CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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REP17/CF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

40th Session

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REPORT OF THE 11th SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Rio de Janeiro, Brazil
3 - 7 April 2017

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SUMMARY AND STATUS OF WORK

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LIST OF ABBREVIATIONS

AECOSAN	Spanish food safety agency
AFB_1	Aflatoxin B_1
AFT	Total aflatoxins
ALARA	As Low As Reasonable Achievable
ARfD	Acute reference dose
AU	African Union
BTX	Brevetoxin
CAC	Codex Alimentarius Commission
CCAFRICA	FAO/WHO Coordinating Committee for Africa
CCCF	Committee on Contaminants in Foods
CCEXEC	Executive Committee
CCFFP	Committee on Fish and Fishery Products
CCFH	Committee on Food Hygiene
CCNMW	Committee on Natural Mineral Waters
CFP	Ciguatera fish poisoning
CL	Circular Letter
COP	Code of Practice
CRD	Conference Room Document
CTX	Ciguatoxin
DA	Domoic acid
DAS	4,15-1 Diacetoxyscirpenol
ECA	European Cocoa Association
EFSA	European Food Safety Authority
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organisation
GAP	Good agricultural practice
GDWQ	Guidelines for Drinking Water Quality
GEMS/Food	Global Environment Monitoring System
GSCTFF	General Standard for Contaminants and Toxins in Food and Feed
HCN	Hydrocyanic acid
IAEA	International Atomic Energy Agency
ICA	International Confectionary Association
ICBWA	International Council of Bottled Water Associations
ICGMA	International Council of Grocery Manufacturers Associations
IFU	International Fruit and Vegetable Juice Association
JECFA	Joint FAO/WHO Expert Committee on Food Additives
3-MCPD	3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol
ML	Maximum Level
NDL PCBs	Non-dioxin-like PCBs
NEA	Nuclear Energy Agency
OECD	Organization for Economic Cooperation and Development
OTA	Ochratoxin A
PAs	Pyrrolizidine alkaloids

PCBs	Polychlorinated Biphenyls
RTE	Ready-To-Eat
STX	Saxitoxin
TDI	Tolerable Daily Intake
TEF	Toxicity equivalent factor
UNEP	United Nations Environmental Programme
USA	United States of America
WG	Working Group
WHO	World Health Organisation
WPTC	World Processing Tomato Council

INTRODUCTION

1. The Codex Committee on Contaminants in Foods (CCCF) held its 11th Session in Rio de Janeiro, Brazil, from 3 to 7 April 2017, at the kind invitation of the Government of Brazil. The Session was chaired by Dr Martijn Weijtens, Deputy Director, Department of Food Quality, Ministry of Economic Affairs of The Netherlands. The Session was attended by 49 Member countries, 1 Member Organization, and Observers from 11 international organizations. The list of participants is provided in Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Mr Renato Alencar Porto, Director of Sanitary Regulation at the Brazilian Health Regulatory Agency (ANVISA). Mr Han Peters, Ambassador of the Kingdom of The Netherlands to Brazil; Dr Léa Contier de Freitas, Head of the Division on Barriers to Trade of the Brazilian National Institute of Metrology, Quality and Technology (INMETRO), and Representatives of FAO and WHO also addressed the meeting.

Division of Competence[1]

3. The Committee 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)[2]

4. The Committee adopted the Provisional Agenda as its Agenda for the Session and agreed:

- to establish an in-session Working Group on the priority list of contaminants and naturally occurring toxicants for evaluation by JECFA, chaired by the United States of America (Agenda Item 14);
- to establish an in-session Working Group on follow up on results of the JECFA evaluation, chaired by the European Union with outcomes to be discussed under Agenda Item 15, time permitting;
- to discuss new work on a Code of Practice for the prevention and reduction of cadmium contamination in cacao, proposed by Peru under Agenda Item 15, time permitting.

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMITTEE AND/OR ITS SUBSIDIARY BODIES (Agenda Item 2)[3]

5. The Committee noted the matters for information and took action on the following:

Codex Alimentarius Commission

Emerging issues: A proposed risk management approach to address detection in food of chemicals of very low public health concern

6. New Zealand welcomed the opportunity to present the new work proposal and recalled the strong support for this new work initiative and its relevance for the wider membership. The delegation thanked members for their valuable input and contribution through the various stages of development of the new work proposal.

7. The delegation recalled the origin, impetus and drivers for the proposed work. These included advances in analytical methods and detection technologies and the need to minimize food losses and wastage arising from the unjustified rejection of food. The delegation also referred to the workshop that was held immediately prior to this session to discuss the proposal and related project document. The delegation acknowledged the very constructive suggestions that came out of the workshop: to clarify the scope of the work and the need to limit the work to chemicals falling within the mandate of the Committee, and the need to ensure that the work incorporated the entire risk analysis framework.

8. New Zealand thanked members for these valuable suggestions and drew their attention to the revised project document as presented in CRD27. In conclusion, the delegation sought the support of the Committee for the recommendations set out in paragraph 19 of CRD27.

Conclusion

9. The Committee noted the information provided and agreed to discuss the recommendations under Agenda Item 15.

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1 CRD01
2 CX/CF 17/11/1
3 CX/CF 17/11/2; CX/CF 17/11/2-Add.1; comments of EU, Kenya and AU (CRD05); Kenya (CRD16); India (CRD18); Nigeria (CRD22)

FAO/WHO Coordinating Committee for Africa

Proposed draft Regional Standard for Fermented Cooked Cassava-based Products

Hydrocyanic acid

10. The JECFA Secretariat confirmed that from a safety perspective the existing ML for HCN could be extended to fermented cassava products. The assessment of cyanogenic glycosides undertaken by JECFA in 2011 resulted in the establishment of an acute and a chronic health-based guidance value for HCN, which is the ultimate toxic component resulting from hydrolysis of the cyanogenic glycosides. These safety-based limits are independent of the product and production process.

11. The Committee recalled that CCCF07[4] agreed that the ML for gari should be recalculated in future to adjust the HCN descriptor to account for all the contributors to the presence of HCN (i.e. total HCN) in the final product in order to achieve consistency in expressing the total level of HCN arising from cyanogenic glycosides in foods derived from cassava. This would require new data and information to allow the safety assessment of this product. The Committee had also encouraged member countries to collect occurrence data on HCN in cassava and cassava products; information on processing (cooking) methods; and consumption patterns following the implementation of the *Code of practice for the reduction of hydrocyanic acid in cassava and cassava products* (CAC/RCP 73-2013) with a view to determine the need and feasibility to establish MLs for HCN in cassava (raw and processed) in the future.

12. Based on the above, the Committee considered this proposal and noted the following comments:

- It is inappropriate to apply the ML for gari to other fermented cooked cassava based-products without considering more information on occurrence of HCN in fermented cassava products, influence of processing such as fermentation and cooking on the level of HCN in the final product. Different types Fermented cooked cassava-based products and consumption patterns have to be considered to represent all fermentation processes worldwide.
- There is a need to harmonize the expression of HCN, noting that it is expressed as free HCN in the case of gari, but as total HCN in the case of cassava flour.
- The GSCTFF states that MLs should only be established if there is a health concern and/or a trade issue;
- The COP provides guidance on how to produce cassava products with safe concentrations of HCN.

Mycotoxins

13. The Committee noted views from members that based on their data, mycotoxins were not a health concern in these products, but concluded that further information was needed before the Committee could reply to CCAFRICA.

Conclusion

14. The Committee agreed to establish an EWG led by Nigeria and working in English only to prepare a discussion paper to advise on the need and feasibility to establish an ML for HCN in all fermented cassava products and address the issue of harmonizing the expression of HCN levels, i.e. free or total HCN. The Codex Secretariat would issue a circular letter (CL) requesting data on occurrence of HCN and other relevant information in fermented cassava products.

15. The Committee also agreed that the EWG would consolidate information on mycotoxin occurrence in these products, and other relevant information, to allow CCCF to determine if mycotoxin contamination in these products would be a health concern in order to provide a more informed reply to CCAFRICA.

Committee on Fats and Oils

MLs for lead

16. The Committee noted the ML for lead in fish oils can be the same as the current ML for lead in edible fats and oils. The Committee therefore agreed to add a reference to the Standard for Fish Oils to the remarks column of the ML for lead in edible fats and oils once the standard is adopted (Appendix II).

ML for arsenic

17. The Committee noted that in seafood, arsenic is mainly found in its less toxic organic form. Similarly, while oils derived from fish can contain elevated levels of total arsenic, the majority is in the form of arsenosugars and arsenolipids.

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4 REP13/CF, paras. 83-86

18. The Committee therefore agreed that the ML for arsenic in fish oils can be the same as the current ML for arsenic in edible fats and oils. However, the Committee considered it appropriate to indicate the ML for fish oils to be specific to inorganic arsenic and to apply a note that total arsenic could be used for screening purposes (Appendix II).

MATTERS OF INTEREST ARISING FROM FAO AND WHO (including JECFA) – (Agenda Item 3)[5]

JECFA - Request for Scientific Advice

19. The Representative of WHO introduced the document and informed the Committee that the full report of the 83rd JECFA meeting had now been published. The outcome of JECFA83 would be discussed by the in-session WG on the follow up on results of the JECFA evaluation and not further considered here. The Representative informed the Committee on the planned JECFA meetings for 2017, dealing with food additives and with residues of veterinary drugs. The JECFA Secretariat receives requests for scientific advice from three Codex Committees (food additives, contaminants, veterinary drugs), from Member States and FAO and WHO programs, and not all requests can be addressed in subsequent meetings. Members who are willing to provide extra-budgetary resources to the scientific advice program are encouraged to contact the Secretariat directly.

GEMS/Food Program

20. The Representative informed the Committee of recent work and advances in the GEMS[6]/Food program in support of the work of this Committee. Active support was provided to three CCCF working groups, and Members including Codex Observers were strongly encouraged to provide data to the GEMS/Food in response to the annual calls for data, in order to assure the occurrence data was as broad and representative as possible. She highlighted the recently published e-learning tool[7] to facilitate the use of GEMS/Food data, and the development of a data sharing agreement to encourage Codex observers to also provide data. Having recognized the active support of GEMS/Food program to the work of EWG and usefulness of tutorials on available on the website, a delegation suggested that a procedure be developed with a flow chart for extraction of the data, taking into account that countries do not know the internal procedures of WHO.

Global Food Consumption Database

21. The Representative then informed the Committee of a pilot project (FAO/WHO GIFT[8]) to collect more detailed consumption data, namely individual food consumption data taking into account age and gender. This work will facilitate refined exposure assessments in the areas of food safety and nutrition.

WHO estimates of the Global Burden of Foodborne Diseases

22. The Representative also informed the Committee that the work to estimate the global burden of foodborne disease from heavy metals (arsenic, cadmium, lead, mercury) is being finalized and will be published in 2017.

Toxicity Equivalent Factors for Marine Biotoxins associated with Bivalve Molluscs

23. The Representative of FAO reported on the development of TEFs for marine biotoxins associated with bivalve molluscs. The Representative recalled that the Committee on Fish and Fishery Products has developed the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) which includes provisions for several marine biotoxins (eg Saxitoxin (STX) group; Domoic acid (DA) group; Brevetoxin (BTX) group; etc). As each of these biotoxin groups includes several analogues with different toxic potencies, in order to be able to assess the total toxicity in the shellfish extract and thus implement the standard, there was the need to derive TEF for each of the biotoxin groups. At CCFFP's request FAO/WHO organized an expert meeting in Rome in February 2016 to discuss the issues associated with development of TEFs for marine biotoxins, and to develop a technical paper on the state of science on the subject, including guidance for food safety managers to implement the provisions for biotoxins in the standard at national level. The technical paper has been published and also resulted in an article in an international scientific journal[9].

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5 CX/CF 17/11/3; CX/CF 17/11/3-Add.1; CX/CF 17/11/3-Add.2; comments of EU, Georgia, Kenya, Samoa, AU and ICBWA (CRD06); Fiji Islands (CRD19); India (CRD18 and CRD37); Dominican Republic (CRD23); Tonga (CRD29); Tanzania (CRD34)

6 https://extranet.who.int/gemsfood/

7 http://203.151.20.206/who3.html

8 http://www.fao.org/gift-individual-food-consumption/en/

9 http://www.fao.org/3/a-i5970e.pdf
Botana L, et al. Derivation of toxicity equivalency factors for marine biotoxins associated with Bivalve Molluscs. Trends in Food Science and Technology. 2017, 59: 15-24.

Microplastics in Fisheries and Aquaculture

24. The Representative of FAO also informed the Committee about the work on microplastics in fisheries and aquaculture. Upon request by the Global Oceans Action Summit for Food Security and Blue Growth, FAO in collaboration with UNEP, has worked with a group of international experts to develop a technical report that takes stock of the scientific knowledge available, and provides latest information on the subject. The report is currently being finalized and will soon be available.

Risk Assessment Methods and Principles

25. The Representative of FAO further noted that the FAO/WHO Secretariat is working to update risk assessment methodologies, taking into account recommendations from expert meetings and the latest scientific developments. This work is critical to assure that the scientific advice provided is based on most up-to-date methodology and science. Some activities in the area of chemical risk assessment include: the harmonization of chronic dietary exposure assessment for different food chemicals and combined exposure from dual uses compounds (pesticides and veterinary drugs); the guidance on ARfD setting for veterinary drugs; the threshold of toxicological concern principle and application to the evaluation of flavoring substances; the guidance on the evaluation and interpretation of genotoxicity tests; and the update of guidance on dose-response modelling.

WHO Guidelines for drinking-water quality and health-related limits for certain substances in the Standard for Natural Mineral Waters (CODEX STAN 108-1981)

26. The Representative of WHO, in introducing document CX/CF 17/11/3-Add.1, reminded the Committee of the history of the discussions within Codex on the WHO Guidelines for Drinking Water Quality and the *Standard for Natural Mineral Waters*. She clarified that there are two Codex standards, one on bottled water which makes direct reference to the WHO GDWQ, and the standard for natural mineral waters for which limits are set for a certain number of compounds (see section 3.2). Previous discussions at CCCF focused on the need (or usefulness) to include these limits in the GSCTFF, and on criteria to differentiate between safety and quality limits, but no further actions were taken by CCCF.

27. The Representative of WHO then informed the Committee of recently published changes in the WHO GDWQ for some elements that are currently included in the *Standard for Natural Mineral Waters*, with the request for the Committee to consider if these changes in the GDWQ should be reflected in the *Standard for Natural Mineral Waters*.

28. The Committee expressed divergent views on whether to begin new work to review the health-related limits for the substances indicated in section 3.2 or not.

29. Those in favor of continuing discussion (by means of a discussion paper, EWG or by reactivating the Committee on Natural Mineral Waters noted that additional data and consideration would be required to explore whether the health-related limits in CCNMW could be aligned with those proposed by WHO in the GDWQ. It was also noted that not aligning created the risk of possible discrepancy between a Codex standard and the WHO guidelines. It was clarified that natural mineral water was very different from tap water.

30. Those not in favor of advancing work in this area noted the importance of understanding the clear distinction between drinking water and natural mineral water and that therefore WHO values for drinking water should not be used as a sole basis for setting limits for natural mineral waters. As the amended limits were higher than previous limits there was no issue for public health and not issues for trade were identified, it was not necessary for CCCF to spend valuable time and resources on this matter.

31. As a possible alternative solution, in light of comments made especially regarding the lack of a public health or trade issue, the Chairperson proposed that the Committee simply note the changes in the WHO guidelines.

Conclusion

32. The Committee noted the work completed by WHO and the revised values in the GDWQ and agreed not to embark on new work on revising the values in *Standard for Natural Mineral Waters* at the present time.

FAO/WHO work on ciguatoxins

33. The Representative of FAO introduced FAO's and WHO's work on ciguatera fish poisoning and current challenges. He noted that CFP was one of the most common food-borne illnesses related to finfish consumption. While its true incidence was not known, it was estimated that 10,000–50,000 people per year suffer from this food borne illness, making it one of the most common types of marine food-borne poisoning worldwide.

34. The Representative introduced the work of FAO and WHO on ciguatoxin that has been undertaken so far and highlighted that analytical methods for detection and quantification of ciguatera to-date are not harmonized and it was unclear which, if any, of the available methods of detection would be suitable as routine methods of analysis.

35. The Representative invited the Committee to consider requesting FAO/WHO for scientific advice, in particular to carry out a risk assessment of ciguatera toxins and based on this provide guidance for the development of risk management options; and to review existing analytical methods for ciguatoxin detection and quantification, with a view to recommending those useful for routine analysis and surveillance.

36. There was general support for the proposal to request scientific advice from FAO/WHO to allow the Committee to develop appropriate risk management options. Delegations pointed out the importance of this matter to their countries, noting that due to climate change the traditional occurrence areas were changing and that consideration of ciguatoxins should not be limited to C-CTX-1 and P-CTX-1, but also to I-CTX. A delegation noted that their country does not currently recommend routine surveillance and sampling to meet specified MLs as risk management measure, but uses guidelines for outbreak management.

37. The European Union informed the Committee of the Euro Cigua Project, four-year project, co-funded by EFSA and coordinated by Spanish Food Safety Agency (AECOSAN) to determine incidence in Europe of ciguatera fish poisoning and epidemiological incidence cases, assess presence of ciguatoxins in food and environment in Europe, and validate the methods for detection, quantification and confirmation that could contribute to future work on ciguatoxins.

Conclusion

38. The Committee:

- agreed to request scientific advice from FAO/WHO to allow the Committee to develop appropriate risk management options;
- noted that the in-session WG on the priority list of contaminants and naturally occurring toxicants for evaluation by JECFA would consider this matter further (see Agenda Item 14).

MATTERS OF INTEREST ARISING FROM OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 4)[10]

International Atomic Energy Agency

39. The Representative of IAEA highlighted activities of interest to the Committee. The Representative thanked the Committee for the opportunity to hold a side event on radionuclides in food and drinking water.

Organization for Economic Cooperation and Development

40. The Representative of the OECD Nuclear Energy Agency presented the results of its workshop on post-accident food safety science, held in Fukushima in November 2016. Despite Japanese state-of-the-art agricultural safety work, and the fact that all marketed food products are well below national radiological criteria, domestic and international consumer confidence remains below pre-accident levels. To help governments address such issues, the NEA developed a coherent post-accident food management framework for domestic, export and import radiological criteria that is consistent with Codex criteria.

PROPOSED DRAFT AND DRAFT MAXIMUM LEVELS FOR LEAD IN FRUITS AND VEGETABLES (FRESH AND PROCESSED) AND OTHER SELECTED COMMODITIES (Agenda Item 5)[11]

41. The United States of America, as Chair of the EWG, introduced the item and reminded the Committee that this work was a follow-up to the JECFA73 evaluation on lead.

Fruit Juices exclusively from berries and other small fruits

42. The Committee recalled that CCCF9 had agreed[12] to retain the ML of 0.05 mg/kg for juices made exclusively from berries and other small fruits and to consider the possibility to lower the ML for this sub-set category to 0.03 mg/kg. CCCF10 had further agreed[13] to postpone the decision on juices obtained exclusively from berries and other small fruits to allow submission of new data and to consider whether the ML for fruit juices, RTE (ML = 0.03 mg/kg) could apply or whether a higher separate ML of 0.04 mg/kg for this subset category should apply and to take a decision at CCCF11.

43. The Committee noted views (i) in favor of applying an ML of 0.03 mg/kg to juices obtained exclusively from berries and other small fruits with some exceptions (currants, elderberries, raspberries, and strawberries), or (ii) in favor of retaining the ML of 0.05 mg/kg for this subset category and rather work on a positive list of juices from berries and small fruits that could comply with lower MLs. A single ML would also facilitate enforcement of the ML by national authorities.

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10 CX/CF 17/11/4

11 CL 2017/23-CF; comments of Costa Rica, Cuba, Ecuador, Egypt, EU, Japan, Kenya, New Zealand, Peru, Republic of Korea, FoodDrinkEurope, IFU and WPTC (CX/CF 17/11/5); USA (CRD12); Thailand (CRD14); Indonesia (CRD17); India (CRD18); Nigeria (CRD22); Dominica (CRD30); IFU (CRD32); Salvador (CRD38)

12 REP15/CF, para. 30

13 REP16/CF para. 53

44. An Observer noted that there were limited datasets on these types of fruit juices to allow the establishment of a worldwide representative ML that would cover all these fruits while remaining health protective with minimum negative trade impact. In addition, they were usually used in mixtures of different berries/small fruits or in mixtures of berries/small fruits with major fruits such as apple or grape juices. The consumption of these types of berry juices were in any case lower than other major commodities in this category such as orange juice or apple juice. The Observer further noted that seasonality and regionality should also be taken into account when considering levels for lead in these fruits which may introduce variability in the levels of lead.

45. The Committee agreed to retain the ML of 0.05 mg/kg for juices obtained exclusively from berries and small fruits and to work on a positive list of these fruits that could achieve lower levels (e.g. 0.03 or 0.04 mg/kg) as more data became available. A delegation noted that some juices in this category could meet the 0.03 or 0.04 mg/kg level based on the 2017 dataset.

Preserved tomatoes

46. The Committee recalled that the ML of 0.05 mg/kg was adopted by CAC39 at Step 5 on the understanding that member countries that raised concerns about practicality of enforcement of the ML, (number and geographical representativeness of samples) would submit relevant data to GEMS/Food in order to finalize the ML at this session.

47. The Committee noted views that even if the dataset had increased, it would still be of limited geographical representativeness to support lowering the ML from 1 to 0.05 mg/kg. Additional data should therefore be gathered before taking a final decision on this matter. In addition, different concentrated products might have difficulty complying with this ML. Other views expressed referred to the decision of CAC39 and supported the adoption of a lower ML of 0.05 mg/kg.

48. The Committee also noted the following views:

- an increased dataset available from GEMS/Foods confirms the ML of 0.05 mg/kg with a violation rate below the cut-off level of ≤5% lot rejections;
- the ML is based on lead levels found in the product as sold;
- concentration factors apply to tomato concentrates rather than preserved tomatoes.

49. Based on the above considerations, the Committee agreed to lower the ML to 0.05 mg/kg and to delete the note in the GSCTFF on the adjustment of the ML to take into account the concentration of the product.

Processed Tomato Concentrates

50. The Committee recalled that CCCF10 had agreed to further consider a lower ML for this food category with a view to its finalization at this session.

51. Brazil indicated they could provide data on tomato concentrates at different ratio of concentrations. The proposed lower ML did not take into account the effect of the different concentration ratios on the achievability of the ML and therefore some tomato concentrates may not comply with the proposed ML. It was further noted that occurrence of lead in food was mainly of environmental origin rather than associated with good management practices. The delegation committed to submit data to GEMS/Food so that a final decision could be taken at the next session of the Committee.

52. The Committee also noted the following views:

- an increased dataset available from GEMS/Foods support a lower ML of 0.05 mg/kg with a violation rate below the cut-off level of ≤5% lot rejections;
- the ML is based on lead levels found in the product as sold;
- the ML for the fresh food category (fruiting vegetables) is 0.05 mg/kg and took into account data from tomatoes;
- the dataset includes a wide range of years and was adequately geographical representative to support lowering the ML from 1.5 to 0.05 mg/kg.

53. Based on the above considerations, the Committee agreed to delete the note in the GSCTFF (on the adjustment of the ML to take into account the concentration of the product). The Committee also agreed to further consider the ML of 0.05 mg/kg in light of additional data submitted by countries concerned in order to make a final decision at its next session.

54. The Committee encouraged countries and observer organizations to submit data to GEMS/Food and any additional information e.g. type of product (tomato paste, tomato puree), concentration factors etc. as remarks to the GEMS/Food database in order to better identify the product when deriving proposed lower MLs for this food category.

Jams, jellies and marmalades

55. The Committee recalled that the ML of 0.1 mg/kg was adopted by CAC39 at Step 5 on the understanding that member countries that raised concerns about the practicality of enforcement of the ML, number and geographical representativeness of samples would submit relevant data to GEMS/Food in order to finalize the ML at this session.

56. The United States of America, as Chair of the EWG, noted that additional data, was submitted that would still support an ML of 0.2 mg/kg with 96% achievability. This ML would be consistent with MLs for various fruits and canned fruits in the GSCTFF. Data submitted from India during finalization of the paper, however, supported an ML of 0.5 mg/kg.

57. The Delegation noted that if elevated lead levels were due to sources other than fruit, these may be addressed by the *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CAC/RCP 56-2004) which recommends strategies for mitigation of lead in finished products including food ingredients, processing and production as well as the use of packaging and storage products.

58. India expressed concerns about the achievability of an ML of 0.2 mg/kg for these products based on the data they provided to GEMS/Food and proposed an ML of 0.5 mg/kg which would eliminate 3% of the samples in international trade. This proposal did not find consensus in the Committee. A delegation proposed to reassess the ML of 0.5 mg/kg.

59. India further noted that although samples were mainly provided from one country based on import data from products from different origins, such data were not representative of the levels of lead at origin as the export products would have to comply with the legislation of the importing country. Canada indicated that they did not have an ML in place for these category of products and therefore such data could be considered worldwide geographically representative.

60. The Committee noted general support for a compromise ML of 0.4 mg/kg that would eliminate 5% of the samples in international trade and would still be in compliance with the cut-off level of ≤5% lot rejections. This compromise was reached on the understanding that the ML could be revised once additional data become available.

61. The Committee thus agreed to lower the ML to 0.4 mg/kg and to re-evaluate jams, jellies and marmalades in future when more data became available. India expressed its reservation to this decision.

Mango chutney

62. The Committee considered the possibility to apply a lower ML of 0.1 mg/kg based on a limited dataset or to extend the ML of jams, jellies and marmalades to mango chutney.

63. India explained that “jams, jellies and marmalades” and “chutneys” were two different food categories. Mango chutney had other ingredients such as salt, spices and ingredients that may influence the levels of lead in the final product. Both products involved different processing technologies that may also affect the levels in the final product. The textures of the products were also different. The Delegation also indicated that mango chutney was widely consumed in certain regions and was a worldwide commodity, therefore additional data and further analysis should be carried out before taking a decision on lowering the ML for this product.

64. The Committee noted views that data available in GEMS/Food indicated full compliance with the proposed lower ML of 0.1 mg/kg.

65. The Committee recognized that mango chutney was an internationally traded commodity widely consumed in certain regions and that further consideration should be given to establishing a lower ML for this product at its next session.

66. The Committee therefore agreed to retain the current ML of 1 mg/kg for mango chutney as a stand-alone category and to encourage member countries concerned to submit data to GEMS/Food in order to make a final decision at its next session.

Canned chestnuts and chestnuts puree

67. The Committee considered the opportunity to (i) extent the ML for canned fruits at 0.1 mg/kg to canned chestnuts and chestnuts puree or (ii) to keep a separate category with an ML of 0.05 mg/kg based on a very limited dataset coming from one country but 100% achievable.

68. The Committee noted views that the *Classification of Food and Feed* (CAC/MISC 4-1989) lists chestnuts in the category of tree nuts and that it might not be appropriate to extent the ML of canned fruits to a category that did not belong to the fruit category.

69. The Committee therefore agreed to keep a single category for canned chestnuts and chestnuts puree with an ML of 0.05 mg/kg.

Canned brassica

70. The Committee considered the opportunity to extend the ML of 0.1 mg/kg for canned vegetables to canned brassica in view of the very limited dataset and to facilitate the enforcement of the ML for this product.

71. The Committee noted support for this approach however some questions needed to be further considered by the next session before advancing the ML for final adoption, in particular:

    (i) to include available data on kale in the dataset to determine whether this would not affect achievability of an ML of 0.1 mg/kg for a single category of canned vegetables (including canned brassica) and;
    (ii) to further consider data on canned brassica as the current analysis was based on pickled brassica and pickled fruits and vegetables which are not included in the same category of canned vegetables.

72. The Codex Secretariat noted that there were two separate standards for canned vegetables (CODEX STAN 297-2009) and canned pickled fruits and vegetables (CODEX STAN 260-2005) and that the ML for canned vegetables only applied to products covered under the standard for canned vegetables.

73. Based on the above considerations, the Committee agreed to further consider a single ML for canned vegetables (including canned brassica) at 0.1 mg/kg at its next session in order to make a final decision on this matter.

Fungi and mushrooms

74. The Committee considered the opportunity to establish a single ML of 0.6 mg/kg for lead for the whole category of fungi and mushrooms (excluding mushroom and fungus products).

75. The Committee noted the following views:

- it would be preferable to have a breakdown of this category as the consumption pattern and relevance in trade of these products varied widely across regions;
- data available did not allow further breakdown of this category and did not differentiate much between different types of fungi and mushrooms;
- further data should be collected to allow a more focused analysis of the main sub-categories in terms consumption and relevance to trade e.g. common mushrooms (*Agaricus bisporous*), shiitake mushrooms (*Lentinula edodes*) and oyster mushrooms (*Pleurotus*);
- the ML should be limited to cultivated mushrooms, it would be difficult to establish MLs for wild mushrooms in view of the variability of the levels of lead due to seasonal and other geoclimatic conditions;
- an ML limited to farmed mushrooms commonly grown across regions would also facilitate enforcement of the ML by national authorities.

76. Based on the above considerations the Committee agreed to further consider an ML for farmed fungi and mushrooms (i.e. common mushroom, shiitake and oyster) at its next session. The Committee encouraged member countries to submit data to GEMS/Food in order to finalize the ML(s) at its next session.

Pulses

77. The Committee agreed to lower the ML from 0.2 to 0.1 mg/kg.

78. Thailand expressed its reservation to this decision. They provided the following rationale: pulses are major commodities in international trade; they are highly consumed worldwide and are staple foods in certain countries or regions; they are dried products that can be further processed to reduce lead contamination; the ML for legume vegetables at 0.1 mg/kg is on a fresh-weight basis, so that the ML for pulses, which are dried products, should not be set at the same level.

Fish

79. The Committee agreed to maintain the ML for fish at 0.3 mg/kg.

Other matters

80. The Committee noted comments on the age of the data used to carry out the derivation of the MLs (e.g. more than 10 - 15 years old) and the establishment of MLs for certain products on very limited datasets.

81. The JECFA Secretariat noted that data available on GEMS/Food are quality checked according to defined criteria. These criteria refer to the validity of the methods and allowed to judge the validity of the results independent of when the analysis was performed.

82. For the size of datasets, it was recalled that CCCF10 had discussed this issue thoroughly and that in principle a minimum dataset of 60 samples would allow statistical analysis for the derivation of MLs, although consideration of an acceptable number of minimum samples should be made on a case-by-case basis. Setting a minimum number of samples for proposing a revised ML might not be applicable in all scenarios.

Future work on the review of existing MLs for lead in the GSCTFF

83. The Committee agreed to continue working on the following food categories: grape juices (to determine if a lower ML could be established as part of the positive list to apply to juices obtained exclusively from berries and other small fruits); processed tomato concentrates; mango chutney; canned brassica vegetables; fungi and mushrooms.

84. In addition, the Committee agreed to review the following categories: salt, wine, edible fats and oils, fats spreads and blended spreads. For the fats, oils and spread categories, the Committee agreed that a simplified approach should be preferable rather than having a detailed breakdown of these categories in order to facilitate the establishment of MLs and their enforcement.

Future work on new food categories for establishment of MLs

85. The Committee noted that current work on the revision of the MLs for lead is limited to those food categories listed in the GSCTFF. There was however wide support to continue working on new MLs for lead for a range of categories e.g. tea, herbal infusions, spices, vegetable juices and nectars, etc.

86. The Committee also recalled that proposals for new work on dried fruits and stalk vegetables had been proposed at previous meetings but the decision was deferred until work on the review of the MLs for the existing categories was completed.

87. The Committee agreed that work on new MLs for lead in food categories, which are currently not listed in the GSCTFF, would need further analysis based on their public health concern and their relevance to international trade. This would imply, amongst other relevant considerations, an analysis of the commodities which significantly contribute to the intake of lead and occurrence of lead in those commodities. The Codex Secretariat noted that the guidance provided in the Procedural Manual and the GSCTFF should assist the Committee in the establishment work priorities for lead in new food categories.

Conclusion

88. The Committee agreed to advance the MLs for:

- preserved tomatoes, Jams, jellies and marmalades, canned chestnuts and pulses to Steps 8 and 5/8;
- processed tomato concentrate and canned brassica vegetables to Step 5.

89. The committee also agreed to:

- propose that CAC revoke the existing MLs for the categories proposed for adoption at Steps 8 and 5/8;
- establish an EWG chaired by the United States of America, working in English, to work on those commodities indicated in paras. 83 and 84;
- request the EWG led by Brazil to prepare a discussion paper on a structured approach to prioritize commodities not in the GSCTFF taking into account public health for which new MLs for lead could be established.

PROPOSED DRAFT MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATE AND COCOA-DERIVED PRODUCTS AT STEP 4 (Agenda Item 6)[14]

90. Ecuador, as Chair of the EWG, also on behalf of the co-Chairs Brazil and Ghana, introduced the item. Ecuador recalled the terms of reference established by CCCF10 to progress work on the MLs and presented their recommendations to the Committee.

General discussion

91. Some members noted that on the basis of the JECFA77 evaluation, the establishment of MLs of cadmium for cocoa and chocolate-derived products was not based on safety concerns, but rather presented a trade concern.

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[14] CL 2017/24-CF; comments of Australia, Canada, Chile, Costa Rica, Cuba, Egypt, EU, Japan, Kenya, Malaysia, Peru, Republic of Korea, USA, AU, ECA, FoodDrinkEurope, ICA and ICGMA (CX/CF 17/11/6); USA (CRD12); Indonesia (CRD17); India (CRD18); Nigeria (CRD22); Dominican Republic (CRD23); Dominica (CRD30); Ghana (CRD31); Tanzania (CRD34); report of the in-session WG (CRD36)

92. Members examined the proposed division of the percentage of total cocoa solids on a dry matter basis into ranges or categories in the proposal of the EWG and there was support for considering MLs for chocolate products for categories with total dry cocoa solids ≤ 30% and >30% - 50%.

93. Concerns were raised regarding the lack of sufficient data for categories in general, but especially for chocolate with a high cocoa content (>50% total dry cocoa solids) and that data presented to support MLs for dry cocoa mixtures and chocolate products may be insufficient and may not capture differences in cadmium levels due to geographic origin.

94. Observer organizations also noted the importance of having a sufficient quantity of data upon which to base global recommendations and the need to consider all trade implications when setting MLs, such as the effect of exclusion of product for non-safety reasons, particularly on small farmers or artisan producers especially from developing countries.

95. Other issues raised included:

- that some of the proposed MLs may not be achievable or that additional product categories of MLs may be needed (e.g. chocolate with very high contents of total dry cocoa solids; dry mixtures of cocoa and sugars with higher levels of cocoa solids > 50%);
- the enforcement aspect in setting MLs for chocolate products based on percentage of total dry cocoa solids as many products do not currently display this information on their labels;
- the need for consistency in the name and the percentage of total dry solids of cocoa for each chocolate or chocolate product relative to the *Standard for Chocolate and Chocolate Products* (CODEX STAN 87-1981);
- consider requesting JECFA to conduct an impact assessment of proposed MLs (including possible higher alternate MLs). The results of the impact assessment should then be used to guide ML selection, rather than achievability alone;
- the need to consider the adequacy of methods for establishing the percentage of total cocoa solids to support the ML.

96. As an initial step, the Committee therefore agreed to establish an in-session WG to propose recommendations for the categorization of chocolates and cocoa derived products and dry mixtures of cocoa and sugars.

Conclusion

97. Further to the recommendations of the in-session WG, the Committee agreed:

- to endorse the proposed categories for “chocolates” and for “cocoa powder and dry mixtures of cocoa and sugars” (Appendix XIII);
- to establish an EWG, chaired by Ecuador and co-chaired by Brazil and Ghana, working in English and Spanish, to prepare proposals for MLs for the identified categories for “chocolates” and “cocoa-powder and dry mixtures of cocoa and sugars” sold for final consumption;
- to discontinue work on intermediate products. Future new work could be proposed on these products in future;
- That the Codex Secretariat would issue a request for data through a CL.

98. The Committee agreed to revise the deadline for completion by two years to 2019 and to inform the CCEXEC accordingly.

99. The Representative of WHO reminded the Committee that the call for data recently published from the GEMS/Food program already includes the request for further occurrence data on cadmium in cocoa and cocoa products, with a submission deadline of 30 June 2017[15]. It was noted that this deadline could be extended to bring it in line with the deadline of the CL. She called on the chairs of the EWG to get in touch with the GEMS/Food manager (vergerp@who.it) as soon as possible.

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ARSENIC CONTAMINATION IN RICE (Agenda Item 7)[16]

100. Japan, as Chair of the EWG, also on behalf of the co-Chair Spain, introduced the item and noted that they had prepared a revised version of the COP based on the written comments submitted to this session. The Committee revised the COP based on the revised version and agreed on several amendments to improve the clarity and accuracy of the text.

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15 http://www.who.int/foodsafety/CFD-ScientificAdvice-2017.pdf

16 CL 2017/25-CF; comments of Australia, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, EU, Kenya, New Zealand, Paraguay, Peru, Republic of Korea, USA and AU (CX/CF 17/11/7); USA (CRD12); Thailand (CRD14); Indonesia (CRD17); India (CRD18); Brazil (CRD20); Senegal (CRD21); Nigeria (CRD22); revised COP for the prevention and reduction of arsenic contamination in rice (CRD25); Ghana (CRD31); Tanzania (CRD34)

101. The Committee also agreed that complementary information for further consideration of measures would be better placed in the report as a guide for the further development of the COP when new data and information on mitigation measures become available as follows:

> The results of ongoing or planned research studies on the effectiveness of measures to prevent and reduce arsenic concentration in rice should be considered in future revisions to this COP. Research on the following topics may help in further developing this COP:
>
> - Effects of soil amendments and fertilizers (e.g. silicates, phosphates and organic materials) on arsenic concentrations in rice including considering the effects of applying different amounts of the materials or applying the materials with different timing and frequency (e.g. one-off or repeated use in each season);
> - Indirect effects (e.g. change of yield, cadmium concentration in rice) of implementing measures to reduce arsenic concentrations in rice;
> - Effects of varying the timing and duration of flooded/aerobic conditions during the rice growth period;
> - Understanding factors affecting arsenic concentrations in rice, including from the arsenic concentrations in soil and/or other factors (e.g. iron, silicates, phosphates concentrations etc.) before cultivation; and
> - Efficiency and cost of removing arsenic in soil using agricultural crops that absorb and accumulate arsenic from the soil or using chemical compounds that adsorb arsenic and are easily separated from the soil.

102. A delegation stated that they did not have any objections to the adoption of the COP. However, as the results of several ongoing studies would be available in 2019, the additional information gained from these studies might need to be added to this COP in order to make it more understandable and more practical. Thus, the delegation noted that there would be a need to revise the COP in 2019 when the outcome from ongoing studies became available.

Conclusion

103. The Committee agreed to send the proposed draft Code of practice for the prevention and reduction of arsenic contamination in rice to CAC40 for adoption at Step 5/8 (Appendix III)

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS IN READY-TO-EAT PEANUTS (Agenda Item 8)[17]

104. India, as Chair of the EWG, presented the item and recalled that the ML of 10 µg/kg for AFT in RTE peanuts had been held at Step 4 at CCCF09 (2015) pending a JECFA exposure assessment for health impact of hypothetical MLs of 4, 8, 10 and 15 µg/kg and calculation of violation rates for the MLs. India had prepared a revised proposal based on the outcome of JECFA83 of an ML of 15 µg/kg for consideration by the Committee. This recommendation was based on the fact that a lower ML would have little further impact on dietary exposure to AFT for the general population and that at this ML the rejection rate would be less than at a lower ML.

105. Delegations opposed to the recommendation pointed out: there was no clear rationale for not maintaining the ML of 10 µg/kg (held at Step 4); violation rates were not that different between the levels of 10 µg/kg and 15 µg/kg (CRD24) and should not be a justification for not maintaining the previously proposed ML; the proposal was the same as the ML for peanuts for further processing, knowing that further processing would reduce aflatoxin levels; the proposal for 15 µg/kg was thus not in line with the criteria in the GSCTFF for the establishment of MLs which states that MLs should be as low as reasonably achievable (ALARA) and should be based on good management practices (e.g. GAPs, GMPs, etc.); the approach for peanuts would also not be consistent with the approach taken for the MLs for other nuts such as almonds, Brazil nuts, hazelnuts, pistachios destined for further processing and RTE.

106. Delegations in favor of the proposal noted that peanuts were usually a small component of the diet and that at the proposed ML of 15 µg/kg the violation rate was already 9.7%, which was higher than the usual cut-off level of less than/equal to a 5% violation rate used by CCCF when applying the ALARA principle in the establishment of MLs to be health protective with a minimum negative impact on trade. These delegations thus expressed the view that a lower ML would offer little additional health protection even in high consuming populations, but would result in greater rejections and have a negative impact on trade.

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17 CL 2017/26-CF; comments of Canada, Chile, Costa Rica, Cuba, Egypt, EU, Japan, Nicaragua, Republic of Korea, USA, AU and ICGMA (CX/CF 17/11/8); USA (CRD12); Indonesia (CRD17); Senegal (CRD21); Nigeria (CRD22); JECFA Secretariat (CRD24), Ghana (CRD31); Tanzania (CRD34)

107. The JECFA Secretariat noted that the Committee should take into consideration that the data underlying JECFA's impact assessment might have included a bias, as the GEMS/Food database did not differentiate between peanuts for further processing and RTE peanuts. Furthermore, the data might have exhibited a bias due to a prevalence of occurrence data from collected from developed countries on peanuts originating from different regions of the world. While the overall bias and the resulting uncertainty was largely unknown, such bias, however, would lead to an underestimation of a potential gain in public health protection that might be achieved with lower MLs. The Secretariat further noted that aflatoxins are contaminants of high public health concern and peanuts are one of the main contributors to total exposure to total aflatoxins in many parts of the world.

Conclusion

108. In view of the lack of consensus on the recommendation and the need for further consideration of the JECFA report, the Committee agreed to:

- request comments on the levels of 10 µg/kg or 15 µg/kg at Step 3 (Appendix IV). Comments should be accompanied by a rationale for the proposed draft ML and any additional/further information to support the proposed draft ML.
- establish an EWG led by India, and working in English only, to consider the comments and information received and to prepare a revised proposal for further comments and consideration by CCCF12.

PROPOSED DRAFT ANNEX ON ERGOT AND ERGOT ALKALOIDS IN CEREAL GRAINS (ANNEX TO THE *CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS* (CAC/RCP 51-2003)) (Agenda Item 9)[18]

109. Germany, as Chair of EWG, also on behalf of the co-Chair the United Kingdom, introduced the item and informed the Committee that a revised annex had been prepared based on all comments submitted.

110. The Committee considered revised annex and agreed to clarify paragraph 2 to indicate that the GAP practices were to address ergot alkaloids related to ergotism. Along these lines, reference to other species not causing ergotism was deleted. Paragraphs 5 and 6 were also amended to make them less prescriptive.

Conclusion

111. The Committee agreed to advance the annex on ergot and ergot alkaloids in cereal grains for adoption at Step 5/8 by CAC40 and inclusion in the *Code of practice for the prevention and reduction of mycotoxin contamination in cereals* (CAC/RCP 51-2003) (Appendix V).

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN SPICES (Agenda Item 10)[19]

112. Spain, as Chair of the EWG, also on behalf of the co-Chairs India and The Netherlands, presented the item and highlighted the recommendations for consideration:

- Consider the proposed draft COP;
- Request CCFH to consider the possibility to include some general practices for hygiene from CX/CF 16/10/12 in the *Code of Hygienic Practice for Low Moisture Foods* (CAC/RCP 75-2015), annex on spices and dried aromatic herbs;
- Refer section 2.3.6 to CCFL for endorsement; and
- Suspend work on annexes for different spices until more information on specific management practices became available.

113. Spain informed the Committee that a revised proposed draft COP based on all comments received had been prepared and proposed that the Committee consider this as the basis for discussion.

114. In addition to editorial and other changes for the purposes of clarity or flexibility, the Committee made the following observations and took the following decisions.

- To encourage research studies on the factors affecting the formation of mycotoxins without making reference to this in the COP itself as they did not belong to the COP and in line with the decision taken on the COP for arsenic in rice (Agenda Item 7).

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18 CL 2017/27-CF; comments of Chile, Colombia, Costa Rica, Cuba, Egypt, EU, Kenya, New Zealand, USA and AU (CX/CF 17/11/9); USA (CRD12); Nigeria (CRD22); Ghana (CRD31); Tanzania (CRD34); revised Annex on ergot and ergot alkaloids in cereal grains (CRD35)

19 CL 2017/28-CF; comments of Canada, Chile, Costa Rica, Cuba, Ecuador, EU, Japan, Kenya, New Zealand, Peru, Republic of Korea, USA and AU (CX/CF 17/11/10); USA (CRD12); Thailand (CRD14); Indonesia (CRD17); Brazil (CRD20); Nigeria (CRD22); revised proposed draft COP for the prevention and reduction of mycotoxin contamination in spices (CRD26); Dominica (CRD30); revised proposed draft COP for the prevention and reduction of mycotoxin contamination in spices (updated) (CRD33); Tanzania (CRD34); Salvador (CRD38)

- To include the need to use treated biosolids in line with the text in the *Code of hygienic practice for fresh fruits and vegetables* (CAC/RCP 53-2003) in the section on *pre-harvest practices*.
- To refer only to water activity and not moisture content in section 2.2.2 "drying on the farm", as moisture content varied in different spices. The water activity was amended throughout the document to 0.65 as it is more correct for spices.
- To indicate that for drying, a safe moisture level should be reached (such as 12 – 14%), rather than to fix the moisture level as this could vary across spices.
- To refer only to irradiation without referencing the specific type of irradiation used for spices. A reference was made to the *Standard for Irradiated Food* (CODEX STAN 106-1983) and *Code of Practice for Radiation Processing of Food* (CAC/RCP 19-1976) to ensure that irradiation practices were in line with these texts.
- To change the title of section 2.3.6 to "*product information and consumer awareness*" to align with other Codex codes of practice and the *General Principles for Food Hygiene* (CAC/RCP 1-1969) and amended the text to focus on consumer advice and awareness. In view of these changes, endorsement by CCFL was not necessary.

Conclusion

115. The Committee agreed to advance the proposed draft COP for the prevention and reduction of mycotoxins contamination in spices for adoption at Step 5/8 by CAC40 (Appendix VI) and to discontinue work on specific annexes.

Other general matters

Annexes to the COP

116. The Committee agreed to discontinue work on annexes until further information on management practices specific spices became available.

Hygiene text for consideration by CCFH

117. The Committee noted that the *Code of Hygienic Practice for Low-moisture Foods* (CAC/RCP 75-2015) and its annex on spices already covered practices for transport and packaging similar to the advice contained in paragraphs 63-69 and 78 of CX/CF 10/16/12, Appendix I, and agreed that there was no need to refer any text to CCFH for consideration for inclusion in CAC/RCP 75-2015.

DISCUSSION PAPER ON MAXIMUM LEVELS FOR MYCOTOXINS IN SPICES (Agenda Item 11)[20]

118. India, as Chair of the EWG, also on behalf of the co-Chair the European Union, introduced the recommendation for the establishment of individual MLs for AFT and OTA for 5 spices: nutmeg, chilli and paprika, ginger, pepper and turmeric. India clarified that proposals had been considered for establishing MLs also for AFB1, but that this was not necessary as AFB1 would be included in AFT. This was also consistent with previous decisions of CCCF when setting MLs for aflatoxins. In addition, establishment of MLs for group of spices was not feasible as contamination and consumption patterns widely vary amongst spices.

119. While there was general support for the proposal, the following comments were made:

- MLs should be established for AFB1, as this was the most toxic and widely distributed form of aflatoxins;
- CCCF had discussed in the past the establishment of MLs for AFB1 but agreed to set MLs for AFT only and there was no indication from current data and information available that spices would be an exception to other commodities subject to aflatoxins contamination to establish two separate MLs for AFT and AFB1;
- the rationale for the selection of the spices was not clear, but work could be supported;
- there was no mention of spices in the JECFA83 report; spices were minor contributors to aflatoxin exposure; therefore the establishment of MLs for these commodities was not in line with criteria in GSCTFF, but if work were agreed, it should be limited AFT and OTA as agreed upon by CCCF10[21];
- scientific advice in the project document needed to better specified; including the need for impact assessment;
- fumonisins should also be considered in addition to AFT and OTA and that data would be submitted.

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20 CX/CF 17/11/11; comments of Ecuador, EU, Kenya, Peru, Republic of Korea and AU (CRD07); USA (CRD12); Thailand (CRD14); Tanzania (CRD34)

21 REP16/CF, para. 148

120. The JECFA Secretariat clarified that:

- a call for data had been published for mycotoxins in spices following discussion at CCCF10. Some data were submitted to GEMS/Food and considered in the recent JECFA assessment, the details would be published in the JECFA monograph. Fumonisins occurrence had also been reported;
- an impact assessment as indicated in the project document was premature as discussions should first take place on which MLs to consider and if they should be considered for individual spices or groups of spices;
- the occurrence data analyzed indicated some very high contamination levels and that it would be important from a public health perspective to eliminate these highly contaminated lots from the market.

121. The Committee also noted that the issue of fumonisins had been addressed by the in-session WG on follow-up of JECFA83 (Agenda Item 15) and that the resulting call for data/CL could also include spices besides maize.

Conclusion

122. The Committee agreed to start new work on MLs for AFT and OTA in nutmeg, chilli and paprika, ginger, pepper and turmeric and to submit the revised project document (Appendix VII) for approval by CAC40.

123. An EWG, led by India, working in English only, subject to approval of new work by CAC40, would prepare a proposal for circulation for comments and consideration by CCCF12.

124. The Committee also recalled a previous decision that EWG chairs should use data from GEMS/Food database and ensure that any data collected by EWGs should be uploaded to the GEMS/Food database. This was consistent with the recommendation of CCCF09 to use the GEMS/Food platform for data submission and analysis for its work in the development of MLs. When additional information needed to be collected that was not part of the database, WG chairs should consult with the GEMS/Food Secretariat when developing templates for the collection of data.[22]

DISCUSSION PAPER ON MAXIMUM LEVELS FOR METHYLMERCURY IN FISH (Agenda Item 12)[23]

125. The Netherlands, as Chair of the EWG, also on behalf of the co-Chairs Canada and New Zealand, introduced the item and recalled the TORs for the EWG, the work process followed and highlighted the recommendations for discussion:

- Whether to establish the ML for tuna as a whole or for specific tuna species, noting that it was possible to distinguish in subspecies based on methylmercury levels;
- Whether to establish MLs for other identified fish species that accumulate methylmercury;
- Whether the MLs should be based on the ALARA principle or should be guided by risk/benefit;
- Not to establish MLs for canned tuna as levels were generally low and these products were consumed in lower quantities than fresh or frozen fish;
- Consider setting MLs based on total mercury and not methylmercury.

General discussion

126. The Committee noted the request from one delegation for more data collection on nutrients and contaminants in fish and the difficulty with methods of analyses for assuring compliance with MLs.

127. Another delegation supported the need for more data collection and further requested JECFA to undertake a risk assessment and an economic impact assessment.

128. The JECFA Secretariat clarified that JECFA and FAO/WHO had already provided several documents on requested scientific advice, most notably a risk/benefit analysis regarding the consumption of fish; and that a trade impact analysis of various MLs for methylmercury would exceed the mandate of JECFA.

Discussion on the recommendations of the EWG

Basis for ML determination (ALARA or risk/benefit)

129. There was wide support to establish MLs based on the ALARA principle, which was in line with the criteria for establishing MLs in the GSCTFF.

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22 REP16/CF, para. 117 and REP15/CF, para. 108

23 CX/CF 17/11/12; comments of EU, Kenya, Peru, Republic of Korea, AIPCE-CEP and AU (CRD08); USA (CRD12); Japan (CRD13); Thailand (CRD14); Morocco (CRD15); India (CRD18); Senegal (CRD21); Dominica (CRD30); Tanzania (CRD34)

ML for tuna as a whole or specific species

130. The Committee noted the general support for setting MLs for tuna. One delegation proposed that, if MLs would be set for tuna as a group, the ML should be based on the species with the highest methylmercury levels and that an appropriate violation rate needs to be determined. The Committee decided that an ML would be established for tuna as a group, and that the subspecies of tuna taken into account for this would be indicated.

ML for other species of fish

131. The Committee considered whether to establish MLs for alfonsino, kingfish/amberjack, marlin, shark, dogfish and swordfish.

132. Delegations that commented noted that:

- certain of the fish species listed, such as Alfonsino, had limited international trade, and setting MLs for such species would be contrary to the GSCTFF which stated that MLs should be established for commodities with significant international trade;
- that if trade was taken into account, consideration should also be given to the impact of MLs for small fishing countries, that might not have significant international trade, but whose fish industry was economically important for their countries.

133. The Netherlands, as Chair of the EWG, clarified that trade aspects would be taken into account when establishing MLs. It was important to reduce methylmercury intake. While there might not be significant international trade of some of the species, these were highly consumed at local level, thus the proposal from the WG.

134. The Committee agreed to establish MLs for the species listed (see para. 134).

ML for canned tuna

135. The Committee agreed not to establish MLs for canned tuna.

Total mercury vs methylmercury

136. The Committee noted the requests to establish MLs for total mercury rather than methylmercury, as analysis of methylmercury was difficult and required the use of expensive high technology methods, which were not always available to especially developing countries, while methods for total mercury were reliable, widely available and less costly. This approach could be taken also if it was assumed that total mercury was indicative of methylmercury and there was no evidence that there were fish with high total mercury, but low methylmercury.

137. It was clarified, that while generally it was shown that methylmercury forms a large part of total mercury for most species, in some species, such as marlin, the available data showed that methylmercury levels were low in comparison to total mercury.

138. The Committee, recalled its previous decision to establish MLs for methylmercury, while screening for total mercury[24], and agreed to continue with this approach.

Other matters

139. The Committee agreed with the recommendation that a footnote to the higher MLs would be developed to indicate the need for additional risk management measures, namely consumer advice, to protect health.

140. The Committee noted that MLs should be accompanied by sampling plans and to make this clear in the project document.

Conclusion

141. The Committee agreed to start new work on MLs for fish (tuna, alfonsino, kingfish/amberjack, marlin, shark, dogfish and swordfish) and to submit the revised project document to the CAC40 for approval.

142. An EWG, chaired by the Netherlands, and co-chaired by Canada and New Zealand, working in English, subject to approval of new work, would prepare proposals for MLs and associated sampling plans for circulation for comments and consideration by CCCF12.

143. The Codex Secretariat would request further data on total mercury and methylmercury in fish through a CL.

[24] REP14/CF, para. 113

DISCUSSION PAPER ON NON-DIOXIN LIKE PCBs IN THE *CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND DIOXIN-LIKE PCBs* (Agenda Item 13)[25]

144. The European Union, as Chair of the EWG, introduced the item and recalled that following JECFA80, CCCF10 had requested the development of a discussion paper to identify if the *Code of Practice for the prevention and reduction of dioxins and dioxin-like PCB contamination in Foods and Feed* (CAC/RCP 62-2006) could be revised to include measures also for non-dioxin like PCBs. The delegation informed the Committee that it was appropriate to revise the document as there were sufficient measures in place for such prevention or reduction as identified in paragraph 14a – e of CX/CF 17/11/13. In addition, additional measures had been identified for the prevention and reduction of dioxins and dioxin-like PCBs, e.g. cooking practice and carry-over from feed to food, and proposed that the revision of the COP also take up these measures.

145. The Committee agreed with the proposal and noted the comment of one delegation to take into account the needs of small enterprises.

Conclusion

146. The Committee agreed to start new work and to forward the project document (Appendix IX) to CAC40 for approval.

147. The Committee further agreed to establish an EWG, chaired by the European Union, working in English only, to revise the COP for comments and consideration at its next session.

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS PROPOSED FOR EVALUATION BY JECFA (Agenda Item 14)[26]

148. The United States of America, as Chair of the in-session WG, presented the report on the outcome of the discussion on the priority list.

Conclusion

149. The Committee:

- accepted the recommendations of the in-session WG and endorsed the priority list of contaminants and naturally occurring toxicants for JECFA evaluation as amended (Appendix XII) and agreed to re-convene the in-session WG at its next session;
- agreed to continue to request comments and/or information on the priority list for consideration by CCCF12;
- agreed not to include mycotoxin in spices in the priority list.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 15)

Follow up to the outcome of JECFA[27]

150. The European Union, as Chair of the in-session WG, presented the report. The Chair of the in-session WG informed the committee that the JECFA Secretariat committed that the monograph on PAs would be published before the next session of CCCF and further work on PAs could be considered at the next session.

Conclusion

151. The Committee agreed to:

- endorse the proposal for new work for adoption by CAC on a Code of Practice for the Reduction of 3-monochloropropane-1,2-diol esters and glycidyl esters in refined oils and products made with refined oils, especially infant formula and to establish an EWG, chaired by USA and co-chaired by the European Union and Malaysia, working in English only, to follow-up on this new work (Appendix X)
- establish an EWG, led by Brazil, working in English to prepare a discussion paper on aflatoxins and sterigmatocystin in cereals (in particular maize, rice, sorghum and wheat) to enable the CCCF to take at CCCF12 an informed decision on the appropriate follow-up as regards possible risk management options for aflatoxins and sterigmatocystin in cereals;
- to request JECFA to update the 2001 JECFA evaluation of T-2/HT-2 toxin taking into account new toxicity studies (i.e. inclusion in the priority list). Furthermore the exposure assessment should be based upon more recent occurrence data on the presence of T-2 and HT-2 toxin and 4,15-1 Diacetoxyscirpenol (DAS) in food. Member countries are requested to provide recent occurrence data on the presence of T-2, HT-2 toxin and 4,15-DAS to the GEMS/Food contaminants database. For the generation of these occurrence data it is necessary to use methods of analysis with appropriate sensitivity;

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25 CX/CF 17/11/13; comments of EU, Republic of Korea and AU (CRD09); USA (CRD12); Tanzania (CRD34)
26 REP16/CF Appendix VI; report of the in-session WG on priorities (CRD02)
27 Report of the in-session WG on follow-up to the JECFA evaluation (CRD03); comments of USA (CRD10)

- call upon countries belonging to the African, Eastern Mediterranean or South-East Asia regions to provide to GEMS/Food contaminants database information on fumonisin levels in maize and to record this in the report of the meeting;

Emerging Issues: A proposed risk management approach to address chemicals inadvertently present in food at very low levels[28]

152. New Zealand presented a revised version of the project document prepared following a workshop held prior to CCCF11.

Conclusion

153. The Committee agreed to:

- endorse new work on the development of risk analysis guidelines to address chemicals inadvertently present in food at low levels;
- forward the project document to the CAC for approval (Appendix XI); and
- Agreed to establish an EWG chaired by New Zealand, co-chaired by the Netherlands, working in Egnlish, to advance this work.

Code of Practice for the prevention and reduction of cadmium contamination in cocoa[29]

154. Peru introduced the item and explained that the proposed COP aimed to guide Member States and the cocoa production industry in preventing and reducing cadmium contamination in cocoa beans during the production and processing phases.

Conclusion

155. The Committee agreed to establish an EWG, led by Peru, working in English, to prepare a discussion paper and project document for discussion on the opportunity to develop such COP and the risk mitigation measures available to that would support the development of a COP.

Development of a forward workplan for CCCF

156. The Codex Secretariat recalled the new and ongoing work commitments made by the Committee and the increasing challenges of having a manageable agenda, to have sufficient time to discuss all the matters scheduled for consideration and to complete work in a timely manner. The Secretariat underlined the importance of operating strategically in order to establish or prioritize items within this workload.

Conclusion

157. The Committee agreed that the Codex Secretariat and Host Country Secretariat would develop a plan to address this issue and report back at the next session.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 16)

158. The Committee was informed that CCCF12 was tentatively scheduled to be held in The Netherlands in approximately one year's time, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

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28 Comments of New Zealand (CRD04 and CRD27); report of the Workshop on very low levels of chemicals in food (CRD28)

29 Comments of Peru (CRD11)

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APPENDIX II

MAXIMUM LEVELS FOR ARSENIC AND LEAD IN SELECTED COMMODITIES

(For adoption)

AMENDMENT TO THE ML FOR EDIBLE FATS AND OILS (ML FOR ARSENIC IN FISH OIL)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Edible fats and oils	0.1	Whole commodity	Relevant Codex commodity standards are CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999 ~~and~~ CODEX STAN 211-1999, and **CODEX STAN XXX-2017 [Standard for Fish Oils – once adopted by CAC]** **For fish oil covered by CODEX STAN XXX-2017, the ML is for inorganic arsenic (As-in).** **Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analysing total arsenic (As-tot) in rice. If the As-tot concentration is below the ML for As-in, no further testing is required and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.**

REVISION OF THE MLs FOR LEAD IN CERTAIN PROCESSED FRUITS AND VEGETABLES
(At Steps 5, 5/8 and 8)
AMENDMENT TO THE ML FOR LEAD IN EDIBLE FATS AND OILS

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Pulses	**0.1 mg/kg** **(Step 5/8)**	Whole commodity	
Jams, jellies and marmalades	**0.4** **(Step 5/8)**		Relevant Codex commodity standard is CODEX STAN 296-2009.
Canned brassica	**0.1** **(Step 5)**	The ML applies to the product as consumed.	**The ML for canned brassica once adopted, will be included in the entry for canned vegetables (ML = 0.1 mg/kg).**
Preserved tomatoes	**0.05 mg/kg** **(Step 8)**		Relevant Codex commodity standard is CODEX STAN 13-1981. ~~In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.~~
Processed tomato concentrates	**0.05 mg/kg** **(Step 5)**		Relevant Codex commodity standard is CODEX STAN 57-1981. ~~In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.~~
Canned chestnuts and canned chestnuts puree	**0.05 mg/kg** **(Step 5/8)**		Relevant Codex commodity standard is CODEX STAN 145-1985.
Edible fats and oils	0.1 **(Amendment to the ML)**	Whole commodity as prepared for wholesale or retail distribution.	Relevant Codex commodity standards are CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999, CODEX STAN 211-1999, and **CODEX STAN XXX-2017 (Standard for Fish Oils – once adopted by CAC)**

APPENDIX III

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF ARSENIC CONTAMINATION IN RICE

(At Step 5/8)

1. INTRODUCTION

1.1 Arsenic is a toxic metalloid that may be found in various foods, including rice. Soil in rice paddy fields can contain naturally occurring arsenic and also can be polluted by irrigation water, rain and air that are contaminated with arsenic from anthropogenic sources such as mining and smelting and materials for agricultural and livestock production. Rice plants absorb arsenic from soil, especially when soil is in reducing conditions, and accumulate it in grain and straw. Rice may contain inorganic arsenic (arsenite and arsenate) and organic arsenic (monomethylarsonic acid and dimethylarsinic acid).

1.2 The effectiveness of measures in the Code of Practice can vary depending on local environmental conditions (e.g. soil properties, management regimes and, temperature). Field studies should be conducted to identify measures that are feasible and effective for local or regional conditions. If possible, the field studies should be conducted across crop years because arsenic uptake in rice crops is highly variable from year to year. Implementation of measures that unnecessarily restrict supply of rice to the market should be avoided.

2. SCOPE

2.1 The Code intends to provide national or relevant food control authorities, producers, manufacturers and other relevant bodies with guidance to prevent and reduce arsenic contamination in rice as follows:

i. Source directed measures; and

ii. Agricultural measures

2.2 The Code also includes guidance on monitoring and risk communication.

3. DEFINITIONS

3.1 ***Paddy rice*** (rice grain) is rice (species *Oryza sativa* L.) which has retained its husk after threshing (GC 0649[1]).

3.2 ***Husked rice*** (brown rice or cargo rice) is paddy rice from which the husk only has been removed. The process of husking and handling may result in some loss of bran (CM 0649[1]).

3.3 ***Polished rice*** (milled rice or white rice) is husked rice from which all or part of the bran and germ have been removed by milling (CM 1205[1]).

3.4 ***Arsenic*** is a metalloid and is found in the environment both from natural occurrence and from anthropogenic activity.

Note: In this paper, the term “arsenic” refers to inorganic and organic arsenic.

3.5 ***Organic arsenic*** is an arsenic compound that contains carbon, including monomethylarsonic acid and dimethylarsinic acid.

3.6 ***Inorganic arsenic*** is an arsenic compound that does not contain carbon. Arsenite (As(III)) and Arsenate (As(V)) are the inorganic arsenic compounds typically found in rice. Inorganic arsenic is considered the significant toxic form of arsenic in rice.

3.7 ***Flooded condition*** is a condition in which a paddy field is filled or covered with water during growth.

3.8 ***Aerobic condition*** of soil is a condition in which a paddy field, where rice is grown, is well drained, non-flooded or unsaturated.

3.9 ***Intermittent ponding*** means a variety of possible water management practices in which a paddy field is alternately in flooded and aerobic/non-flooded condition.

4. MEASURES TO PREVENT AND REDUCE ARSENIC CONTAMINATION

4.1 Inorganic arsenic is the most toxic form of arsenic in rice. Measures to reduce arsenic levels (e.g. aerobic growth) may affect inorganic and organic arsenic differently. The most important goal is to reduce inorganic arsenic levels in rice.

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1 *Classification of Food and Feed* (CAC/MISC 4-1989)

4.2 Measures to prevent and reduce arsenic contamination in rice are recommended particularly on highly contaminated areas. National or relevant food control authorities may consider implementing the measures in Section 4.3 as a priority. The measures in Section 4.4 may be implemented if necessary.

4.3 Source Directed Measures

4.3.1 Sources of arsenic in the environment are: 1) natural sources, including volcanic action, elution from soil or sediment such as Holocene sediments, geogenic weathering and low temperature volatilization; and 2) anthropogenic sources, including emission from industries, especially from mining and smelting of non-ferrous metals; burning of fossil fuels; use of arsenic pesticides; and disposal of timber treated with copper chrome arsenate (CCA). In the paddy environment, use of soil amendments and fertilizers contaminated with significant concentration of arsenic are also sources of arsenic[2].

4.3.2 National or relevant food control authorities should consider implementation of source directed measures in the *Code of Practice concerning Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001). In particular, authorities can consider whether measures in the following areas are appropriate for their countries:

- Irrigation water;
  - Identification of irrigation water with high arsenic concentration
  - Reduction of arsenic from irrigation water with high arsenic concentration
  - Avoidance of use of irrigation water with high arsenic concentration for rice production
- Paddy field;
  - Identification of paddy fields in which arsenic concentration in soil is high and/or where rice with a high concentration of inorganic arsenic is produced
- Identification and control of potential sources of arsenic:
  - Atmospheric emissions and waste water from industries;
  - Materials used in agricultural and livestock production such as pesticides, veterinary medicines, feed, soil amendments and fertilizers; and
  - Waste (such as timber treated with copper chrome arsenate).

4.4 Agricultural Measures

4.4.1 National or relevant food control authorities should educate rice producers about practices to prevent and reduce arsenic concentration in rice. Education programmes may include:

- Publishing and disseminating technical guidance on rice cultivation techniques to reduce arsenic in rice
- Establishing farmer field schools

4.4.2 Aerobic conditions or intermittent ponding during rice production, instead of flooded conditions, may reduce arsenic concentration while there is a possibility to increase cadmium concentration in rice. Studies have shown aerobic soils reduce arsenic uptake as compared to flooded soils even when there are high amounts of arsenic in the soil. Intermittent ponding can also reduce availability of arsenic for plant uptake compared to flooded soils.

4.4.3 However, if cadmium concentrations in rice are of concern in a geographic region, risk managers should ensure that implementation of arsenic control measures would not increase cadmium concentrations in rice to unsafe levels[3]. If appropriate, risk managers may consider implementation of source directed measures for cadmium reduction in soil, water or fertilisers that are used for rice production[4].

4.4.4 It is also noted that implementation of aerobic or intermittent ponding conditions may result in a decrease in rice production in some areas and may not be an available practice in all areas. Aerobic growth may also have to be balanced with the use of flooding for weed control or temperature control in cooler areas.

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2 Many fertilizers contain trace levels of arsenic. “Contaminated” should not be interpreted as equivalent to trace levels of arsenic.

3 Use of some rice cultivars that absorb little amount of cadmium, if available, may be a solution.

4 See the *Code of Practice concerning Source Directed Measures to Reduce Contamination of Food with Chemicals* (CAC/RCP 49-2001).

4.4.5 National or relevant food control authorities may identify rice cultivars with low arsenic uptake and/or low arsenic concentration and encourage public research institutes or private firms to develop such rice cultivars. Producers could select such rice cultivars, if available and suitable.

5. MONITORING

5.1 The effectiveness of measures to reduce levels of arsenic should be monitored by determining the concentrations of inorganic arsenic in rice.

5.2 If agricultural land or ground waters used for growing rice are widely contaminated by natural sources, non-point source or past activities, monitoring of arsenic concentrations in soil and/or irrigation water may also be necessary.

6. RISK COMMUNICATION

6.1 National or relevant food control authorities should consider sharing information on risks and benefits of consuming polished and/or husked rice among stakeholders in the light of arsenic concentrations and nutrient components, considering both concerns regarding arsenic concentrations and the nutritional benefits of rice consumption.

6.2 National or relevant food control authorities should consider sharing the following information with distributors and consumers and should consider encouraging them to implement practices that would reduce arsenic concentration during processing and cooking.

6.3 Polished rice contains less inorganic arsenic than husked rice, because polishing removes the bran layer which contains most of the inorganic arsenic. Husked rice polished at the higher polishing rate results in polished rice with lower arsenic concentrations. However, there are also benefits associated with consumption of husked rice.

6.4 Arsenic concentration in rice can be reduced by washing rice, applying “rinse-free”[5] treatment or cooking rice with large amounts of water followed by discarding excess water.

6.5 When water used for cooking is highly contaminated with arsenic, national or relevant food control authorities should inform consumers that they should avoid use of such water for washing and cooking rice, as rice absorbs arsenic in water. Consumers should be encouraged to use water for washing and cooking rice that contains lower concentration of arsenic.

[5] “Rinse-free” rice, also known as “Musemmai”, is rice in which bran that remains on the surface after polishing is completely removed and thus it is not necessary to wash before cooking.

APPENDIX IV

PROPOSED DRAFT MAXIMUM LEVEL FOR TOTAL AFLATOXINS (AFT) FOR READY-TO-EAT PEANUTS

(At Step 3)

AFLATOXINS, TOTAL

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Peanuts	[10] or [15]		The ML applies to peanuts “ready to eat”

APPENDIX V

ANNEX 6 TO THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXIN CONTAMINATION IN CEREALS (CAC/RCP 51-2003)

PREVENTION AND REDUCTION OF CONTAMINATION BY ERGOT AND ERGOT ALKALOIDS IN CEREAL GRAINS

RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP) AND GOOD MANUFACTURING PRACTICES (GMP)

(at Step 5/8)

1. The recommended practices are in principle relevant for all cereals but in particular applicable to the crops most sensitive to ergot sclerotia contamination, such as rye, triticale, sorghum and pearl millet. The increased prevalence of ergot sclerotia in wheat may also be an emerging issue in some countries.

2. Good Agricultural Practices include methods to reduce *Claviceps* (mainly *C. purpurea*) infection and ergot alkaloid (related to ergotism) contamination of cereals during crop growth and development, harvest, storage, transport and processing. This Annex refers to the control of the Claviceps species only.

Planting and crop rotation

3. Refer to paragraph 11 in the general Code of Practice.

Tillage and preparing for seeding (Planting)

4. Refer to paragraphs 12-16 in the general Code of Practice.

5. Early and simultaneous flowering of the crop is the best way to counteract *Claviceps* infection. The following recommendations help to prevent *Claviceps* infection of cereals:

   a. Ensure use of ergot-free seeding material and good establishment with optimum plant populations, applications of fertiliser and plant growth regulators and good drainage.

   b. Ensure good control of grass weeds (especially those that are hosts to *Claviceps*) within a field. Particular attention should be paid to grass weed populations on the headlands of a field. Both cultural and chemical methods can be used. The control of grass weeds should be continued, especially when ergot contamination is known to have occurred on a field.

   c. The laying of sufficiently wide tramlines for agricultural vehicles to avoid the green shoots that increase the risk of infection, may be considered.

6. Where the preceding cereal crop had been infected with ergot disease (or where there is a substantial grass weed population that was infected with ergot disease):

   a. The cultivation of the subsequent cereal crop should be by inversion ploughing.

   b. Ploughing should not then be used in the subsequent cereal crop as this may return sclerotia to the land surface.

   c. Where minimal cultivations are used, the seed depth should be at least 5 cm (0.16 ft).

   d. Alternatively, the field should be kept free from cereal production in the second year.

   e. Where low and zero tillage crop rotation practices are normally followed, other mitigation measures take on greater importance (measures at pre-harvest stage, drying and cleaning).

Pre-harvest

7. Refer to paragraphs 17-23 in the general Code of Practice.

8. Consider a partial harvesting of the crop as an option. Field/subsections with a high incidence of ergot, may be threshed separately, while ensuring the safety of humans and animals. More sclerotia can be found near a field margin (greater than 1 m) in comparison with zones deeper in the field (at least 30 m from field margin). Separate harvesting of field borders (3-4 m zone) could significantly decrease ergot sclerotia in the yield.

Harvest

9. Refer to paragraphs 24-27 in the general Code of Practice.

10. Air-stream cleaning should be used, as far as possible, to remove ergot sclerotia and dust from the grain.

Drying and cleaning before storage

11. Refer to paragraphs 28-33 in the general Code of Practice.

12. Sclerotia present in the harvested grain have a softer, more supple structure than the harvested cereal grains.

    a. Therefore any sticky material from the sclerotia could adhere to the surface of the grain. In addition, breakage can occur very easily, and the very fine ergot dust could become deposited on the grains' surface. Thus, it is important that the ergot sclerotia are removed from the cereal grain as soon as practicable.

    b. In addition, it is important to eliminate as many ergot sclerotia and dust particles as possible at each stage of the food processing chain to prevent carryover to the next stage of processing.

Storage after drying and cleaning

13. Refer to paragraphs 34-43 in the general Code of Practice.

Transport from storage

14. Refer to paragraphs 44-46 in the general Code of Practice.

Processing and cleaning after storage

15. Refer to paragraphs 47-54 in the general Code of Practice.

16. Colour sorting based on the clear-cut distinction between the colour of ergot sclerotia and that of cereal grain should be considered, since this is an efficient method to remove sclerotia. Other recommended separation techniques, such as weigh selectors, gravity tables or indented cylinder separators (trieurs) may also be used.

17. Following the use of the above-mentioned separation techniques, other processes that support the cleaning of the cereal (scrubbing, brushing, peeling and scouring) should be considered in order to remove the ergot dust on the surface.

18. To prevent ergot dust from accumulating in the milled flour, the flour filter in the crusher area of the mill unit may be replaced as appropriate.

19. All waste material should be disposed of in a manner to prevent re-entry into the food or feed supply chain.

APPENDIX VI

PROPOSED DRAFT CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF MYCOTOXINS IN SPICES (At Step 5/8)

1. INTRODUCTION

1. The production, processing, packaging and distribution of spices can be very complex. These processes can span long periods of time and possibly include a wide range of establishments. Dried product processing generally involves cleaning (e.g. culling, sorting to remove debris), grading, sometimes soaking, slicing, drying, and on occasion grinding/cracking. Some spices are also treated to mitigate microbial contamination. Processing and packaging/repackaging may also take place in multiple locations over long periods, since spices are prepared for different purposes.

A. Objectives

2. The objective of this document is to establish a general code of practice for the prevention and reduction of mycotoxins in spices in order to attain as low as reasonably achievable level of these toxins by applying specific Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs) and Good Storage Practices (GSPs) throughout all the steps in the food chain, thus reducing consumers' exposure through preventive measures.

B. Scope, use and definitions

Scope

3. This Code applies to spices - whole, broken, ground or blended. Dried aromatic herbs are not included under the scope of this COP.

Use

4. This Code should be used in conjunction with the Code of Hygienic Practice for Low Moisture Foods (CAC/RCP 75-2015) and its annex on spice and culinary herbs, and other relevant Codex Codes of Practice.

5. This Code is a recommendation to which producers, transporters, processors and manufacturers in different countries should adhere as far as possible taking into account the local conditions and difficulties in implementation of all the measures specified therein while ensuring the safety of their products in all circumstances. Flexibility in the application of certain requirements of the primary production of spices can be exercised, where necessary, provided that the product will be subjected to control measures sufficient to obtain a safe product.

Definitions

6. ***Spices*****:** dried plants or parts of plants (roots, rhizomes, bulbs, bark, flowers, fruits, and seeds) used in foods for flavouring, colouring, and imparting aroma. The term applies equally to spices in the whole, broken, ground and blended forms, including also spices harvested as dried.

7. **Source Plant**: plant (non-dried) from which the spice is derived.

2. RECOMMENDED PRACTICES BASED ON GOOD AGRICULTURAL PRACTICES (GAP), GOOD MANUFACTURING PRACTICES (GMP) AND GOOD STORAGE PRACTICES (GSP)

2.1 Pre-harvest agricultural conditions

8. Spices are susceptible to contamination by toxigenic fungi in the field, during drying and storage. The use of appropriate GAP to reduce the toxigenic fungi growth and dissemination is recommended.

9. When appropriate, an appropriate crop rotation or sequence is recommended in order to regenerate the soil fertility and reduce the inoculum load of the relevant toxigenic fungi, to minimize the carry-over of mould from one year to the next. It is also appropriate to avoid vicinity of crops which are known to be host plants for *Aspergillus flavus,* such as maize.

10. Reduction of plant stress using irrigation, fertilization, pruning and pest and disease control should be implemented.

11. Insect damage which enhances fungal infection in the vicinity of the crop, can be minimized by proper use of registered insecticides and other appropriate practices within an integrated pest management program.

12. When conditions require, recommended insecticides may be necessary to minimize damage to source plants, which may later favour entry and development of toxigenic fungi; for example, through open galleries made by caterpillars.

13. Weeds around the crop should be controlled by use of mechanical methods or by the use of appropriate registered selective herbicides or other safe and suitable weed eradication practices. Avoiding the use of livestock manure as fertilizer can help control the proliferation of both weeds and toxigenic fungi. It may also be useful to establish an appropriate planting density to further discourage weed proliferation during plant development.

14. The use of recommended soil fungicides in the process of farm soil preparation may be beneficial to reduce the inoculum load of toxigenic fungi. The presence of debris in bare seed may also provide a vector for fungal infection. At sowing, use disinfected seeds to prevent mould and insects and carefully choose the planting season so that the collection of plants takes place in the driest season. This good practice is essential in areas with a warm and humid climate.

15. The use of fungicides is a very effective practice to prevent fungal growth. However, fungicides must be applied with special care since some of them could lead to the reduction of certain non-toxigenic fungal flora and stimulation of other toxigenic fungi growth.

16. It is recommended that untreated organic waste not be applied to soil as it could allow the proliferation of toxigenic fungi, human pathogens, food spoilage bacteria, and also weed seeds and other unwanted plants. This is particularly important for spices that are swathed rather than straight cut, as rain splash is more likely to contaminate swathed spices. The use of properly treated organic waste (compost) or treated sewage (or biosolids) is encouraged in order to improve soil fertility and increase competitive fungi.

17. Spray irrigation should be avoided during the flowering period for all the spices coming from aerial parts of the plant. This could increase both the rate of normal dispersion of spores and the chances of source plant infection with toxigenic fungi. It is recommended also to avoid flood irrigation because it could spread disease throughout the field.

18. Soil with good drainage must be chosen in order to avoid water logging.

19. It is recommended that diseased and injured plants or parts thereof be removed from the field in order to reduce the inoculum load of toxigenic fungi.

2.2 Post-harvest agricultural conditions

2.2.1 *Harvest*

20. During the harvesting operation, the moisture content should be determined in each load of the harvested commodity since it affects drying times. To the extent possible, avoid harvesting crops with high moisture content (for instance, due to precipitation or morning dew and/or during late afternoon) as it takes a longer time to dry and increase the likelihood of fungus growth and mycotoxin formation.

21. Mechanical damage of the plant material, a type of stress that occurs during the post-harvest manipulation of crops, which is accompanied by physiological and morphological changes that increase the possibility of subsequent fungal contamination, should be avoided.

22. Spices coming from aerial parts of the plant that have fallen to the ground are known to be exposed to mould growth. Crops that are affected by mould or infected should be removed. Alternatively, the source plant that has fallen to the ground can be collected separately and can be included in the main lot after it has been washed, cleaned, dried and evaluated for contamination.

23. When it is feasible, the soil under the plant should be covered with a clean sheet of plastic during harvest to prevent commodities from getting contaminated by dirt or mixed up with mouldy parts of the plant that have fallen prior to harvesting. It is not applicable to spice rhizomes.

24. Wherever possible a system for differential harvesting should be applied, so that once products are ripe they are harvested. This ensures good quality and helps prevent mould growth and mycotoxin production from overripe crops. In case of harvesting unripe crops, more time is needed to dry than ripe crops.

25. If possible, only the amount that can be processed in a timely manner should be picked in order to minimize growth of toxigenic moulds prior to processing.

26. It is important that the pre- harvest interval advised on the label of the fungicide is observed.

27. Wherever possible, the harvesting procedures implemented each season should be documented by making notes of measurements (e.g. temperature, moisture, and humidity) and any deviation or changes from recommended practices. This information may be very useful for explaining the cause(s) of fungal growth and mycotoxin formation during a particular crop year and may help to avoid similar mistakes in the future.

2.2.2 *Drying on the farm*

28. The main purpose of the drying operation is to efficiently decrease the high water content of the just harvested spices to a safe level in order to get a stable, safe and good quality product. Drying of crops should begin immediately after harvest and farmers should not hold the crop in piles or in bags for long period of time. When necessary, plastic sheets should be used to cover the crop in the event of rain during the drying process. The drying yard should be located away from contaminant sources such as dusty areas and should receive maximum sun exposure and air circulation, during most of the day, to speed up the drying of the spices. Shady and low areas should be avoided.

29. The surface for the drying yard should be chosen according to the climate of the region, cost and quality of the dried product, as any type of surface has advantages and disadvantages. Bare soil is not appropriate for rainy areas. Plastic canvas gets humid under the spice layer, promoting fungal growth. In rainy or wet regions spices must be covered and re-spread, once the surface has dried.

30. The pace and total time of the harvest should be based on the available area of the drying yard and the average time necessary for drying, considering both good and bad weather.

31. The following practical measures should be incorporated into the drying process;

    a. Dry spices only in thin layers, 3 to 5 cm in depth. In some cases (e.g. low air humidity, good air circulation and sun intensity, or in usually dry regions), thicker layers can be used.

    b. Turn over the spice layer constantly during the daytime to allow faster drying, to reduce the risk of fungi growing and help to produce a better quality product.

    c. Allow for the appropriate ventilation of the wet spice during the night in order to avoid condensation.

    d. Do not mix different types of spices nor spices from different days of harvest. Use a specific identification for each one of them to identify each type of spice and day of harvest.

    e. Protect the drying yard area from animals, which can be a source of biological contamination for the drying spice.

    f. In order to avoid insect damage during drying, check for the presence of insects and if necessary use integrated pest management in drying yard for the control thereof.

    g. Monitor the drying process regularly. Start taking samples from different points of each lot, two or three days before it is expected to be fully dry and continue re-evaluating it daily until it reaches the desired moisture content. Instrumental measurements should be adopted at field level.

    h. Avoid rewetting the spices because it favours rapid fungal growth and the possibility of aflatoxin and OTA production.

32. Provide a clear and practical training for drying yard workers, including adequate use of moisture measuring equipment.

33. Repair, clean, protect and keep equipment in a clean storage area until the next season. Moisture measuring equipment should be regularly cross checked and calibrated once a year before harvest

34. In the sun drying process, the product is spread on surfaces such as cement or brick terraces, tarpaulin, plastic canvas, bamboo and sisal mats, raised tables covered in wire mesh or fish farm netting (paragraphs 49 and 55.1a also apply on the farm).

35. The drying process can be divided into three stages. In each stage, aflatoxin and OTA producing fungi will have varying opportunities for growth:

    a. At the first stage, there is a slight decrease in moisture content. The high moisture content ($a_w > 0.95$) provides unsuitable conditions for aflatoxin and OTA producing fungi to grow. However, other microorganisms, such as other hydrophilic fungi (yeasts and moulds) and bacteria, may spoil the product if it is kept too long at $a_w > 0.95$ after harvest.

b. The second stage is the one of maximum loss in moisture content. During this stage (a_w lower than 0.95 but higher than 0.80), there are favourable conditions for aflatoxin and OTA producing fungi to grow and therefore it is necessary to implement precautionary measures as recommended in paragraphs 28 to 33.

c. The third stage which starts at a_w 0.80, is much drier compared to the previous two stages. There is a slower slight decrease in the remaining moisture content. Conditions at this stage do not favour the growth of aflatoxin and OTA producing fungi.

36. Therefore the most important point is to control the period of time in which the spices remain in the drying yard, in the range of water activity where aflatoxin and OTA-producing fungi can grow (aw 0.8–0.95). Five days or less in the drying yard is enough and effective to prevent aflatoxin and OTA accumulation. In general, a maximum a_w of 0.65 is sufficient for protecting spices from damage by fungi.

2.2.3 *Transport*

37. Containers and transportation devices (e.g. wagons, trucks) to be used for collecting and transporting the harvested commodity from the field to drying and storage facilities after drying, should be clean, dry and free of crop residues, old plants, plant dust, insects and visible fungal growth before use and re-use.

38. Harvested commodities that have not been dried to a safe storage moisture level at farm level should not be stored, but shall be transported to a processing plant to be dried without delay.. When necessary, it is recommended that the trucks and containers should allow appropriate aeration and minimize the condensation effects, under conditions protected from rain (e.g. lateral openings).

2.2.4 *Storage (source plant)*

39. Fresh material for spices or source plants should be processed as quickly as possible. Avoid storage of source plants as any period of storage (in a bag or in a pile) increases the likelihood of mould growth. Wherever possible, start drying on the day of harvesting. Source plants should be packed in bags made of porous material such as jute bags or woven plastic bags. Avoid non-porous plastic bags for packing of dried products.

40. Gunny bags should be stored off the floor (on pallets) and away from the walls (at least 30 cm) so that any potential condensation does not cause the product to become wet and to avoid the chance of moisture entering through the wall. Internal walls, floor surfaces, the junctions of the floor with the walls and the junctions between two walls should be made with a smooth, water-proof, non-absorbent, washable and non-toxic material.

41. Control of insect and rodent activity and maintenance of appropriate moisture levels and temperature in the storage room is essential. Insects and rodents can spread contamination and spoil the crop.

42. Storage facilities should include dry, well-vented structures that provide protection from rain, drainage of surface water, protection from entry of rodents and birds, and minimum temperature fluctuations.

43. The storage facilities should be cleaned and disinfected with appropriate substances (which should not cause off-odours, flavours or contaminate the crop). The use of registered fumigants or insecticides within the permissible level may be useful.

44. Store fresh material for spices or source plants in suitable storage temperature, for example, 5 to 8 degrees Celsius. Care must be taken in cold storage to prevent condensation from the chiller units falling onto the product.

45. Relative humidity of storage conditions should be controlled as appropriate, for example, less than 75 % for lower water activity of source plant.

2.3 Industrial processing conditions

2.3.1 *Sorting*

46. It is necessary to separate the raw material upon receipt, to prevent any cross-contamination during the cleaning, washing, and processing stages.

47. Raw materials should be inspected and sorted prior to introduction into the processing line. The inspection may include visual inspection and removal of foreign material, the absence of any musty odours and analytical tests for mycotoxin contamination.

48. When necessary, prior to drying, the harvested products should be sorted to remove any visible organic debris or mouldy products before washing with potable water. Prior to washing, there should be a selection process to eliminate any fresh source plant showing symptoms of fungal infection, and small portions of any contaminated part should be removed, because they can contaminate a whole batch. This procedure can be carried out on the farm. The discarded materials should be properly disposed of in order to avoid the recontamination of the clean material. If washing is not needed it should not be carried out as washing might spread the contamination of certain hot spots to the rest of the harvest.

2.3.2 *Processing*

49. The time between harvesting and drying should be as short as possible, including transport from the field to post-harvest facilities. Drying should be done on a concrete surface, preferably a raised platform. Whenever possible, avoid drying on plastic sheets or tarpaulins as the moisture remains in contact with the source plants during the drying process. In case those plastic sheets or tarpaulins are used, extra care should be taken for homogeneous drying by shifting the spices at regular intervals.

50. Proper storage is necessary to prevent biological activity through adequate drying to an appropriate moisture level for the spice. The raw material for spices may need to be covered with plastic sheets at night to avoid having dew come in contact with the raw material. Care must be given to minimize moisture condensation. Growth of mould prior to, during and after drying may result in mycotoxin production. Inappropriate handling of raw materials may support the growth of several spoilage and toxigenic moulds prior to drying. Proper drying of spices to achieve a water activity below 0.65 is adequate to prevent mycotoxin production. Below a water activity of 0.65, there is hardly any mould growth.

51. The drying area should be elevated to prevent pest ingress and potential flooding, and should be constructed of a material that can easily be cleaned and that will not contaminate the stored spices.

52. A concrete pad can serve this purpose and in this case it should have a slightly sloping surface to allow water runoff from the product and may require a perimeter fence to prevent farm animals, pets, pests, etc. from accessing the source plant or raw material for spices as it is drying.

53. It is important to ensure that the drying yard is cleaned prior to use.

54. Drying of source plants may be performed mechanically (for rapid drying) or naturally (e.g. slower drying under the sun for several days). Both processes are detailed in the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015), Annex III, Annex on Spices and Dried Aromatic Herbs, For instance, mechanical drying is recommended for plant sources such as nutmeg as the harvest occurs during the rainy season.

55. Drying methods:

    1. Sun drying

        a. Drying should not occur directly on the ground. Use trays, bamboo mats or drying yards, and make sure that these are clean as it is known that mould spores from previous use could re-contaminate product during drying. Techniques for cleaning all of the above should be taught to farmers. Never use unhygienic materials (such as cow dung paste) in bamboo mats to fill the holes.

        b. The availability of additional tarpaulins should be ensured to cover the source plant (raw material) in case of any unexpected rain. When using tarpaulins, care should be taken that condensation of water is prevented, e.g. by keeping lateral holes to increase ventilation.

        c. Drying areas should be raised from the ground to prevent water or pests from entering. Sun drying by using trays put on racks at a sufficient distance from soil may be applied. This practice allows air circulation to accelerate the drying.

        d. Pathways should be made in the drying area to prevent walking on the source plant, as this can damage the source plants and leads to mould growth.

        e. The layer of drying spices should not be more than 4 cm thick, the drying raw material must be regularly raked (5-10 times per day) and should be protected during drying from rain, night dew and any other sources of moisture. Raw materials that have been dried should not be allowed to get wet again during storage or at any other time.

    2. Controlled drying

        a. A controlled drying system can be employed to give better quality, reduce fungal contamination and ensure less risk of mycotoxin production.

b. Solar drying is one method, where raw materials are protected in polythene tunnels and the temperature is controlled through the use of air circulation. Such tunnels should be designed so that the risk of condensation on the crop is eliminated.

c. Hot air drying can also be employed and care should be taken to ensure that there is no risk of fumes from the fuel coming into contact with the product. This can be best achieved through the use of a heat exchanger so that only clean air comes into contact with the product.

d. A solar heat exchanger can also be used where hot air is generated from the sun's rays.

e. The recommended optimum drying temperature is 50-60 Celsius degrees and relative humidity in the drying chamber should be reduced for the spice to achieve a safe moisture level (12-14% has been shown to be safe in most cases).

3. Smoke drying

a. Refer to the *Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes* (CAC/RCP 68-2009). This type of controlled drying must be carried out in drying houses. Drying houses have a variable size, but the structure is either rounded or squared, around five meters high. The material used to build the drying house is terracotta or bricks. The smoke is produced with wood and the temperature must be under control.

b. This system is conducive to slow, gentle, non-aggressive drying so that within 10 to 15 days the water content of the fruit falls from 80 % to under 15 %. The final product obtained has a smoky taste and aroma and a very stable colour.

56. Before grinding the source plant, a cleaning step can be applied as an optional choice.

57. Sterilization processes are effective in reducing the mould load in spices. These mould-reducing processes should be considered once the spice is dry (final processing). There is at least one process authorized for reduction of fungal growth in spices (irradiation) in some countries/regions. Irradiation should be applied in accordance with *Code of practice for radiation processing of food* (CAC/RCP 19-1976). It should not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices. It has been proven to be efficient in eliminating fungi in chilli, coriander, cumin, turmeric and Ashanti pepper. Moreover, other treatments, such as UV, can be utilized to reduce or eliminate toxigenic fungal spores in spices. However, these treatments do not reduce the level of mycotoxins formed earlier in the chain.

2.3.3 *Storage after Drying and Cleaning*

58. Fungal growth on stored spices is mainly influenced by temperature and relative humidity of the storage facility and the moisture content of the spice. Storage condition should best keep the spices at a_w of <0.65.

59. Temperature levels within large warehouses can be ideal for mould growth, particularly towards the roof, thus suitable ventilation should be provided in order to ensure proper management/control of both temperature and humidity.

60. It is recommended that local ventilation systems be employed to produce currents of cold, dry air to assure good ventilation. Storage in a clean, dry place; protected from dust, debris, insects, rodents, other animals and birds, and away from areas of excessive human or equipment traffic is also recommended. Product should be stored in well maintained warehouses that do not allow the ingress of water through open windows, gaps beneath doors, or leaks in the storage enclosure.

61. Spices should not be stored with other food commodities (such as fruits, vegetables, fish) or non-food products (such as kerosene, lubricating oils) that may affect the moisture content leading to the growth of toxigenic fungi or alter the flavour or colour of the spice and provoking the unacceptable contamination of the spice with these non-food products

62. It is also important to ensure that product is stored off the floor and away from the walls so that any potential condensation does not cause the product to become wet. In addition, there should be good air circulation through the warehouse to prevent condensation and mould growth.

63. To the extent possible, storage locations should prevent access by rodents or other animals and birds and should be isolated from areas of excessive human or equipment traffic.

64. Practices should be in place to minimize insect infestation in the spices at all stages of production, particularly during storage. Increased insect populations raise both the temperature and moisture content of the spices allowing for the subsequent growth of moulds and production of mycotoxins. The movement of insects through the spices can facilitate the distribution of the moulds and mycotoxins throughout the product.

65. The effectiveness of chemical compounds used to prevent fungal growth and mycotoxin production has to be demonstrated. Treatments with approved chemicals including sodium bisulfite, ozone, or acids and bases represent an opportunity to control fungal growth and mycotoxin biosynthesis in stored spices. The use of bases such as ammonia that can affect the aroma of spices is not recommended.

66. The storage procedures implemented each season should be documented by making notes of measurements (e.g. temperature, moisture, and humidity) and any deviation or changes from recommended practices. This information may be very useful for explaining the cause(s) of fungal growth and mycotoxin formation during a particular crop year and may help to avoid similar conditions in the future.

2.3.4 *Transport from Storage*

67. It is important that the operator select reliable transport service-providers that adopt this code of practice and ensure appropriate transport conditions.

2.3.4.1 *Preventing moisture accumulation*

68. When the commodity is moved into or out of the warehouse, ensure that it is protected from the rain.

69. During transportation, attention should be given to avoid re-entry of water/moisture into the commodity and to ensure that pests or debris cannot penetrate into the commodity.

70. Regular checks should be made to ensure that the truck is covered and that there are no rips in the covers and no leaks on the undersides of trucks which could allow water from the road to get into the truck. Check from the inside by closing all doors and looking for holes where daylight is visible.

71. Trucks must be clean, dry and odour-free which helps to prevent cross contamination from previously transported products.

72. The pallets or wooden floors of transport containers should be dry. For products that require a long period of transportation, temperature and humidity should be monitored, where appropriate. Spices absorb moisture quickly if the bags get wet and as a result the moisture content increases considerably.

2.3.4.2 *Hygiene practices during transportation*

73. Refer to the *Code of Hygienic Practice for Low-Moisture Foods* (CAC/RCP 75-2015), Annex III on Spices and Dried Aromatic Herbs.

74. Bags should preferably be placed on a layer of pallets to avoid contact with the floor where condensation from the ceiling and walls may gather. If available, fully ventilated containers are preferable for spices in bags, especially if shipped from a high humidity region.

75. Desiccant boxes filled with calcium chloride can absorb around 100 % of their own weight in moisture and may be used for added protection.

76. It is important that care is taken not to damage these dry-bags and any spillages should be cleaned up immediately.

77. It is important to maintain ample space between bags and the roof of the containers or transportation devices. Use of the saddle stow method, which minimizes side contact and maximizes airflow between the bags, is recommended.

2.3.5 *Packaging*

78. Because dried spices are hygroscopic, they must be packaged quickly after processing using a material that serves as a barrier to moisture. The use of packaging technologies that prevent the inflow of moisture, such as vacuum or modified atmosphere, with the use of the appropriate packaging material is an option of use.

79. Use of appropriate packaging can help to prevent insect contact with the commodity and therefore, limits mould growth. Packaged commodities should be kept free of moisture or humidity.

80. Packaging activities can occur in the growing/harvest area. Such packing operations should include the same sanitary practices, where practical, as packing spices in establishments or should be modified as needed to minimize risks. To prevent germination and growth of fungal spores, the products must be dried to a safe moisture level prior to packing.

81. New bags should be used when packing spices in the growing/harvest area for transport, storage, or for further sale, to prevent the potential for microbial, physical and chemical contamination.

82. Containers should be inspected immediately before use to ensure that they are in a satisfactory condition, as defined by the manufacturer, and where necessary, cleaned and/or disinfected; when washed, they should be well drained and dried before filling.

83. Removal of discarded plant material should be done on a regular basis in order to avoid accumulation that could promote the presence of pests.

2.3.6 *Product information and consumer awareness*

84. The manufacturer should comply with the provisions set up in the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) when indicating the best-before date and specific storage instructions for the commodity. This date will be justified by completing appropriate studies that take into account the characteristics of the packaging, examining unfavourable conditions that may promote mould growth and verifying the quality of the final product in order to give assurance that no mycotoxin contamination will occur until the end of the shelf-life indicated for consumption of that commodity.

85. .Consideration should be given to provide consumer information on following storage instructions to maintain the product in a cool, dry, well-ventilated area away from heat sources such as ovens and areas with high humidity and avoid storing in a refrigerator to prevent condensation, etc. This consumer information may include tips for good use to avoid mould growth by avoiding contact with wet utensils and wooden spoons, closing containers tightly immediately after use, avoiding unnecessary stockpiling and checking the best-before date.

APPENDIX VII

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON ESTABLISHMENT OF MAXIMUM LEVELS FOR MYCOTOXINS IN DRIED OR DEHYDRATED FORMS OF NUTMEG, CHILI AND PAPRIKA, GINGER, PEPPER, AND TURMERICAND ASSOCIATED SAMPLING PLANS

1. Purpose and Scope

- The purpose of the work is to ensure fair practices in international food trade and to protect public health by harmonizing the levels of mycotoxins in dried/dehydrated forms of nutmeg, chili and paprika, ginger, pepper, and turmeric.
- The scope of the work is to establish Codex maximum levels (MLs) of total aflatoxins and ochratoxin A in dried/dehydrated forms of nutmeg, chili and paprika, ginger, pepper, and turmeric and associated sampling plan(s).

2. **Relevance and Timeliness**

Nutmeg (Binomial name: *Myristica fragrans.*), chilli and paprika (Binomial name: *Capsicum annuum* L.), ginger (Binomial name: *Zingiber officinale*), pepper (Binomial name: *Piper nigrum* L.), and turmeric (Binomial name: *Curcuma longa* L.) in dried or dehydrated forms are spices prominently produced and traded globally. They are traded in both whole and ground forms. These spices are reported to have higher susceptibility towards mycotoxin contamination.

Aflatoxins (AFs) were evaluated by the JECFA at its thirty-first, forty-sixth, forty-ninth and fifty-sixth meetings. Ochratoxin A (OTA) was evaluated by the JECFA at its thirty-seventh, forty-fourth and fifty-sixth meetings. The Provisional tolerable weekly intake (PTWI) of 100 ng/kg body weight is maintained for OTA at the latest (JECFA, 2007).

The hazardous nature of mycotoxins to humans and animals has necessitated the need for establishment of control measures and tolerance levels by national and international authorities. Many countries in the world have MLs for Aflatoxin B_1, total aflatoxins and ochratoxin A in spices. But different regulations (MLs) for mycotoxins in various countries are a potential impediment to the international trade.

3. **Main aspects to be covered**

- Establishment of MLs for total aflatoxins and for ochratoxin A in dried or dehydrated nutmeg, chili and paprika, ginger, pepper, and turmeric.

4. **Assessment against the Criteria for the establishment of work priorities**

This proposal complies with the following criteria for establishing priorities of work:

a) Diversification of national legislation and apparent resultant or potential impediments to international trade.

Spices are commodities worldwide traded. About 41 countries and the European Union have different MLs for mycotoxins in spices/foods. Diversification of national and regional legislations has the potential to create technical barriers to trade, therefore there is a need to harmonize measures at international level.

b) Work already undertaken by other organizations in this field

The risk assessment has been already done for aflatoxins and ochratoxin A by JECFA.

5. Relevance to the Codex Strategic Objectives

The proposed work has relevance with Codex Strategic Goals 1 and 2.

Goal 1: Establish international food standards that address current and emerging food issues

- Mycotoxins are potential contaminants in various spices. Therefore, establishment of MLs for mycotoxins in dried or dehydrated nutmeg, chili and paprika, ginger, pepper, and turmeric is necessary to ensure consumers' health and to promote fair practices in trade.

Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

The establishment of MLs shall take into account the exposure assessment proposal by JECFA.

6. Information on the relation between the proposal and other existing Codex documents

There are no Codex maximum levels for mycotoxins in spices set by the Codex Alimentarius Commission.

7. Identification of any requirement for and availability of expert scientific advice

Exposure assessment for health impact on proposed MLs for spice(s)/mycotoxin(s) combinations might be required.

8. Identification of any need for technical input to the standard from external bodies

Not anticipated at this stage.

9. Proposed time-line for completion of the work

Subject to approval by the Codex Alimentarius Commission, the proposed new work to establish maximum levels for mycotoxins in dried or dehydrated forms of nutmeg, chili and paprika, ginger, pepper, and turmeric will be considered by CCCF12 with a view to its adoption in 2019, depending upon the availability of scientific advice (see point 7).

APPENDIX VIII

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR METHYLMERCURY IN FISH

1- Purpose and Scope of the new work

This work aims to establish Maximum Levels (MLs) for methylmercury in fish, including associated sampling plans.

2- Relevance and timeliness

The current GLs for methylmercury in fish (1 mg/kg for predatory fish and 0.5 mg/kg for other fish species2) were adopted in 1991[1]. In 2003, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) revised the provisional tolerable weekly intake (PTWI) for methylmercury to 1.6 µg/kg body weight from 3.3 µg/kg body weight, based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans)[2]. Also, the current Guideline Levels (GLs) did not take into account net effects that include both adverse contributions from methylmercury and beneficial contributions from nutrients in fish on the same health endpoints (CX/CF 13/7/16, para. 75; REP13/CF, para. 118).

In this context, the current GLs for methylmercury in fish should be reviewed to establish appropriate ML(s) taking into consideration the results of discussion of the Codex Committee on Contaminants in Food (CCCF), risk assessments by the JECFA and the conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption[3].

3- Main aspects to be covered

ML(s) for methylmercury in fish, taking into account the following:

a) Results of discussions of the CCCF

b) Risk assessments by JECFA

c) Conclusions of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption

d) Achievability of the MLs

A call for data for methylmercury levels and EPA+DHA levels in fish would be needed to revisit the proposed MLs.

- An associated sampling plan

4- Assessment against the criteria for the establishment of work priorities

- *Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.*

The new work will establish Maximum Level(s) for methylmercury in fish.

- *Diversification of national legislation and apparent resultant or potential impediments to international trade.*

The international trade of fish and fishery products is increasing, and the new work will provide an internationally-harmonized standard.

- *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).*

While the analyses on benefit and risk of fish consumption have been conducted by several Codex members, the proposed work to establish ML(s) for methylmercury in fish globally has not been undertaken by any other international organizations in this field nor suggested by any relevant international intergovernmental bodies.

[1] CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food (GSCTFF).
[2] Joint FAO/WHO Expert Committee on Food Additives (JECFA), report of the sixty-first meeting, Rome 10-19 June 2003 (ftp://ftp.fao.org/es/esn/jecfa/jecfa61sc.pdf).
[3] the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption, FAO Fisheries and Aquaculture Report No. 978. Rome, 25-92 January 2010. Accessed Feb 8, 2017: http://www.fao.org/docrep/014/ba0136e/ba0136e00.pdf)

- *Consideration of the global magnitude of the problem or issue*

The consumption and international trade of fish and fishery products are increasing globally, and thus this work is of worldwide interest and becoming increasingly significant.

5- Relevance to Codex Strategic Goals

The proposed work falls under the following Codex Strategic Goals of the Codex Strategic Plan 2014-2019:

- *Strategic goal 1: Establish international food standards that address current and emerging food issues*

This work was proposed in response to needs identified by Members in relation to food safety, nutrition and fair practices in the food trade. There is already significant trade in fish species which have methylmercury levels which exceed the current GLs.

- *Strategic goal 2: Ensure the application of risk analysis principles in the development of Codex standards*

This work will use the scientific advice of the joint FAO/WHO expert bodies to the fullest extent possible. Also, all relevant factors will be fully considered in exploring risk management options.

- *Strategic goal 5: Promoting maximum application of codex standards*

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work

6- Information on the relationship between the proposal and other existing Codex documents

This new work is recommended following the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF).

7- Identification of any requirement for and availability of expert scientific advice

Expert scientific advice has been already provided by JECFA and the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption.

8- Identification of any need for technical input to the standard from external bodies

Currently, there is no need for additional technical input from external bodies.

9- The proposed timeline for completion of the new work, including the starting date, proposed date of adoption at Step 5 and the proposed date for the adoption by the Commission, the timeframe for developing a standard should not normally exceed 5 years.

Subject to the approval by the Codex Alimentarius Commission in 2017, the proposed draft ML(s) for methylmercury in fish will be considered at CCCF12 with a view to its finalization in 2020 at the latest.

APPENDIX IX

PROJECT DOCUMENT

PROPOSAL FOR NEW WORK ON THE REVISION OF THE CODE OF PRACTICE FOR THE PREVENTION AND REDUCTION OF DIOXIN AND PCB CONTAMINATION IN FOOD AND FEED (CAC/RCP 62-2006)

1. Purpose and Scope

The purpose of the proposed new work is to provide to member countries and the food and feed producing industry, guidance to prevent and reduce non dioxin-like (NDL) polychlorinated biphenyl (PCB) contamination in food and feed.

2. Relevance and Timeliness

At its 80th meeting in 2015, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed the toxicity of NDL-PCBs[1]. JECFA concluded that based on the available data, dietary exposures to NDL-PCBs are unlikely to be a health concern for adults and children. For breastfed infants, the safety margins would be expected to be lower. However, based on present knowledge, the benefits of breastfeeding are considered to outweigh the potential disadvantages that may be associated with the presence of NDL-PCBs in breast milk.

Therefore it remains important that efforts are undertaken to reduce or prevent human exposure to NDL-PCBs by adherence to good agricultural practices and good animal feeding practices.

3. Main aspects to be covered

Review and update the *Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feed* (CAC/RCP 62-2006) to include NDL-PCBs in its scope and rename as Code of Practice for the Prevention and Reduction of Dioxin and PCB Contamination in Food and Feed (CAC/RCP 62-2006).

4. Assessment against the Criteria for the establishment of work priorities

a) Consumer protection from the point of view of health, food safety, ensuring fair practice in the food trade and taking into account the identified needs of the developing countries.

The updated Code of Practice will provide additional guidance for member countries and the food and feed industry to reduce or prevent NDL-PCB contamination in feed and food, thus minimising dietary exposure to NDL-PCBs.

b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

The Code of Practice would provide internationally recognised scientific and technical guidance in order to eventually improve and/or enhance international trade.

c) Work already undertaken by other organisations in this field

A risk assessment for NDL-PCBs was completed by the JECFA in 2015 at its 80th meeting.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under all five Codex Strategic Goals:

Goal 1: Promoting Sound Regulatory Frameworks

The result of this work will assist in promoting sound regulatory frameworks in international trade by using scientific knowledge and practical experience for the prevention and reduction of NDL-PCB contamination in food and feed.

This work will harmonise procedures for developed and developing countries with a view to promote maximum application of Codex standards for fair trade.

[1] Safety evaluation of certain food additives and contaminants. Supplement 1: Non-dioxin-like polychlorinated biphenyls, WHO Food Additives Series: 71-S1.
Available at: http://apps.who.int/iris/bitstream/10665/246225/1/9789241661713-eng.pdf

Goal 2: Promoting widest and consistent application of scientific principles and risk analysis.

This work will help in providing risk management options and strategies to control NDL-PCB contamination in food and feed.

Goal 3: Strengthening Codex work-management capabilities

The Code of Practice will provide a general framework for the management of feed and food safety risks associated with the prevention and reduction of NDL-PCB contamination of food and feed that can be applied by developed and developing countries.

Goal 4: Promoting cooperation between seamless linkages between Codex and other multilateral bodies.

The work will supplement the information already provided by the UN Stockholm Convention on Persistent Organic Pollutants.

Goal 5: Promoting maximum application of Codex standards

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work and provide expert advice as needed.

6. Information on the relation between the proposal and other existing Codex documents

This new work is recommended by the Committee following discussion on the feasibility to review and update the *Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds* (CAC/RCP 62-2006) to include NDL-PCBs in its scope. This is based on a discussion paper (CX/CF 17/11/13) presented at the 11th Session of the Codex Committee on Contaminants in Foods (2017).

The recommendations based on Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), Good Storage Practices (GSPs) Good Animal Feeding Practices (GAFPs) and Good Laboratory Practices (GLPs) contained in the *Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Foods and Feeds* (CAC/RCP 62-2006), are also relevant to the prevention and reduction of NDL-PCBs, in particular the recommendations applicable to DL-PCBs.

7. Identification of any requirement for and availability of expert scientific advice

A risk assessment was completed by the JECFA at its 80th meeting (WHO Food Additives Series: 71-S1)

8. Identification of any need for technical input to the standard from external bodies

Currently, there is no need for additional technical input from external bodies.

9. Proposed time-line for completion of the work

Subject to approval by the Codex Alimentarius Commission in 2017, the draft Code of Practice will be submitted for consideration by CCCF in 2018. Final adoption by the Commission is foreseen for 2019.

APPENDIX X

PROJECT DOCUMENT

Proposal for new work on a Code of Practice for the Reduction of 3-monochloropropane-1,2-diol esters and glycidyl esters in refined oils and products made with refined oils, especially infant formula

1. The purpose and scope of the project

The purpose of the proposed new work is to develop a Code of Practice (COP) for the reduction of 3-monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) in refined edible oils and products containing refined oils or products made with these oils, especially infant formula, in light of the conclusions of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the Summary and Conclusions of its 83rd Session (November 2016), JECFA stated that (1) formula-fed infants can exceed the provisional maximum tolerable daily intake (PMTDI) for 3-MCPDE and (2) the margins of exposure (MOE) for GE for infants, children, and adults may be a health concern. The scope of the new work encompasses measures applicable to agricultural practices, oil milling and refining processes, and sources and uses of the refined oils in products made from these oils, especially infant formula.

There are currently no regulatory limits for these contaminants. However, countries are continuing to evaluate levels in their food supply and to assess the risk of these contaminants. This COP will reduce contamination to As Low As Reasonably Achievable (ALARA) while individual countries develop appropriate risk management options to control these contaminants in food.

2. Relevance and timeliness

At its 83rd session, JECFA developed dietary exposure estimates for 3-MCPDE and GE. JECFA reported that toxicology data demonstrate that the kidney and male reproductive organs are the primary target organs of 3-MCPD and 3-MCPDE; 3-MCPD has also been shown to be carcinogenic but not through a genotoxic mode of action. JECFA established a group PMTDI of 4 µg/kg bw/day for 3-MCPD and 3-MCPDE based on renal tubular hyperplasia in male rats. JECFA noted that the estimates of mean dietary exposure to 3-MCPD for formula-fed infants could exceed the PMTDI by up to 2.5-fold (depending on country).

JECFA concluded that glycidol is genotoxic and determined carcinogenicity to be the most sensitive endpoint for developing a point of departure ($BMDL_{10}$=2.4 mg/kg bw per day) for mesotheliomas in male rats. JECFA, who based the MOEs on national estimates of dietary exposures, concluded that the lower range of the MOEs for infants, children, and adults (i.e., MOEs = 490, 1100, and 3000, respectively) were low for a genotoxic and carcinogenic compound and may indicate a health concern.

Given potential health concerns associated with 3-MCPDE and GE, it is important to reduce exposures to 3-MCPDE and GE from refined oils, particularly for infants, who are exposed to these oils through their consumption of infant formula. The new work aims to reduce exposures through the development of a COP to reduce levels of 3-MCPDE and GE in refined oils and products made with refined oils, especially infant formula.

3. Main aspects to be covered

The COP will address measures, supported by scientific data, to reduce 3-MCPDE and GE in refined oils. Although 3-MCPDE and GE are produced primarily during deodorization, measures applicable to agricultural practices (e.g. harvesting and storage of fruit), oil milling and refining processes (e.g., fruit selection and processing, degumming/bleaching, deodorization) and sources and uses of the refined oils, including in other products, especially infant formula (e.g. oil selection, processing modifications), will be addressed.

4. Assessment against the criteria for the establishment of work priorities

General criterion

To protect consumers' health (particularly infants and young children), exposures to 3-MCPDE and GE should be reduced as low as reasonably achievable through best practices. A COP compiling agricultural and industrial measures to reduce 3-MCPDE and GE will identify steps that can be taken to reduce these contaminants in refined oils and products made from these oils, especially infant formula. A COP will facilitate fair trade by making information on recommended practices available to all member countries.

a. Diversification of national legislations and apparent resultant or potential impediments to international trade.

Implementation of a COP is needed to ensure that information on recommended practices is available to all member countries. It will also provide the means to enable exporters to ensure levels of 3-MCPDE and GE in oils and infant formula to be as low as achievable and assist compliance with any MLs that may be established in future, either nationally or internationally.

b. Scope of work and establishment of priorities between the various sections of the work.

The COP will provide measures to reduce 3-MCPDE and GE in refined oils and products made with refined oils, especially infant formula, as it will address all aspects of production of refined oils from agricultural production to processing to use in other products.

c. Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

Codes of practice or toolboxes to mitigate 3-MCPDE and GE in oils and other foods have been developed by FEDIOL (the European Vegetable Oil and Protein Meal Industry) and BLL (the German Federation for Food Law and Food Science).

5. Relevance to Codex Strategic Goals

Goal 1: Establish international food standards that address current and emerging food issues

Establishing a COP to reduce levels of 3-MCPDE and GE in refined oils will address a current food issue addressed in JECFA's 2016 summary and conclusions (JECFA/83/SC).

Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

This work will assist in applying risk analysis principles in the development of Codex standards by using scientific data and results from the JECFA assessment to support the reduction in 3-MCPDE and GE in refined oils, thereby reducing exposures and risks to sensitive populations (infants and children).

Goal 3: Facilitate the effective participation of all Codex members

A COP will make information on recommended practices to reduce 3-MCPDE and GE available to all member countries.

Goal 4: Implement effective and efficient work management systems and practices

A COP will help ensure development and implementation of effective and efficient work management systems and practices by agricultural producers and industrial processors to produce refined oils and other products, made with refined oils, with lower levels of 3-MCPDE and GE.

6. Information on the relationship between the proposal and other existing Codex documents

In 2008, Codex established a COP (CAC/RCP 64-2008) and a Maximum Level (CODEX STAN 193-1995) for related compounds, 3-MCPDs (chloropropanols), in acid hydrolyzed vegetable proteins. Although CCCF requested an evaluation by JECFA of 3-MCPDE and GE as early as 2009, sufficient research was not available to conduct an assessment until more recently. This new work is supported by JECFA's 2016 assessment of 3-MCPDE and GE (JECFA/83/SC, 83rd meeting, Summary and Conclusions).

7. Identification of any requirement for any availability of expert scientific advice

The JECFA Secretariat has already provided needed expert scientific advice (JECFA/83/SC).

8. Identification of any need for technical input to the standard from external bodies

Currently, there is no identified need for additional technical input from external bodies.

9. The proposed timeline for completion of the new work, including the starting date, proposed date for adoption at Step 5 and the proposed data for adoption by the Commission

Work on the COP will commence following approval by the Codex Alimentarius Commission in July 2017. Final adoption by the Commission can be expected by 2020.

APPENDIX XI

PROJECT DOCUMENT

GUIDELINES (BEST PRACTICE) FOR RISK ANALYSIS OF CHEMICALS INADVERTENTLY PRESENT IN FOOD AT LOW LEVELS

1. **Purpose**

The purpose of this work is to provide guidelines which will promote an internationally harmonised approach to addressing possible public health and trade issues arising from detections of low levels of chemicals inadvertently present in the food of interest.

The work will be based on a review of current regulatory approaches and global best practices taking into account risk analysis principles and frameworks. Case studies and examples that will inform development of the guidelines will be sought as appropriate.

2. **Scope**

Chemicals which are inadvertently present at low levels in the food of interest and are not subject to international recommendations or national legislation

3. **Its relevance and timeliness**

The potential for very low levels of chemicals to inadvertently get into food at various stages of production and processing (e.g. cleaning agents) has long been recognised by regulatory authorities around the world. Regulatory authorities and scientific bodies, at national levels have, over the years, developed sound, pragmatic approaches to responding to such detections. However, there is no internationally harmonised approach.

The Codex Alimentarius Commission (CAC) is ideally placed to consider and promote an internationally harmonised approach for regulators to address possible public health and trade issues when responding to inadvertent presence and detections in food of low levels of chemicals for which no international recommendations or national legislation exisits. In almost all previous cases, such situations do not constitute a risk to public health. There is now a sound body of science that can be drawn upon to assist with developing a harmonised international regulatory approach.

4. **The main aspects to be covered**

The proposed work will review current regulatory approaches to risk analysis of chemicals that may inadvertently be present in the food of interest.

Regulatory authorities already have pragmatic and well established processes for addressing chemicals inadvertently present in food at low levels and for which no regulatory standards or guidelines exist. In respect of risk assessment currently the Threshold of Toxicological Concern (TTC) approach appears to have the most international attention. This can be used to assess potential human health concerns for chemicals (for which there is little if any toxicology data) based on their structures and potential human exposures. The TTC approach is not a substitute for the risk assessment and establishment of regulatory standards for regulated compounds such as pesticides and food/feed additives. In particular it is not applicable when compound-specific assessment and toxicity data are available or are required under existing international regulatory frameworks.

The TTC approach has been recently reviewed by an expert consultation convened by the European Food Safety Authority (EFSA) and the World Health Organization (WHO), with the participation of the US Food and Drug Administration (FDA) to update and extend the TTC framework. The report of this consultation was released in March 2016, and recommends a globally harmonised decision tree framework for the application of the TTC in the risk assessment of chemicals.

The TTC approach is one of several approaches available for risk assessment of chemicals to determine if they are of any public health concern. The proposed new work will provide the opportunity to review the range of risk tools currently available. Other known approaches include the following:

- The use of computer modelling such as the QSAR (quantitative structure activity relationships) toolbox;
- Read-across; and
- Margin of exposure approach.

In respect of risk management considerable guidance can be developed on best practices on taking up scientific advice and making risk management decisions that take in to account public health, trade concerns and other factors such as food wastage. Risk management may also include other actions such as increased monitoring and traceability requirements.

Both risk assessment and risk management should be guided by predetermined risk assessment policy. For example, are the chemicals in the food of interest subject to regulation in other food types?

The guidelines will include a section on risk communication. This is a challenging area for risk managers communicating decisions in the absence of regulatory limits in the foods of interest.

5. **An assessment against the *criteria for the establishment of work priorities***

General Criterion

Relevance to the Codex Strategic Objectives

The proposed work would contribute to the Commission's ***Strategic Goal 1* to *establish international food standards that address current and emerging food issues*** by promoting a harmonised approach to risk analysis.

Advanced analytical methods and testing technologies increasingly result in detections that are of very low exposure and very low potential health concern. An internationally harmonised risk analysis approach is important to avoid undue precaution in terms of food safety and/or food security and help minimise any unnecessary negative impact on trade. It will also help national authorities to make efficient use of limited national resources.

Criteria applicable to general subjects

a. Diversification of national legislations and apparent or potential impediments to international trade

As noted in the covering paper regulatory authorities in a number of countries have already in place sound science based approaches to address detection of very low levels of chemicals inadvertently found in food. A globally harmonised approach to address such detections is particularly relevant against the background of advances in analytical methods and testing technologies and the imperatives of climate change and sustainable agricultural practices and need to reduce food losses and wastage.

b. Scope of work and establishment of priorities between the various sections of work

See 1 above

c. Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body (ies)

See information presented in 3 above

d. Amenability of the subject of the proposal to standardisation

The proposed work would draw on the experience gained from current regulatory approaches. Members would benefit from an internationally harmonised risk analysis approach to address chemicals inadvertently present in food at very low levels.

e. Consideration of the global magnitude of the problem or issue

As noted in this paper, the issue of detection of very low levels of chemicals inadvertently present in food is of significant interest to the wider membership of Codex as advances in analytical methods lead to detection of ever decreasing levels in food of chemicals which may be of very low public health concern. An internationally harmonised approach will be helpful to:

- Promoting a science and risk based approach to responding to such inadvertent presence and detections in food;
- Promote efficient use of limited global and national risk analysis resources to addressing chemicals of greatest public health concern;
- Minimise any potential impediments to international trade;
- Support the global goal of reducing food losses and wastage through rejection of food without adequate technical justification; and
- Enhance risk communication to consumers and promote confidence in national regulatory approaches.

6. **Information on the relation between the proposal and other existing Codex documents**

The proposed work will be strongly linked to and guided by, but not limited to the:

- *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*; and
- *Working Principles for Risk Analysis for Food Safety for Application by Governments*.

7. **Identification of any requirement for and availability of expert scientific advice**

It is expected that the CCCF will, as part of its deliberations, review current approaches to risk assessment and risk management of chemicals inadvertently found in food at low levels and for which no international regulatory frameworks and/or standards exist.

8. **Identification of any need for technical input to the standard from external bodies so that this can be planned for the proposed timeline for completion of the new work**

None identified at this stage.

9. **Proposed timeline for completion of work**

Approval of work by CAC in 2017. First consideration by CCCF12 (2018). Final adoption by CAC (Step 8) in 2019.

APPENDIX XII

PRIORITY LIST OF CONTAMINANTS AND NATURALLY OCCURRING TOXICANTS FOR EVALUATION BY JECFA

Contaminants and Naturally Occurring Toxicants	Background and Question(s) to be Answered	Data Availability (When, What)	Proposed By
Dioxins[1]	Full evaluation (toxicological assessment and exposure assessment) to update 2001 JECFA assessment and incorporate data on developmental effects from in utero exposures.	EFSA assessment available end 2017/early 2018 Canada: occurrence data on foods of animal origin.	Canada
Inorganic Arsenic	2001 JECFA evaluation based on cancer effects. This evaluation would focus on non-cancer effects (neurodevelopmental, immunological and cardiovascular) and could inform future risk management needs. NOTE: needs to be put in context to cancer risk assessment.	US: occurrence data on rice cereals, and rice and non-rice products; 2016 risk assessment; 2016 draft action level for inorganic arsenic in rice cereal US: rodent behavioural study has been proposed Brazil: occurrence data in rice; poultry and pork total As Japan and China: occurrence data on rice and rice products (already submitted to GEMS/Food) NZ: total diet study; rice and products. India: occurrence data in rice	USA
Scopoletin	Full evaluation (toxicological assessment and exposure assessment) in fermented Noni juice	CCNASWP still working on standard for noni juice and data availability US: literature based quick review, limited data to derive HBGV	FAO/WHO Coordinating Committee for North America and South-West Pacific (CCNASWP)
Ergot alkaloids[2]	Full evaluation (toxicological assessment and exposure assessment)	EFSA (2012) report EU: occurrence data (collecting); assessment on exposures to ergot alkaloids (EFSA report May 2017) Canada: occurrence information (commodity-specific data, i.e., grading standards)	EU; Canada
Ciguatoxins[3]	Full evaluation (toxicological assessment and exposure assessment), including geographic distribution and rate of illness; congeners; methods of detection	India (CRD37) EU: Eurocigua project, RASFF EFSA (2010) US: occurrence data (outbreak management) Australia: illness data	CCCF
Trichothecenes (T2 and HT2)	Update of risk assessment, including exposure assessment (T2, HT2, DAS)	*To be confirmed*	83rd JECFA, recommendation supported by CCCF11.

[1]Lower priority: JECFA evaluation to build on the ongoing work at national and regional re-assessment of dioxins.
[2]Ergot is mentioned in quality chapter, suggestion for integration into GSCTFF.
[3]Proposals from CCCF11 for new contaminants and naturally occurring toxicants for JECFA Priority List.

APPENDIX XIII

PROPOSED DRAFT OF MAXIMUM LEVELS FOR CADMIUM IN CHOCOLATE AND COCOA–DERIVED PRODUCTS

Categorization of chocolates and cocoa powder and dry mixtures of cocoa and sugars (for development of the MLs for cadmium)

a) Categorization for chocolates

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Notes/Remarks
Chocolate products containing or declaring <30% total cocoa solids on a dry matter basis		Including milk chocolate, family milk chocolate, milk chocolate couverture, Gianduja milk chocolate, table chocolate, Milk chocolate Vermicelli/milk chocolate flakes
Chocolate and chocolate products containing or declaring ≥ 30% to < 50% total cocoa solids on a dry matter basis		Including sweet chocolate, Gianduja chocolate, semi – bitter chocolate para mesa, Chocolate Vermicelli / chocolate flakes, bitter table chocolate
Chocolate containing or declaring ≥ 50% to <70% total cocoa solids on a dry matter basis		
Chocolate containing or declaring ≥ 70% total cocoa solids on a dry matter basis		

b) Categorization for cocoa powder and dry mixtures of cocoa and sugars sold for final consumption

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Notes/Remarks
Dry mixtures of cocoa and sugars containing <29% total cocoa solids on a dry matter basis		
Dry mixtures of cocoa and sugars containing ≥29 to < 50% total cocoa solids on a dry matter basis		Including chocolate powder
Dry mixtures of cocoa and sugars containing ≥50% total cocoa solids on a dry matter basis		Including chocolate powder
Cocoa powder (100% total cocoa solids on a dry matter basis)		Product sold for final consumption