clarify how to address a trade criterion to select species for ML setting, the Codex Secretariat clarified that there was no specific trade criterion defined on which to base ML setting and that CCCF should be guided overall by the dual mandate of Codex and more specifically by the rules/principles established by CCCF, especially in the Preamble to the GSCTFF.
151. She drew attention of the Committee to the dual mandate of Codex, viz. *“protecting the health of the consumers and ensuring fair practices in the food trade;”* and stated that normally CCCF fulfilled this mandate by setting MLs for contaminants of public health concern or importance for commodities that are moving in international trade.
152. She furthermore drew attention to the general principles for establishing MLs in the Preamble of the GSCTFF, specifically that:

*“MLs should be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.”*

*“Maximum levels shall be based on sound scientific principles leading to levels, which are acceptable worldwide, so that there is no unjustified barrier to international trade.”*

*“MLs shall only be set for food in which the contaminant may be found in amounts that are significant for the total exposure of the consumer, taking into consideration the Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Section IV of the Procedural Manual).”*

153. Noting the above, it was noted that the extent of trade was not touched upon, but rather whether there was a known or expected trade problem, and thus one could argue that not having harmonized MLs could lead to such a problem in trade. The role of Codex was to develop internationally agreed MLs informed by scientific risk assessment and having the least impact on trade. To ensure no unjustified barrier to international trade, and having no negative impact on food security, CCCF established MLs based on ALARA with a reasonable rejection rate.

154. She also noted that while there were trade criteria in the "*Criteria for the establishment of work priorities (criteria applicable for commodities)*" which touched on volume of production and consumption in individual countries and volume and pattern of trade between countries, it was understood that that this was applicable to new work proposals for commodity standards which were normally quality related, rather than safety standards. These criteria were also not applicable to horizontal standards and such criteria were never developed as was noted in a paper prepared by the Secretariat in the review of the Critical Review<sup>21</sup>.
155. Thus guided by the Preamble of GSCTFF, it would appear that there was no basis to weigh the amount of trade / trade significance in the setting of MLs. It was also questionable if it would be feasible to define a trade criterion (such as looking at trade volumes or value) as it would not necessarily be the case that if a commodity is traded in lower volumes, that there wouldn't be public health concern where a commodity is highly consumed. In addition, lower volumes could still have large economic relevance.
156. In the case of safety standards, and when looking at the dual mandate of Codex, consumer health protection would in many ways "have greater importance than" the issue of trade. When taking risk management decisions, CCCF would need to ensure that such measures have the least trade disruptive effect while guaranteeing that public health is not unduly affected. Such efforts can be assisted at times if an assessment of the impact of a hypothetical MLs on dietary exposure is requested as needed from JECFA.

#### Conclusion

157. CCCF agreed to start new work on MLs for methylmercury in orange roughy and pink cusk eel and to amend the project document accordingly.

#### Sampling plans

158. CCCF noted the support for further work on the sampling plan following the approach proposed in Appendix III of CX/CF 21/14/11 and that further work should ensure the practicality of the sampling plan.

#### Literature review on risk management measures

159. There was general support for undertaking a literature review to identify the feasibility of developing guidance for the management of methylmercury levels in fish. The EWG Chair clarified that the literature review aimed to identify practical measures for the management of methylmercury in fish (e.g. at the catch, sorting and processing level).

#### General Conclusion

160. CCCCFF agreed to:
- i) to submit the project document for new work on MLs for methylmercury in orange roughy and pink cusk eel (Appendix XX) to CAC44 for approval;
  - ii) to discontinue the review of MLs for any other additional species;
  - iii) establish an EWG chaired by New Zealand, and co-chaired by Canada, working in English to:
    - a. develop MLs for orange rough and pink cusk eel;
    - b. consider further data to establish the feasibility of setting an ML for Patagonian toothfish;
    - c. develop the sampling plan; and
    - d. conduct a literature review to assess the feasibility of developing guidance for the management of methylmercury in fish.
  - iv) request the JECFA Secretariat to issue a call for data specific for Patagonian toothfish.

### **HYDROCYANIC ACID AND MYCOTOXINS CONTAMINATION IN CASSAVA AND CASSAVA-BASED PRODUCTS (Agenda Item 14)<sup>22</sup>**

#### Mycotoxins in cassava and cassava-based products

161. Nigeria, as Chair of the EWG, introduced this item, and highlighted that, based on the replies to CL 2019/74-CF and CL 2020/51-CF, as well as data and information provided by members of the EWG, it was possible to identify risk mitigation measures available to date that have proven to be cost-effective and applicable worldwide by large, medium and small-scale farmers and producers. The replies also provided the scope of the COP as to the relevant mycotoxins (i.e. aflatoxins and ochratoxin A) and the stages of the production chain to be covered by the COP (i.e. pre-planting, planting, post-harvest processing including fermentation, drying, storing and distribution). The EWG Chair further informed CCCF that based on these facts, there was general support for the development of a Code of practice to prevent and reduce mycotoxins contamination in these products as presented in the Appendix I to CX/CF 21/14/12.

<sup>21</sup> CX/EXEC 20/78/4

<sup>22</sup> CX/CF 21/14/12

162. CCCF agreed with the development of the COP and to include a few amendments in the project document to improve clarity as proposed in CRD03.

### **Conclusion**

163. CCCF agreed:
- i) to submit the project document on the development of a Code of practice for the prevention and reduction of mycotoxins contamination in cassava and cassava-based products to CAC44 for approval as new work (Appendix VI); and
  - ii) to establish an EWG, chaired by Nigeria and co-chaired by Ghana, working in English, to work on the development of a Code of Practice for the prevention and reduction of mycotoxins contamination in cassava and cassava-based products, with focus on aflatoxins and OTA, and the stages of production as identified in the project document, based on the data and information provided in Appendix II to CX/CF 21/14/12; and

### **Hydrocyanic cyanide (HCN) in cassava and cassava-based products**

164. Nigeria, as Chair of the EWG, further stated that data and information on hydrocyanic acid (HCN) in cassava and cassava-based products as reported in Appendix III to CX/CF 21/14/12 indicated that it would be advisable to await new/additional data/information to become available in future, especially from ongoing studies in this field, to re-assess the need and feasibility to establish MLs for these products.
165. CCCF concurred with this recommendation and recalled that the MLs for HCN in gari and cassava flour as contained in the GSCTFF remain unchanged.

### **Conclusion**

166. CCCF agreed to discontinue the discussion on the establishment of HCN in cassava/cassava-based products and to await new/additional data to become available in the future, especially from ongoing studies in this field, to reassess the need and feasibility to establish new MLs for HCN in cassava and cassava-based products.

### **CADMIUM AND LEAD IN QUINOA (Agenda Item 15)<sup>23</sup>**

167. The JECFA Secretariat presented the paper, focusing on the analysis undertaken, the key findings and recommendations.
168. CCCF first considered whether it was necessary to establish MLs for cadmium and lead in quinoa, followed by a discussion on whether to extend the MLs for these contaminants in cereal grains to quinoa as presented in GSCTFF or whether separate MLs for cadmium and lead in quinoa should be established.
169. While there was wide support for the establishment of MLs for cadmium and lead in quinoa, there were however divergent views on whether to extend the MLs for cereal grains in GSCTFF to quinoa or to develop separate MLs.
170. Delegations in favour of extending the MLs for cereal grains to quinoa pointed out that MLs were urgently needed in view of the growing trade and consumption of quinoa.
171. Delegations in favour of separate MLs pointed out that:
- Quinoa is a pseudocereal and the conditions for growing were different from other cereals and therefore the establishment of MLs for quinoa should be based on quinoa-specific data.
  - It was not possible to extrapolate the MLs for cereals to quinoa due to differences in uptake for example of cadmium, which depends on the cultivar and the soil.
  - The data set used for the JECFA Secretariat analysis was very limited and further data were needed which should be more geographically representative. That data generation was ongoing in certain countries and could be submitted to GEMS/Foods to support establishment of MLs specific for quinoa.
172. Other delegations questioned the appropriateness to establish MLs at this time, as:
- There was no basis for MLs from a public health perspective since the analysis by the JECFA Secretariat showed that the extension of the current MLs for cadmium and lead in cereals to quinoa in CXS193 or the establishment of separate MLs at the levels proposed in the analysis, i.e. 0.1 or 0.2 mg/kg for cadmium and 0.1 or 0.2 mg/kg for lead, would have little impact on exposure from these contaminants for the general population.
  - Setting such MLs would have cost and trade implications without any further benefit to public health.

<sup>23</sup> CX/CF 21/14/13; CX/CF 21/14/13-Add.1 (Australia, Canada, Chile, Cuba, Ecuador, Egypt, EU, Iraq, Japan, USA and IAEA)

- No information had been provided that MLs were needed for trade harmonization. However, if CCCF were to proceed with the setting of MLs, that it should be clear that that would not be on the basis of public health protection.

173. Noting the diverse views expressed on whether or not to establish MLs, and if MLs were to be established, whether to extend the MLs for cadmium and lead in cereals to quinoa in CXS193 or whether to have separate MLs for quinoa, the limited data available, the need to consider the different cultivars and growing conditions, and ongoing work on data generation, the Chair proposed to postpone the discussion on MLs for cadmium and lead in quinoa for 3 years to allow data generation and submission to GEMS/Foods. CCCF supported this proposal.

#### **Conclusion**

174. CCCF agreed:

- to request the JECFA Secretariat to issue a call for data cadmium and lead in quinoa and quinoa-based products, including foods for infants and young children, in 2-years' time;
- that call for data should include a request for data on occurrence of lead and cadmium, and in addition consumption data, and country of origin should be indicated in the remarks field in order to help assess the geographic representativeness of the data; and
- the JECFA Secretariat would prepare an analysis of the new data and prepare a paper for consideration by CCCF17.

#### **RADIOACTIVITY IN FEED AND FOOD (INCLUDING DRINKING WATER) IN NORMAL CIRCUMSTANCES (Agenda Item 16)<sup>24</sup>**

175. The European Union, as Chair of the EWG, introduced the item and recalled that, following information provided by the Representative of the Joint FAO/IAEA Division, CCCF13 had agreed that explorative work should be undertaken on food safety and trade issues associated with radionuclides in food (including drinking water) and feed in non-emergency situations. An Electronic Working Group, chaired by EU, and co-chaired by Japan was established to produce a discussion paper to increase the understanding of the presence of radioactivity in food and feed in non-emergency situations and to enable CCCF to take an informed decision on possible follow-up actions at this session.
176. The EWG Chair indicated that in the EWG comments were made as regards the need to have a stronger case made to CCCF to work further on this issue, to clarify the relation between the work to be possibly undertaken by CCCF and work already and planned to be undertaken by FAO, IAEA, WHO and UNSCEAR, and to clarify the terms used and to ensure consistent use of these terms. The discussion paper as presented in the Appendix I of CX/CF 21/14/14 takes into account these comments.
177. The EWG Chair further noted that in the discussion paper it is concluded that naturally occurring radionuclides (i.e. mainly <sup>40</sup>K, <sup>210</sup>Po, <sup>210</sup>Pb, <sup>228</sup>Ra and <sup>226</sup>Ra) are found in many different foods and tend to give radiation doses higher than those provided by artificially produced radionuclides (such as <sup>134</sup>Cs, <sup>137</sup>Cs, <sup>131</sup>I and <sup>90</sup>Sr) in situations not affected by a nuclear emergency situation in the past, but no specific safety problem for food, feed or drinking water due to the presence of naturally occurring radionuclides had been identified. Furthermore no international trade issues had been identified due to the presence of naturally occurring radionuclides in food, feed and drinking water.

#### **Discussion**

178. Following comments, the Representative of the Joint FAO/IAEA Centre clarified that the informative document would be presented to CCCF before publication. The EWG Chair further clarified that the informative document would focus on naturally occurring radionuclides, shall inform on regional variations in presence of naturally occurring radionuclides in food (including drinking water) and feed, uptake variations depending on the type of food, and that the regular update on any development in the field of radioactivity will relate to naturally occurring and artificially produced radionuclides.

#### **Conclusion**

179. CCCF agreed:

- that no further work is required to be done by CCCF at this time given that naturally occurring radionuclides in food, feed and water do not seem to be an issue for food safety and trade;
- to welcome the offer of IAEA to elaborate with the collaboration of FAO and WHO an informative document for the food safety regulators community, providing the state of the art of natural radioactivity in food/feed/water, thereby also reflecting regional variations; and

- iii) to request IAEA to be kept informed of any development in the field of naturally occurring and artificially produced radioactivity, in particular on the FAO/IAEA/WHO work to develop methodologies that can be used to produce criteria with which to assess radionuclides in food.

**GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION (Agenda item 17)<sup>25</sup>**

- 180. The European Union introduced the report of the Chair of the EWG and recalled that CCCF12 (2018) considered the proposal of the JECFA Secretariat to develop a general guidance on data analysis for ML development that would help EWGs to take consistent approaches for data analysis. CCCF18 agreed to establish an EWG chaired by EU, co-chaired by Japan, the Netherlands and USA to prepare a discussion paper. In 2019, the EWG Chair informed CCCF13 that it had not been possible to prepare discussion paper in time for consideration by the established EWG and instead, the EWG Chair prepared a paper containing a non-exhaustive list of topics for consideration by CCCF and it was agreed to extend the scope of the work to address improved data collection and agreed to re-established the EWG chaired by EU, co-chaired by Japan, the Netherlands and USA, to further develop the discussion paper based on the discussion at that session.
- 181. At the present session, CCCF was informed that the discussion paper in the Annex to CX/CF 21/14/15 was prepared by the EWG Chair and that due to the very late availability of the paper, no consultation with the Co-Chairs and EWG members had taken place.

Discussion

- 182. The discussion paper was presented with more details provided on application of rejection rates, identification and handling of outliers (extreme values) and presentation of data in EWG reports to CCCF.
- 183. CCCF was invited to provide views on the appropriateness of the identified topics and other possible topics for inclusion in a guidance for data analysis for ML development and improved data collection, and in particular on the suggestion to include discussion on elements to take into account when determining an appropriate rejection rate .

General comments

- 184. The general view was that the appropriate rejection rate, deviating from the 5% rejection rate which is regularly used as reference, is to be determined on a case by case. A possible guidance should only provide elements for consideration with sufficient flexibility for the choice of the rejection rate when setting MLs in CCCF.
- 185. There was general support to the topics identified in the discussion paper. Several delegations indicated that the guidance should focus first on data submission (collection), data analysis and data presentation as this had priority and were not in favour of including discussion on elements for choosing appropriate rejection rates while others indicated that such guidance would be helpful.
- 186. As regards the issue of identification and handling of outliers, the JECFA Secretariat expressed their support to the work of the EWG and indicated that they could provide information on how outliers and extreme values, as well as other issues of data analysis as indicated in the paper, are handled by JECFA when evaluating available occurrence data for exposure assessments. It was welcomed that JECFA would supply such information to the EWG.

Additional comments

- 187. The following additional topics/issues were raised during the exchange of views:

*Reporting LOQs*

- 188. The importance of reporting the LOQ and to provide guidance on how to report levels of contaminants which are a sum of compounds and of which certain compounds are not quantified (lowerbound versus upperbound).

*Reporting occurrence data on GEMS/Food*

- 189. The important elements to be provided when reporting occurrence data should be specified in the call for data for submission to the GEMS/Food database.
- 190. The EWG Chair indicated that data can be submitted to the GEMS/food database not only in response of a specific call for data and therefore general guidance on what information is important to be provided when submitting occurrence data to GEMS/Food database was appropriate.

*Availability of data on GEMS/Food*

*Handling of data not submitted to GEMS/Food*

- 191. The handling of data not submitted to GEMS/Food database and consider the obligation that data must be submitted to GEMS/Food database for consideration in data analysis.

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<sup>25</sup> CX/CF 21/14/15

192. For the data analysis of large datasets, it is important that all relevant information is provided in specific fields (for sorting / filtering of data) and not in the “comment field”.
193. In addition, guidance on how the EWG should deal with specific situations would be appropriate, e.g. no data available in GEMS/Food database, or if additional information on origin or purpose of food was not provided..

*Data from imports*

194. Data from imports are biased as they have to comply with specifications of the importing country and are not necessarily representative for the presence of a contaminant in a certain commodity. Therefore, consideration should be given to exclude such data sets from the data analysis.

*FAO/WHO inputs into the guidance*

195. The importance of input of FAO, WHO and GEMS/Food database managers into this guidance.

*Step-wise approach to the development of the guidance*

196. Given the extensive scope of the document, consideration could be given to break down the work and to determine topics for discussions in a first phase, with the understanding that the other topics will be discussed at a later stage.

*Handling of outliers*

197. The importance of guidance on how to identify and deal with outliers.

*Availability of calls for data in all UN languages*

198. The need to have calls for data into all UN languages to ensure better participation of non-English speaking countries into the data submission.
199. In order to facilitate the participation of certain countries in the work of the EWG, the importance to be able to work in other languages than English was highlighted. The EWG Chair noted that this was not feasible in view of the extensive work ahead and the commitment to present the outcome of the discussions of the EWG at CCCF15 but indicated that comments could be submitted in French and Spanish in the EWG, but that the working document (i.e. the guidance) will be presented in English only.
200. The Codex Secretariat informed that all Codex documents, in particular circular letters, are available in English, French and Spanish.
201. The JECFA Secretariat indicated that they would consider to provide calls for data and other JECFA documents in UN languages other than English but stressed that this would require additional resources which are not currently available, and as such, would require consultation on a case by case basis. The Secretariat encouraged Codex members to consider administer extra-budgetary resources to JECFA to cover the expenses for providing calls for data and other JECFA documents in UN languages other than English.

**Conclusion**

202. CCCF agreed:
- i) that the work should be focused on data collection, data analysis and data presentation as a priority in the coming year and that discussion on elements for consideration of appropriate rejection rates would not be taken up for now;
  - ii) that a circular letter will be issued requesting Codex members and observers to submit comments on the topics identified in the Annex to CX/CF 21/14/15, for consideration by the EWG in addition to the comments made at this session; and
  - iii) to re-establish the EWG chaired by EU, co-chaired by Japan, the Netherlands and USA, working in English only, to prepare guidance on data analysis for development of MLs and for improved data collection based on the comments provided at this session and those in reply to the circular letter.
203. The Chair urged the EWG Chair to start work within the EWG without any further delays and to regularly report on its progress to the Codex Secretariat and the Chair of CCCF to ensure a timely completion of the guidance for discussion at CCCF15, given the importance of this work for future discussions on MLs within CCCF.
204. The Chair encouraged Codex members and observers to actively participate in this EWG. She also reiterated that the EWG Chairs dealing with MLs, i.e. Ecuador, Brazil, India and New Zealand, should work in close collaboration with the EWG on data analysis in order to take into account, to the extent possible, the outcomes of the discussions in this EWG when proposing MLs for consideration at CCCF15.

## **APPROACH TO IDENTIFY THE NEED FOR REVISION OF STANDARDS AND RELATED TEXTS DEVELOPED BY CCCF (Agenda Item 18)<sup>26</sup>**

205. Canada, as Chair of the EWG, introduced this item, reminding that there was no structured approach to review existing standards and related texts for contaminants in food and feed including maximum levels (MLs), guideline levels (GLs) and codes of practice (COP) to determine the need for their revision. The EWG had been tasked to propose a practical approach to identify the need for revision of existing standards and related texts developed by CCCF for consideration at this session.
206. Three options had been proposed by the EWG as described in paragraph 2 of CX/CF 21/14/16. A circular letter CL 2020/53-CF had been issued recommending consideration of the available options for a 3 year trial period and based on the broad support for Option 2 the EWG was presenting a systematic approach for how CCCF would implement and operationalize this option on a 3-year trial bases:
207. The EWG Chair clarified that this option would be provide flexibility and be place the least administrative burden on CCCF. Furthermore, she emphasized that this structured approach would not preclude the continued ad hoc review of existing Codex standards and related texts upon nomination by a Codex member and consistent with the guidance provided in the Preamble to the GSCTFF and the Procedural Manual.
208. The EWG Chair also informed that proposed prioritization criteria for identifying standards and related texts for review had been developed which took into account both potential human health impact and possible trade disruptions.

### Discussion

209. CCCF expressed general support to implement Option 2 on a 3-year trial basis as outlined in paragraph 9 – 13 of CX/CF 21/14/16.
210. A view was expressed that in a case that ML was established for a certain contaminant due to health concerns, the ML should not be increased by the review, unless i) there was a trade disruption caused by a change of the Codex Classification of Food and Feed or commodity standard (and consequently additional commodities are covered by the ML for which no occurrence data were assessed for the establishment of the ML); and/or ii) if a better description of the commodity covered by the ML could mitigate to a certain extent the observed trade disruptions (e.g. by adding “intended for further processing” or by specifying the portion of the commodity /product to which the ML applies)
211. The EWG Chair clarified that the prioritization criteria were flexible and based on the result of 3-year trial further consideration could be given to the criteria.

### Conclusion

212. CCCF agreed:
  - i) to agree to implement the pilot on the review of Codex standards for contaminants in food and feed (Option 2) on a three-year basis as outlined in paragraphs 9-13 of CX/CF 21/14/16 using the prioritization criteria as presented in Appendix I of CX/CF 21/14/16;
  - ii) to request the Codex Secretariat to circulate the tracking lists for comments, in the form of a circular letter, in advance of CCCF15 (2022) based on input provided by Canada;
  - iii) to consider the comments in reply to the CL in an in-session WG to be established at CCCF15 (2022), chaired by Canada, in order to make recommendations to CCCF on the need to revise Codex standards and related texts for contaminants in food and feed; and
  - iv) to note that the pilot (Option 2) could be evaluated as outlined in paragraphs 14-16 of CX/CF 21/14/16 to further improve the procedures for review on a needed basis.

## **FORWARD WORK-PLAN FOR CCCF (Agenda Item 19)<sup>27</sup>**

### Review of contaminant/staple food combinations for future work of CCCF

213. The Host Country Secretariat introduced the item and noted that the paper was developed in collaboration with the Codex and JECFA Secretariats. Referring to CX/21/14/17, and noting that the paper had been issued just prior to the session, she explained that it would be circulated for comments and thus was being presented at this session for information only.

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<sup>26</sup> CX/CF 21/14/16;

<sup>27</sup> CX/CF 21/14/17



214. She recalled the intent of the forward plan, which was to identify areas for food contaminants of public health and trade concern in staple foods moving in international which might need to be addressed by CCCF in future. She recalled that this paper was developed as a result of the discussion on the forward plan at CCCF13, that it was agreed to focus on staple foods as contamination in these foods could have a significant impact on exposure and thus a health risk to populations, and that the intent of the document was to provide an approach/methodology (screening method) so that a list of contaminant/staple food combinations could be identified for further follow-up by CCCF.
215. The approach was illustrated by three examples, which could be expanded if there was agreement on the approach presented. The choice to take up work from the list of interest that would be developed should take account of the workload of CCCF and form part of a prioritization process for CCCF together with, the follow-up to JECFA/FAO/WHO evaluations/expert meetings, the review of existing standards for contaminants in food and feed and possible other proposed new work.
216. She further explained that if there was agreement on this approach, based on comments received to the CL, the approach/methodology could be further refined, such as refining the list of staple foods which had now a varying level of detail, and identifying further contaminant/staple food combinations beyond the three examples of staple foods. The intent was that, once the framework is finalized and agreed by CCCF, a mechanism for taking the work further could be identified by CCCF15, e.g. for an EWG to take the work forward.

### **Conclusion**

217. CCCF agreed that:
- i) the Codex Secretariat would issue a CL requesting comments on the approach/methodology proposed; and
  - ii) the Host Country Secretariat, JECFA and Codex Secretariats will consider the comments received and further develop the paper for consideration by CCCF15.

### **Project plan for the evaluation of implementation of COPs of CCCF**

218. The Codex Secretariat introduced the item, and recalled that at CCCF13, the Host Country Secretariat introduced a proposal on developing a pilot project to evaluate the implementation of COPs in the context of the forward workplan discussion. CCCF13 had agreed with the approach to launch a pilot project and that a more detailed proposal would be prepared and presented to this session.
219. She however reported that a more detailed proposal had not been prepared in light of ongoing discussions among the Host Country Secretariat, FAO, WHO and the Codex secretariat on how to approach the pilot. The project fell within the purview of FAO and WHO in terms of its technical assistance programmes and also with the Codex Secretariat especially in light of the ongoing discussion on the monitoring of use of standards in Codex as one of the objectives of the Codex Strategic Plan 2020-2025.
220. In view of the above, the Codex Secretariat, in consultation with FAO and WHO, and also with the Host Country Secretariat, will continue looking at ways of taking this project forward in the context of monitoring the use of Codex standards and will keep CCCF informed on progress.
221. The Representative of FAO informed CCCF that FAO continued to be available to provide technical assistance and capacity building on a needs basis.

### **Conclusion**

222. CCCF agreed with the recommendation of the Codex Secretariat as stated in paragraph 220.

### **JECFA EVALUATIONS (Agenda Item 20)<sup>28</sup>**

#### **Priority list of contaminants for evaluation by JECFA**

223. The Codex Secretariat recalled that due to the virtual nature of CCCF14, the usual in-session of the Working Group on Priorities chaired by USA could not be held and instead, the Codex Secretariat prepared a working document CX/CF 21/14/18 to update the priority list as shown in the Annex to this document, based on the outcomes of the JECFA evaluations on ergot alkaloids (removed) and trichothecenes (T2 and HT2) (add information related to the status of the JECFA evaluation), the issues raised under Agenda Item 2 on scopoletin, and the replies to CL 2020/24-CF by which no new compounds had been added and only an additional note were made in relation to data availability on arsenic.

<sup>28</sup> CL 2020/24-CF; CX/CF 21/14/18; CX/CF 21/14/18-Add.1 (Canada, Chile and Ecuador); CX/CF 21/14/2-Add.1; CX/CF 21/14/3

224. With regard to scopoletin, the Codex Secretariat recalled that this compound had been included in the priority list at the request of CCNASWP13 (2014) and retained in the list at the request of CCNASWP14 (2016) and CCNASWP15 (2019). She drew attention to a consultant's report on the findings of the toxicological data review available in the Annex of CX/CF 21/14/2-Add.1 which was not for discussion by CCCF but for consideration by CCNASWP16 (2022). The Secretariat proposed to keep scopoletin in the priority list awaiting feedback from CCNASWP16 on whether countries from the south-west Pacific region could provide the data and studies required to support the evaluation of scopoletin by JECFA and their subsequent consideration by CCCF. She further advised that Codex members and observers interested in noni products/scopoletin, besides those from the south-west Pacific region, were encouraged to generate/provide relevant data/information to GEMS/Food to enable the evaluation of scopoletin by JECFA and their subsequent consideration by the Committee. CCCF concurred with these recommendations.

### **Conclusion**

225. CCCF agreed to:

- i) endorse the priority list as amended (Appendix VIII);
- ii) keep scopoletin in the priority list awaiting feedback from CCNASWP16 on the necessary data and studies to perform evaluation of scopoletin and to encourage Codex members to generate and submit data to GEMS/Food;
- iii) continue to request comments and/or information on the priority list for consideration by CCCF15; and
- iv) re-convene the in-session WG at CCCF15 chaired by USA.

### **Follow-up work to the outcomes of JECFA evaluations and FAO/WHO expert consultations**

226. The Codex Secretariat further recalled that due to the virtual nature of CCCF14, the in-session Working Group on the Follow-Up to JECFA Evaluations and FAO/WHO Expert Consultations led by EU could not be held and that instead, the Secretariat prepare a working document CX/CF 21/14/18 highlighting the recently concluded JECFA evaluations and FAO/WHO expert consultations relevant to the work of CCCF.
227. The European Union provided further information on the compounds listed in CX/CF 21/14/18 as follows:
- *Pyrrolizidine alkaloids*: JECFA80 (2015) had evaluated PAs on request of CCCF05 (2011), and CCCF10 (2016) agreed to discuss PAs once the full JECFA evaluation became available. He drew attention to the key outcomes of the JECFA evaluation and noted that now that the report had been published CCCF should consider follow-up actions which could include possible revisions to the *Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed* (CXC 74-2014) or consider the feasibility of other risk management measures (i.e. MLs).
  - *Ciguatera Poisoning*: The report of the FAO/WHO Expert Meeting on Ciguatera Fish Poisoning (2018) was published in 2020. He noted that the expert meeting was convened at the request of CCCF11 (2017) to request scientific advice from FAO and WHO to allow CCCF to develop appropriate risk management options to address this matter. The Expert Meeting concluded that there are many gaps in the available information about ciguatera poisoning, and there were some needs that require urgent attention regarding both risk management and research and drew attention to the FAO/IAEA/IOC-UNESCO initiatives as highlighted in CX/CF 21/14/3.
  - *Trichothecenes*: JECFA90 (2020) updated the risk assessment including an exposure assessment on T-2 and HT-2, at the request of CCCF11 (2017). The full evaluation was not yet complete and was still on the priority list for JECFA evaluations, thus follow-up actions could be considered once the full evaluation became available.
  - *Ergot alkaloids*: JECFA91 (2021) evaluated ergot alkaloids at the request of CCCF13 (2019). JECFA91 noted that some exposure estimates exceeded the group health-based guidance (HBGV) established for ergot alkaloids, and that this may indicate a human health concern. However, the full JECFA evaluation was not yet available, and proposed that follow-up actions be considered once the full evaluation became available.
  - *(-) scopolamine and (±) hyoscyamine (tropane alkaloids)*: The FAO/WHO Expert Meeting (2020) was convened to respond to a request for scientific advice from the World Food Program (WFP) after poisoning incidents from the distributed food aids. The Expert Meeting had proposed operational limits that should be health protective for adults and children for WFP products, but that these limits could be extended also to other cereals and grain products when consumed in comparable quantities.

*Edible insects*

228. The Codex Secretariat recalled that this issue was brought to the attention of the Committee under Agenda Item 3 and referred for consideration under this Agenda Item. The Secretariat noted that there was an interest from Codex members to consider work in CCCF on edible insects. However, this was a cross-cutting issue that might need action in other committees in Codex, such as CCFH and CCRVDF. Therefore, it would not be advisable to consider this issue in isolation in each committee. The Secretariat therefore proposed that guidance should be sought from CCEXEC on how best to proceed in a more cohesive way on risk management measures to ensure safety of edible insects. She further noted that edible insects could be considered as an emerging food safety issue where Codex should give a timely response in line with Goal 1 of the Codex Strategic Plan 2020-2025. CCCF concurred with this recommendation.

**Conclusion**

229. CCCF agreed to:
- i) establish an EWG chaired by EU, working in English, to prepare a discussion paper on pyrrolizidine alkaloids to look into the feasibility of possible follow-up actions for consideration by CCCF15;
  - ii) issue a circular letter requesting comments on possible follow-up actions to the outcomes of the JECFA evaluations and FAO/WHO expert consultations in particular those for which the full report was already available, such as ciguatera poisoning and tropane alkaloids, for consideration by the in-session WG to be convened at CCCF15;
  - iii) re-convene the in-session WG at CCCF15 chaired by EU; and
  - iv) to request guidance from CCEXEC on the best approach to address the safety of edible insects in Codex.

**OTHER BUSINESS AND FUTURE WORK (Agenda Item 21)**

230. CCCF noted that no other business had been proposed.

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 22)**

231. CCCF was informed that CCCF15 was scheduled to be held in approximately one year's time, the final arrangement subject to confirmation by the Host Country and the Codex Secretariats.

## LIST OF CRDs

CRD No.	Agenda Item	Submitted by
01	Division of Competence	EU (Division of Competence between EU and its Member States)
02	5, 6, 7, 8, 9, 10(a), 11, 12, 13, 14, 18, 20	Tanzania
03	2, 5, 7, 10(a), 10(b), 11, 12, 13, 14, 18	EU
04	2, 7, 9, 14, 15	Nigeria
05	5, 11	International Confectionery Association
06	5, 6, 7, 8, 10(a), 10(b), 13, 14	Uganda
07	13	Japan
08	7, 8, 10(b), 13, 14, 15	Thailand
09	2, 8, 10(a), 14, 15	India
10	5, 6, 7, 8, 9, 10(a), 10(b), 13, 14, 15, 18	Republic of Korea
11	2, 11, 12, 13, 14, 16, 18, 19, 20	United States of America
12	2, 7, 8, 9, 14	Indonesia
13	5, 6, 7, 8, 9	Dominican Republic
14	5, 6, 10(a)	El Salvador
15	2, 5, 6, 7, 8, 9, 10(a), 10(b), 11, 12, 13, 18, 20	African Union (AU)
16	5, 6, 7, 8, 9, 10(a), 10(b), 11, 13, 14	Senegal
17	8	China
18	6, 7, 8, 9, 10(a), 15	Ecuador
19	8	Turkey
20	8, 9, 10(a), 10(b), 15	Mali
21	10(a)	WFP