CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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CF/10 INF/1
March 2016
ENGLISH ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS

10th Session
Rotterdam, The Netherlands 4 - 8 April 2016

WORKING DOCUMENT FOR INFORMATION AND USE IN DISCUSSIONS RELATED TO CONTAMINANTS AND TOXINS IN THE GSCTFF

(Prepared by Japan and the Netherlands)

Background

1. This document has been prepared by Japan and the Netherlands in accordance with the recommendation endorsed by the 38th Session of the Codex Committee on Food Additives and Contaminants[1] and on the basis of the Document CX/CF 07/1/6 published for the First Codex Committee on Contaminants in Foods (CCCF) held in 2007. It incorporates all the decisions made at the Ninth CCCF[2] and subsequently adopted by the 38th Codex Alimentarius Commission in 2015[3].

2. As the Third Session of CCCF agreed to discontinue work on the food categorization system to be used for the purpose of the General Standard for Contaminants and Toxins in Foods and Feeds (GSCTF)[4], the following changes are made in the list of MLs:

   - Where an ML was adopted at Step 8 or 5/8 by the Commission with the Codex Code for the commodity, the Codex Code was retained in the List; and
   - Where an ML was adopted at Step 8 or 5/8 by the Commission without Codex Code for the commodity, the Codex Code was removed if it was added after the adoption.

   Some texts were added in the Explanatory Notes to indicate whether and where commodity descriptions are found.

3. In order to assist consideration of maximum levels in various steps, issues arising from previous Codex discussions of maximum levels for a contaminant/toxin and JECFA recommendations to CCCF are surrounded by broken lines while information on the nature and toxicity is surrounded by solid lines in the list.

4. The list of maximum levels for contaminants and toxins in foods is attached to this document (starting from page 2). Schedule I (renamed "Schedule" in 2014)[5] is no longer included in this Information Document as agreed by the Fourth CCCF but is available in the GSCTFF (CODEX STAN 193-1995).

1 ALINORM 06/29/12, para. 116
2 REP15/CF
3 REP15/CAC
4 ALINORM 09/31/41, para. 37
5 REP 14/CF Appendix VII

Working Document for Information and Use in Discussions on the GSCTF

This working document presents contaminants and toxins that are or have been dealt with in the CCFAC and CCCF. It does not only encompass the contaminants and toxins for which Codex standards exist or are being developed, but also those for which further information is sought or about which a Codex decision has been taken.

The Working Document has the purpose of providing an overview of the situation regarding Codex decisions about this subject and guidance about further actions required. Therefore also relevant information and references are added to the list.

The list of maximum levels / guideline levels is thus active, which needs regular update.

The situation regarding contaminants and toxins is very complex and many substances are or have been the subject of scientific research and discussion regarding their occurrence in foods and their significance for human and animal health. On a national level, there are many activities, sometimes implying legal measures which may affect international trade in foods and feeds. It is obviously important for the CCCF to take note of the developments in this field and to consider the necessity of actions. In order to obtain an overview of the situation, the CCCF shall develop and maintain a working document in which more comprehensive information regarding contaminants and toxins in foods is presented in a summary form.

The Working Document has two parts: *Part 1* containing maximum and guideline levels developed by CCFAC/CCCF and contaminant provisions included in commodity standards; and *Part 2* containing maximum levels developed for copper, iron and zinc which are regarded as quality factors as opposed to safety factors. *Part 1* also contains those levels still at various Steps of the Codex elaboration procedure for the facilitation of consideration of proposed maximum levels by the CCCF.

INDEX OF CONTAMINANTS IN ALPHABETICAL ORDER

Background of the Working Document

The Working Document was established in its current form when the 36th Codex Committee on Food Additives and Contaminants (CCFAC) agreed to integrate the Annotated List of Contaminants and Toxins in Foods (Annex IV then to the Preamble of the General Standard for Contaminants and Toxins in Foods [GSCTF], Part 1 and Part2) into a separate document "Working document for information and use in discussions on the GSCTF"(ALINORM 04/27/12, para. 119). Annex IV had the purpose of providing an overview of the situation regarding Codex decisions about contaminants and toxins and guidance about further actions required. It was originally included in the GSCTF as an introduction text without the lists of contaminants and toxins (ALINORM 97/12, para. 68). All is now included in the Working Document.

It was agreed that the Working Document (ANNEX IV at the time) would:

- contain information not only for contaminants and toxins for which Codex standards exist or are being developed, but also those for which further information is sought or about which a Codex decision has been taken, and that relevant information and references are added in order to give guidance about further actions required (ALINORM 04/27/12, para. 116 and Appendix XIII);
- include references to validated methods of analysis as well as references to information on toxicological guidance, if available (ALINORM 95/12A, para. 99);
- exclude references to revoked standards (ALINORM 04/27/12, para. 116); and
- include maximum levels for quality-related parameters such as copper, zinc, iron, etc. as a record of the complete range of contaminants in the Codex system (ALINORM 04/27/12, para. 120).

The format of the Working Document is that of Schedule I. This results from the agreement of the 32nd CCFAC to create a new Schedule I to the GSCTF, for which a working document was created in its format, and under the name of Schedule I. It was noted that Schedule I would not be added to the GSCTF until the relevant levels were adopted by the Commission (ALINORM 01/12, para. 79).

At the following Sessions of the Committee, it was agreed that this Schedule I:

- should include all current maximum and guideline levels for contaminants in food and those under elaboration by the Committee, as well as current maximum and guideline levels contained in Codex commodity standards, with an indication of their step status (ALINORM 01/12, para. 118);
- would contain two lists, i.e., List 1 with MLs for contaminants and toxins already adopted as final texts and List 2 with MLs for contaminants and toxins under discussion at different steps of the Codex procedure (ALINORM 03/12, para. 104); and
- would be used as a working document during the Working Group and the plenary sessions (ALINORM 03/12, para. 104).

In this Schedule I as prepared for the 36th CCFAC, it was identified that List 2 was in fact ANNEX IV, and was renamed accordingly to distinguish it clearly from Schedule I, the list of adopted Standards (CX/FAC 04/36/16). The Committee endorsed the recommendation to include Schedule I (List 1) in the GSCTF (ALINORM 04/27/12, para. 117). The Committee noted that ANNEX IV was useful in providing an overview of the situation regarding Codex decisions about contaminants and toxins, and to give guidance about further actions required by CCFAC. The Committee agreed with the recommendation that such information should be part of a working document to be updated yearly and presented at each session of the Committee, and requested the delegations of the Netherlands and Japan to perform this task (ALINORM 04/27/12, paras 118 and 119).

During the work of the editorial amendments to GSCTFF, which was adopted at 37th CAC, the 8th CCCF agreed to delete (i) short information notes on the substance at the end of the provisions on contaminants in Schedule I, (ii) scientific references and (iii) operating characteristic curves (OC curves) in the sampling plans from Schedule I in the GSCTFF. The Committee agreed that all information that is deleted would be transferred to this Working Document (INF 1)[6]. Therefore, this document is keeping such information which is not included in the current GSCTFF.

The current Working Document is the subsequent result.

6 REP14/CF, paras. 87-89

EXPLANATORY NOTES

Reference to JECFA:	References to the JECFA meeting in which the contaminant was evaluated and the year of that meeting.
Toxicological guidance value:	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed in milligrams (mg) per kg body weight (bw). The year of recommendations and additional explanation are included.
Contaminant definition:	Definition of the contaminant in the form of which the ML or GL applies or which may or should be analyzed in commodities/products.
Synonyms:	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Related code of practice:	Name of any code(s) of practice related to the contaminant and its (their) reference number(s).
Commodity/ product name:	The commodities or products, to which the ML or GL applies, other than the terms feed or food, are those that are intended for human consumption, unless otherwise specified. The ML or GL contained in Codex commodity standards apply to the commodities within the scope of the Codex commodity standard. Reference to the Codex Standard is provided and the definition of the commodity/product is the definition as provided in the Codex commodity standard. When the ML or GL applies only to the commodity within the scope of the Codex commodity standard then the reference is mentioned as “Relevant Codex commodity standard(s) is (are) …”. In case the reference to Codex commodity standards is provided as example for commodities to which the ML or GL applies then the reference is mentioned as “Relevant Codex Commodity standards include …” For the other commodities or products not contained in Codex commodity standards the definition of the commodity or product is provided in the Classification of Foods and Animal Feeds (CAC/MISC 4), unless otherwise specified. In case a ML or GL applies to a product group (e.g. legume vegetables), the ML or GL applies to all individual products belonging to the group as defined in CAC/MISC 4. For any other commodities or products other than those described above, where necessary, the definition of the commodity/product is provided in “Notes/Remarks”.
Step:	Step of the Codex Elaboration Procedure at which each maximum level is (at the time of the publication of this paper). See the Codex Procedural Manual. The term “Adopted” is used for an adopted MLs and Codex Standards.
Reference or adoption year:	Reference number of the commodity standard in which the maximum level is established or the year of adoption of the maximum level following the recommendation of the Codex Committee on Food Additives and Contaminants (up to 2006) and the Codex Committee on Contaminants in Food (after 2007).
Portion of the Commodity/Product to which the maximum level (ML) or guideline level (GL) applies	The portion of the feed or food to which the ML or GL applies, is the portion defined in the Codex commodity standard or CAC/MISC 4 or defined at the establishment of the ML or GL, unless otherwise specified.

Definitions of some toxicological terms

PMTDI:	*(Provisional Maximum Tolerable Daily Intake).* *The use of the term "provisional" expresses the tentative nature of the evaluation, in view of the paucity of reliable data on the consequences of human exposure at levels approaching those with which JECFA is concerned.* The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.
PTWI:	*(Provisional Tolerable Weekly Intake)* *For contaminants that may accumulate within the body over a period of time, JECFA has used the PTWI and PTMI. On any particular day, consumption of food containing above-average levels of the contaminant may exceed the proportionate share of its weekly or monthly tolerable intake (TI). JECFA's assessment takes into account such daily variations, its real concern being prolonged exposure to the contaminant, because of its ability to accumulate within the body over a period of time* An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.
PTMI:	*(Provisional Tolerable Monthly Intake)* An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods
ADI:	*(Acceptable Daily Intake)* The estimate of the amount of a chemical in food or drinking-water, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of the evaluation. The ADI is expressed in milligrams of the chemical per kilogram of body weight (a standard adult person weighs 60 kg). It is applied to food additives, residues of pesticides and residues of veterinary drugs in food.
ARfD	*(Acute Reference Dose)* The estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation. The ARfD is expressed in milligrams of the chemical per kilogram of body weight.
BMDL:	*(Benchmark Dose Lower Limit)* The lower one-sided confidence limit of the benchmark dose (BMD) for a predetermined level of response, called the benchmark response (BMR), such as a 5 or 10% incidence of an effect. It is determined by dose-response modeling of toxicological data.
MOE	*(Margin of Exposure)* The ratio between the BMDL and the estimated intake in humans. It can be used to prioritize different contaminants, providing that a consistent approach has been adopted. Its acceptability depends on its magnitude and is ultimately a risk management decision.

A full list of toxicological terms and explanations can be found in Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food.
http://www.who.int/foodsafety/publications/chemical-food/en/

Metals

Aluminium

Reference to JECFA:	67 (2006), 74 (2011)
Toxicological guidance value:	PTWI 2 mg/kg bw (2011, for all aluminium compounds in food, including additives)
Synonyms:	Al
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/ Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

The WHO Representative clarified that exposure through food contact utensils and containers had been considered during the evaluation by JECFA and that it was concluded that they were not main contributors for human exposure to aluminium (ALINORM 07/30/41, para. 31).

The 67th JECFA (2006) established a PTWI for Al of 1 mg/kg bw for all aluminium compounds in food, including additives; previously established ADIs and PTWI for aluminium compounds were withdrawn. The JECFA concluded that aluminium compounds have the potential to affect the reproductive system and developing nervous system at doses lower than those used in establishing the previous PTWI.

The evaluation of the PTWI was based on the combined evidence from several studies: the studies conducted with dietary administration of aluminium compounds were considered most appropriate. The lowest LOELs for Al of different studies in mice, rats and dogs were in the range of 50-75 mg/kg bw per day. An uncertainty factor of 100 was applied (to 50 mg/kg bw per day) to allow for inter- and intraspecies differences. An additional uncertainty factor of 3 was applied to cover deficiencies in the database (absence of NOELs in majority of studies and absence of long-term studies on relevant toxicological endpoints). Also, deficiencies are counterbalanced by the probable lower bioavailability of the less soluble aluminium compounds present in food. Because of the potential for bioaccumulation the JECFA confirmed that the resulting health-based guidance value should be expressed as a PTWI.

The JECFA noted that the PTWI is likely to be exceeded to a large extent by some population groups, particularly children, who regularly consume foods that include aluminium-containing additives. The JECFA also noted that dietary exposure to Al is expected to be very high for infants fed on soya-based formula.

The 67th JECFA recommended: Further data on the bioavailability of different aluminium-containing food additives are required; There is a need for an appropriate study of developmental toxicity and a multigeneration study incorporating neurobehavioral end-points, to be conducted on a relevant aluminium compound(s); Studies to identify the forms of aluminium present in soya formulae, and their bioavailability, are needed before an evaluation of the potential risk for infants fed on soya formulae can be considered.

At the 74th JECFA (2011) evaluated aluminium-containing food additives (including new food additives potassium aluminium silicate and potassium aluminium silicate–based pearlescent pigments). New data was submitted including studies of bioavailability and reproductive, developmental and neurobehavioral effects. The absorption of aluminium compounds is found to be generally in the region of 0.01-0.3% with soluble compounds appearing to be more bioavailable. It was not possible though to draw conclusions on quantitative differences in the overall toxicokinetics of different aluminium-containing food additives or between experimental animals and humans. Recent evidence did not show effects of aluminium on reproductive outcomes. JECFA concluded that there continues to be a lack of consistency regarding the reported neurodevelopmental effects in animals and most studies involved administration of aluminium compounds in drinking-water rather than in the diet.

Metals

Aluminium

The JECFA noted that a study, in which aluminium citrate was administered in drinking-water, provided a NOAEL of 30 mg/kg bw per day. Based on the higher solubility of aluminium citrate compared to many other aluminium compounds and the fact that it is likely to be more bioavailable from drinking-water than from food, the JECFA concluded that the NOAEL of 30 mg/kg bw per day was an appropriate basis for establishing a PTWI for aluminium compounds. Because long-term studies on the relevant toxicological endpoints had become available since the 67th meeting, an additional uncertainty factor for deficiencies in the database was considered to be no longer necessary. A PTWI of 2 mg/kg bw was established by applying an uncertainty factor of 100 for interspecies and intraspecies differences.

The PTWI applies to all aluminium compounds in food, including food additives. The JECFA noted that dietary exposure of children to aluminium-containing food additives, including high-level dietary exposure, can exceed the PTWI by up to 2-fold. For potassium aluminium silicate-based pearlescent pigments at the maximum proposed use levels and using conservative estimates, the JECFA noted that dietary exposure at the highest range of estimates is 200 times higher than the PTWI.

The 74th JECFA recommended: Provisions for food additives containing aluminium included in the GFSA should be compatible with the revised PTWI for aluminium compounds of 2 mg/kg bw as aluminium from all sources. Furthermore, there is a need for convincing data to demonstrate that Al is not bioavailable from potassium aluminium silicate-based pearlescent pigments. Studies to identify the forms of Al present in soya-based formula and their bioavailability are still required.

Aluminium occurs in the environment in the form of silicates, oxides and hydroxides, combined with other elements, such as sodium and fluorine, and as complexes with organic matter. Aluminium is a major component of the earth's crust. It is released to the environment both by natural processes and from anthropogenic sources, whereby natural processes far outweigh the contribution of anthropogenic sources. Mobilization of aluminium through human actions is mostly indirect and occurs as a result of emission of acidifying substances to the atmosphere. Aluminium is highly concentrated in soil-derived dusts from natural processes, coal combustion, and activities as mining and agriculture. In addition, aluminium finds use in a wide variety of applications including structural materials in construction, automobiles and aircraft, packaging materials, various containers and kitchen utensils and pharmaceuticals (Environmental health criteria for aluminium; International Programme on Chemical Safety (IPCS); 1997).

Non-occupational human exposure to aluminium is primarily through ingestion of food and water. Food being the principal contributor, as aluminium is naturally present in varying amounts in most foodstuffs consumed. The intake of aluminium can be increased greatly through the use of aluminium-containing pharmaceutical products (especially antacids) (Environmental health criteria for aluminium; International Programme on Chemical Safety (IPCS); 1997).

Aluminium and its compounds appear to be poorly absorbed in humans; the mechanism of gastrointestinal absorption has not yet been fully elucidated. Variability results from the chemical properties of the element and the formation of various chemical species, which is dependent upon the pH, ionic strength, presence of competing elements and complexing agents within the gastrointestinal tract. The urine is the most important route of aluminium excretion. Aluminium has a long half-life (Environmental health criteria for aluminium; International Programme on Chemical Safety (IPCS); 1997).

Metals

Arsenic

Reference to JECFA: 5 (1960), 10 (1967), 27 (1983), 33 (1988), 72 (2010)
Toxicological guidance value: $BMDL_{0.5}$: 3.0 µg/kg bw per day (2.0-7.0 µg/kg bw per day based on the range of estimated total dietary exposure)(2010, for inorganic arsenic)
Contaminant definition: Arsenic: total (As-tot) when not otherwise mentioned; inorganic arsenic (As-in); or other specification
Synonyms: As
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity to which the ML applies	Notes/Remarks	Notes for CCCF
Edible fats and oils	0.1	Adopted	CS 19-1981 CS 33-1981 CS 210-1999 CS 211-1999	FO	Whole commodity	Relevant Codex commodity standards are CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999 and CODEX STAN 211-1999.	
Fat spreads and blended spreads	0.1	Adopted	CS 256-2007	FO		Relevant Codex commodity standard is CODEX STAN 256-2007.	1)
Natural mineral waters	0.01	Adopted	CS 108-1981	NMW, CF		Relevant Codex commodity standard is CODEX STAN 108-1981. Calculated as total As mg/l.	Changed from 0.05 mg/l in 2001. 2)
Salt, food grade	0.5	Adopted	CS 150-1985	NFSDU		Relevant Codex commodity standard is CODEX STAN 150-1985.	
Rice, polished	0.2	Adopted	2014	CF	Whole commodity	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.	
Rice, husked	0.35	7		CF	Whole commodity	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, followup testing shall be conducted to determine if the As-in concentration is above the ML.	REP15/CF Appendix V CX/CF 16/10/5

Metals

Arsenic

1) The Standard for fat spreads and blended spreads contain the following wording for the mentioned contaminant MLs: "The products covered by the provisions of this Standard shall comply with MLs being established by the CAC but in the meantime the following limits will apply". (only applying to Pb and As)
2) The Standard for Natural Mineral Waters contains the level in the Section 3.2 "Health-related limits for certain substances". The 2nd CCCF (2008) temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41 para. 23-27). After establishment of an EWG by 4th CCCF, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, para 89-90).

A position document CX/FAC 99/22 on arsenic discussed in the 31st CCFAC in 1999 noted that several countries have established MLs for arsenic in food commodities and some of these were stringent regarding seafoods, so trade problems might occur. The present range of Codex MLs for arsenic in some commodities do not cover all national MLs. The document concluded however that in general there are no indications that specific Codex MLs for arsenic in food commodities would be necessary. Also, at present there is no sufficient basis to decide about the establishment of Codex MLs for arsenic, due to the uncertainties mentioned about the levels of naturally occurring arsenic species in foods, about their toxicity and about the availability of suitable analytical methods. It was acknowledged that at present especially the ML for arsenic in drinking water and in mineral water is relevant. The CCFAC agreed that a finalized position paper would form the basis for future work until such time as routine methodology became available to determine toxic arsenic compounds in food (ALINORM 99/12A, para. 137).

The 72nd JECFA in February 2010 derived an inorganic arsenic BMDL for a 0.5% increased incidence of lung cancer ($BMDL_{0.5}$) by using a range of assumptions to estimate exposure from drinking-water and food, with differing concentrations of inorganic arsenic. The $BMDL_{0.5}$ was computed to be 3.0 µg/kg bw per day (2–7 µg/kg bw per day based on the range of estimated total dietary exposure). The uncertainties in this BMDL relate to the assumptions regarding total exposure and to extrapolation of the $BMDL_{0.5}$ to other populations due to the influence of nutritional status, such as low protein intake, and other lifestyle factors on the effects observed in the studied population. The Committee noted that the PTWI of 15 µg/kg bw (2.1 µg/kg bw per day) is in the region of the $BMDL_{0.5}$ and therefore was no longer appropriate, and the Committee withdrew the previous PTWI.

Reported mean dietary exposure to inorganic arsenic in the United States of America (USA) and various European and Asian countries ranged from 0.1 to 3.0 µg/kg bw per day. The Committee noted that drinking-water was a major contributor to total inorganic arsenic dietary exposures and, depending on the concentration, can also be an important source of arsenic in food through food preparation and possibly irrigation of crops, particularly rice. For certain regions of the world where concentrations of inorganic arsenic in drinking-water are elevated (e.g. above the World Health Organization guideline value of 10 µg/l), the Committee noted that there is a possibility that adverse effects could occur as a result of exposure to inorganic arsenic from water and food.

The 72nd JECFA also noted that more accurate information on the inorganic arsenic content of foods as they are consumed is needed to improve assessments of dietary exposures of inorganic arsenic species. Analytical constraints to achieving this goal include the lack of validated methods for selective determination of inorganic arsenic species in food matrices and the lack of certified reference materials for inorganic arsenic in foods. The proportion of inorganic arsenic in some foods was found to vary widely, indicating that dietary exposures to inorganic arsenic should be based on actual data rather than using generalized conversion factors from total arsenic measurements.

The 5th CCCF (2011) agreed to initiate new work on maximum levels for arsenic in rice subject to approval by the 34th Session of the Commission and also agreed to re-convene the electronic Working Group, led by China and working in English, would prepare a working paper considering MLs for arsenic in rice based on the considerations made at plenary for deliberation at the next session of the Committee.

The 34th CAC (2011) approved the new work (REP11/CAC, para.142).

Metals

Arsenic

The 6th CCCF (2012) agreed that an electronic working group chaired by China and co-chaired by Japan would prepare a discussion paper on the possibility to develop a code of practice. In addition, China would prepare proposals for maximum levels for inorganic arsenic in rice (raw and processed) for consideration by the 8th Session of the Committee based on additional data provided by that time to GEMS Food. The committee also agreed to retain at Step 4 the proposed draft maximum levels for inorganic or total arsenic in rice (raw) at 0.3 mg/kg and inorganic arsenic in rice (polished) at 0.2 mg/kg until the Committee resumed the consideration of this matter at its 8th Session based on the outcome of proposals to be prepared by China and to inform the Executive Committee accordingly (REP12/CF, paras. 63-65).

The 7th CCCF (2013) agreed to re-establish the EWG led by China and co-chaired by Japan to further develop the discussion paper, and to look into management practices to determine which risk management measures were readily available to the extent that could provide the basis for the preliminary development of a COP and, if so, to attach a proposed draft COP for consideration by the 8th session of the Committee (REP13/CF, para. 107).
The 7th CCCF also agreed that the above-mentioned EWG would also prepare a discussion paper on proposals for maximum levels for inorganic arsenic in rice and rice products for consideration at the 8th session. The Committee encouraged members to submit relevant data to the EWG, especially those from rice-producing countries, and data on indica rice, to reflect them into the discussion paper (REP13/CF, para. 110).

The 8th CCCF (2014) noted extensive support for an ML of 0.2 mg/kg of inorganic arsenic for polished rice and analysis for total arsenic as screening method However, divergent views were expressed as to what the ML for husked rice should be in terms of protection of human health while not having a negative impact on international trade, in particular as rice was a major staple-food in Asian countries and the ML established may affect availability of rice. Possible levels discussed were 0.25 mg/kg, 0.3 mg/kg and the proposed ML of 0.4 mg/kg. The Committee could not reach agreement on an ML for husked rice. However, in view of the relevance of this matter for many Codex members, the Committee encouraged countries, especially rice-producing countries to submit data to GEMS/Food. Data submitted could then be considered in the EWG in order to facilitate the discussion of this matter at the 9th CCCF before taking a final decision on the feasibility to establish an ML for this product. In view of this, the remaining recommendations on the development of a “polishing procedure” and the establishment of a worldwide “conversion factor” were not considered (REP 14/CF, paras. 37, 42-43).

The Committee agreed to forward the proposed draft ML of 0.2 mg/kg for inorganic arsenic in polished rice to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th CAC (REP 14/CF, para. 46 and Appendix III).
The Committee agreed to return the proposed draft ML for inorganic arsenic in husked rice to Step 2/3 for further elaboration in the EWG, circulation for comments at Step 3 and consideration at the next session of the Committee and further agreed to re-establish the EWG led by China and co-chaired by Japan to a prepare a proposed draft ML for husked rice (REP 14/CF, para. 45 and 47).

The Committee noted wide support for the development of a Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice as supportive for the implementation of the MLs. A proposal however was made that current available management practices for containing arsenic contamination in rice mainly relate to source directed measures and whether it would be more appropriate to revise the Code of Practice for Source Directed Measures (CAC/RCP 49-2001) to address measures to reduce arsenic contamination rather than proceeding with the development of a separate COP at this point in time. In this regard, it was noted that although most of the management measures readily available at present mainly refer to source directed measures, other management measures were also available and relevant and should be included in the COP (REP 14/CF, para. 94).

The Committee agreed to initiate new work on a Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice for approval by the 37th Session of the Commission (Appendix VIII). The Committee agreed to establish an EWG, led by Japan and co-chaired by China, and working in English only, to develop the COP for comments at Step 3 and consideration at the next session of the Committee (REP 14/CF, paras. 95-96, Appendix VIII).

Metals

Arsenic

The 37th CAC adopted the proposed draft ML of 0.2 mg/kg for inorganic arsenic in polished rice at Step 5/8. Egypt and Sri Lanka expressed reservation about the ML (REP14/CAC, paras. 79-82, Appendix III).

The 9th CCCF (2015) noted general support for the establishment of an ML for inorganic arsenic in husked rice and proceeded with the discussion of the possible levels. However controversial discussion was made on the proposed ML between 0.25, 0.3, 0.35 and 0.4 mg/kg. As a compromise solution, the Committee agreed on an ML for husked rice at 0.35 mg/kg and to send this proposal to the Commission for adoption at Step 5. The delegations of the EU, Japan and Norway expressed their reservation to this decision. The Committee agreed that the ML for inorganic arsenic in husked rice should be accompanied by a note on analysis of total arsenic as a screening method. However, in view of the opinions expressed in relation to the need for more geographically representative data, the Committee agreed to re-establish the EWG, chaired by Japan and co-chaired by China, to further consider new/additional data provided by countries especially main rice-producing countries and countries where husked rice was a major staple food. The Committee should then consider the outcome of the analysis performed by the EWG based on the current and new/additional data to confirm or change the ML of 0.35 mg/kg at its next session. The Committee encouraged countries concerned to submit data to GEMS/Food so that the ML could be finalised at the next session of CCCF (REP 15/CF, paras 56-69).

The Committee agreed to return the COP for the prevention and reduction of arsenic contamination in rice to Step 2/3 for further development, comments and consideration by the 10th Session. The Committee also agreed to re-establish the EWG, led by Japan and co-chaired by China to further develop the COP in light of comments submitted and decisions taken at this session (REP 15/CF, paras 73-74).

The 10th CCCF discussed the report of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for evaluation by JECFA and agreed to include inorganic arsenic for evaluation of non-cancer effects (neurodevelopmental, immunological and cardiovascular) (REP 15/CF, para. 147).

The 38th CAC (2015) adopted the proposed draft ML for inorganic arsenic in husked rice at Step 5 as proposed by the Committee and advanced the draft ML to Step 6 for comments.

Arsenic is a metalloid element which is normally occurring in mineral bound form in the earth's crust and which can become more easily available by natural sources such as volcanic activity and weathering of minerals, and by anthropogenic activity causing emissions in the environment, such as ore smelting, burning of coal and specific uses, such as arsenic-based wood preservatives, pesticides or veterinary or human medicinal drugs. As a result of naturally occurring metabolic processes in the biosphere arsenic occurs as a large number of organic or inorganic chemical forms in food (species). Especially in the marine environment arsenic is often found in high concentrations of organic forms, up to 50 mg/kg of arsenic on a wet weight basis in some seafood including seaweed, fish, shellfish and crustaceans. In fresh water and in the terrestrial environments arsenic is normally found in much lower levels (typically 0-20 µg/kg) in crop plants and in livestock. Higher levels may be found in rice, mushrooms and sometimes in poultry which is fed fish meal containing arsenic. Levels of arsenic in drinking water are of concern in many countries; levels exceeding 200 mg/l have been reported, which can adversely affect the health of consumers. The most toxic forms of arsenic are the inorganic arsenic (III) and (V) compounds; the inorganic arsenic trioxide is well known as a rat poison, which was also sometimes used for homicide. Methylated forms of arsenic have a low acute toxicity; arsenobetaine which is the principal arsenic form in fish and crustaceans is considered non-toxic. In shellfish, molluscs and seaweed dimethylarsinylriboside derivatives occur ("arsenosugars"), the possible toxicity of which is not known in detail. Only a few percent of the total arsenic in fish is present in inorganic form, which is the only form about which a PTWI has been developed by JECFA.
The human epidemiological data used for this risk assessment is based on exposure to inorganic arsenic in drinking water. IARC has classified inorganic arsenic as a human carcinogen, and the estimated lifetime risk for arsenic-induced skin cancer which may be caused by drinking water at or in excess of the WHO guideline for arsenic in drinking water is estimated at 6×10^{-4}.

Metals

Arsenic

The analysis of total arsenic in food has up to date suffered from difficulties with respect to accuracy and precision. Furthermore, specified data for arsenic are strongly needed because of the large differences in toxicity to humans of the various forms of arsenic.

The intake of total arsenic in the human diet is usually dominated by organic arsenic derived from seafood. The available data about the possible human exposure to inorganic arsenic (often using the assumption that non-seafood commodities contain only inorganic arsenic) suggest that the PTWI will normally not be exceeded, unless there is a large contribution from drinking water. Further research is needed about the fate of organic arsenicals and the possibility that they might be converted to more toxic inorganic forms of arsenic, whether by processing or by metabolism in animals or humans.

Metals

Cadmium

Reference to JECFA: 16 (1972), 33 (1988), 41 (1993), 55 (2000), 61 (2003), 64 (2005), 73 (2010), 77 (2013)
Toxicological guidance value: PTMI 25 µg/kg bw (2010)
Contaminant definition: Cadmium, total
Synonyms: Cd
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Brassica vegetables	0.05	Adopted	2005	FAC	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: "buttons" only.	The ML does not apply to Brassica leafy vegetables.	VB 0040
Bulb vegetables	0.05	Adopted	2005	FAC	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.		VA 0035
Fruiting vegetables	0.05	Adopted	2005	FAC	Whole commodity after removal of stems. Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to tomatoes and edible fungi.	VC 0045 VO 0050
Leafy vegetables	0.2	Adopted	2005	FAC	Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.	The ML also applies to Brassica leafy vegetables.	VL 0053
Legume vegetables	0.1	Adopted	2001	FAC	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.		VP 0060
Pulses	0.1	Adopted	2001	FAC	Whole commodity	The ML does not apply to soya bean (dry).	VD 0070
Root and tuber vegetables	0.1	Adopted	2005	FAC	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.	The ML does not apply to celeriac.	VR 0075 VR 0589
Stalk and stem vegetables	0.1	Adopted	2005	FAC	Whole commodity as marketed after removal of obviously decomposed or withered leaves. Rhubarb: leaf stems only. Globe artichoke: flower head only. Celery and asparagus: remove adhering soil.		VS 0078

Metals

Cadmium

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Cereal grains	0.1	Adopted	2001	FAC	Whole commodity	The ML does not apply to buckwheat, cañihua, quinoa, wheat and rice.	GC 0081
Rice, polished	0.4	Adopted	2006	FAC	Whole commodity		CM 1205
Wheat	0.2	Adopted	2005	FAC	Whole commodity	The ML applies to common wheat, durum wheat, spelt and emmer.	GC 0654
Cephalopods	2	Adopted	2006	FAC	Whole commodity after removal of shell.	The ML applies to cuttlefishes, octopuses and squids without viscera.	IM 0152
Marine bivalve molluscs	2	Adopted	2006	FAC	Whole commodity after removal of shell.	The ML applies to clams, cockles and mussels but not to oysters and scallops.	IM 0151
Natural mineral waters	0.003	Adopted	CS 108-1981	NMW, CF		Relevant Codex commodity standard is CODEX STAN 108-1981. The ML is expressed in mg/l.	1)
Salt, food grade	0.5	Adopted	CS 150-1985	NFSDU		Relevant Codex commodity standard is CODEX STAN 150-1985.	
Cocoa liquor	3.0	4		CF		Cocoa liquor is the product obtained from cocoa nib, which is obtained from cocoa beans of merchantable quality, which have been cleaned and freed from shell with the most technically complete method, without removing or adding any of its constituent's elements.	CX/CF 16/10/9
Cocoa powder	4.0	4		CF		Cocoa powder is the product obtained from cocoa cake transformed into powder.	CX/CF 16/10/9

1) The Standard for Natural Mineral Waters contains the level in the Section 3.2 "Health-related limits for certain substances". The 2nd CCCF (2008) temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41 para. 23-27). After establishment of an EWG by CCCF4, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, para 89-90).

At the 61th JECFA (2003) it was estimated that the total intake of cadmium ranged from 2.8 to 4.2 µg/kg bw per week. This was calculated from available data on concentrations and food consumption taken from the GEMS/Food regional diets and corresponds to approximately 40-60% of the current PTWI of 7 µg/kg bw/week. Regarding major dietary sources of cadmium, the following foods

contributed 10% or more to PTWI in at least one of the GEMS/Food regions: rice, wheat, starchy roots/tubers, and molluscs. Vegetable (excluding leafy vegetables) contribute >5% to the PTWI in two regions.

The 36th CCFAC (2004) decided to discontinue the work on developing MLs for cadmium in fruits, meat of cattle, pigs, sheep and poultry; horse meat; herbs, fresh; fungi (edible); celeriac; soya beans (dry); and peanuts as no levels were necessary because these foods were no major contributors to cadmium intake (ALINORM 04/27/12, para. 176).

The 64th JECFA (2005) conducted intake and impact assessment requested by the 36th session of CCFAC for the seven commodity groups; rice, wheat, potatoes, stem and root vegetables, leafy vegetables, other vegetables and molluscs taking into account different MLs. The JECFA concluded that the effect of different MLs on the overall intake of cadmium would be very small.

The 73rd JECFA (2010) re-evaluated cadmium as there had been a number of new epidemiological studies that had reported cadmium-related biomarkers in urine following environmental exposure. Urinary β2-microglobulin level was chosen as the most suitable biomarker for cadmium toxicity because it was widely recognized as a marker for renal pathology and consequently had the largest number of available data. Because of the long half-life of cadmium in human kidneys (15 years), it was concluded that determination of a critical concentration of cadmium in the urine was most reliable using data from individuals of 50 years of age and older. Using the dose-response relationship of β2-microglobulin excretion in urine to cadmium excretion in urine for this population group, a critical concentration of 5.24 (confidence interval 4.94–5.57) µg of cadmium per gram creatinine was estimated. Using a one-compartment toxicokinetic model, a corresponding dietary cadmium exposure of 0.8 µg/kg body weight per day or 25 µg/kg body weight per month was estimated based on the lower bound of the 5th percentile dietary cadmium exposure (on a population level). Considering the exceptionally long half-life of cadmium and the fact that daily or weekly daily ingestion in food would have a small or even negligible effect on overall exposure, the Committee decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI). The Committee withdrew the PTWI of 7 µg/kg body weight and established a PTMI of 25 µg/kg body weight.

The 5th CCCF (2011) agreed that no follow-up was necessary since the estimates of exposure to cadmium through the diet for all age groups, including consumers with high exposure and subgroups with special dietary habits (e.g. vegetarians), examined by the72nd JECFA were below this PTMI.

The 77th JECFA (2013) conducted an assessment of exposure from cocoa and cocoa products at the request of the 6th CCCF (2012). The estimates of mean population dietary exposure to cadmium from products containing cocoa and its derivatives for the 17 new GEMS/Food Cluster Diets ranged from 0.005 to 0.39 µg/kg bw per month, which equated to 0.02–1.6% of the PTMI of 25 µg/kg bw. The potential dietary exposures to cadmium for high consumers of products containing cocoa and its derivatives in addition to cadmium derived from other foods were estimated to be 30–69% of the PTMI for adults and 96% of the PTMI for children 0.5–12 years of age. The Committee noted that this total cadmium dietary exposure for high consumers of cocoa and cocoa products was likely to be overestimated and did not consider it to be of concern.

The 8th CCCF (2014) agreed to initiate new work on MLs for cadmium in chocolate and cocoa-derived products for approval by the 37th CAC. The Committee agreed to establish an EWG led by Ecuador, co-chaired by Ghana and Brazil to prepare proposals for MLs for comments at Step 3 and consideration at the next session of the Committee, subject to approval by CAC. (REP 14/CF, paras. 141-142, Appendix XI)

The 37th CAC (2014) approved the new work (REP 14/CAC, para. 96, Appendix VI).

The 9th CCCF (2015) agreed to re-establish the EWG, chaired by Ecuador and co-chaired by Brazil and Ghana to reconsider the proposed draft MLs taking into account the comments submitted to this session. The Committee noted the EWG should clearly identify the products for which the MLs were being established and provide the rationale for the MLs. The Committee agreed to return the proposed draft MLs to Step 2/3 for further consideration by the EWG, circulation for comments and further consideration by the next session of CCCF (REP 15/CF, paras. 52-55).

Metals

Cadmium

Cadmium is a relatively rare element, released to the air, land, and water by human activities. In general, the two major sources of contamination are the production and utilization of cadmium and the disposal of wastes containing cadmium. Increases in soil cadmium content will result in an increase in the uptake of cadmium by plants; the pathway of human exposure from agricultural crops is thus susceptible to increases in soil cadmium. The cadmium uptake by plants from soil is greater at low soil pH. Edible free-living food organisms such as shellfish, crustaceans, and fungi are natural accumulators of cadmium. Similar to humans, there are increased levels of cadmium in the liver and kidney of horses and some feral terrestrial animals. Regular consumption of these items can result in increased exposure. Tobacco is an important source of cadmium uptake in smokers (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992)

Data from experimental animals and humans show that pulmonary absorption is higher than gastrointestinal absorption. The gastrointestinal absorption of cadmium is influenced by the type of diet and nutritional status. Cadmium absorbed from the lungs or the gastrointestinal tract mainly accumulates in the liver and kidneys. Although cadmium accumulates in the placenta, transfer to the fetus is low. Excretion is normally slow, and the biological half-time is very long (decades). The binding of intracellular cadmium to metallothionein in tissues protects against the toxicity of cadmium. Excretion occurs mainly via urine (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992)

The kidney is considered the critical target organ for the general population as well as for occupationally exposed populations. The accumulation of cadmium in the kidney leads to renal dysfunction. Chronic obstructive airway disease is associated with long-term high-level occupational exposure by inhalation (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992).

The IARC classified cadmium and cadmium compounds in group 1, carcinogenic to humans (1993).

Metals

Lead

Reference to JECFA: 10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999), 73 (2010)
Toxicological guidance value: - (PTWI withdrawn in 2010)
Contaminant definition: Lead, total
Synonyms: Pb
Related code of practice: Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CAC/RCP 56-2004)
Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Berries and other small fruits	0.1	Adopted	2015	CF	Whole commodity after removal of caps and stems.	The ML does not apply to cranberry, currant and elderberry.	
Cranberry	0.2	Adopted	2015	CF	Whole commodity after removal of caps and stems.		
Currants	0.2	Adopted	2015	CF	Fruit with stem.		
Elderberry	0.2	Adopted	2015	CF	Whole commodity after removal of caps and stems.		
Fruits with the exception of berries and other small fruits	0.1	Adopted	2001	FAC	Whole commodity. Pome fruits: whole commodity after removal of stems. Stone fruits, dates and olives: whole commodity after removal of stems and stones, but the level calculated and expressed on the whole commodity without stem. Pineapple: whole commodity after removal of crown. Avocado, mangos and similar fruit with hard seeds: whole commodity after removal of stone but calculated on whole fruit.		
Brassica vegetables	0.1	Adopted	2015	CF	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: “buttons” only.	The ML does not apply to kale and leafy Brassica vegetables.	

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Bulb vegetables	0.1	Adopted	2001	FAC	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.		VA 0035
Fruiting vegetables	0.05	Adopted	2015	CF	Whole commodity after removal of stems. Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to fungi and mushrooms.	The 9th CCCF noted that in view of the exclusion of fungi and mushrooms from the ML for fruiting vegetables, MLs for these commodities would be considered by the EWG. (REP 15/CF, para. 47)
Leafy vegetables	0.3	Adopted	2001	FAC	Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.	The ML applies to leafy Brassica vegetables but does not apply to spinach.	VL 0053
Legume vegetables	0.1	Adopted	2015	CF	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.		
Pulses	0.2	Adopted	2001	FAC	Whole commodity		VD 0070
Root and tuber vegetables	0.1	Adopted	2001	FAC	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.		VR 0075
Fungi and mushrooms	0.3	4		CF		Relevant Codex commodity standard is CODEX STAN 38-1981. The ML applies to fresh fungi only and does not apply to fungus products.	CX/CF 16/10/7
Canned fruits	0.1	Adopted	2015	CF	The ML applies to the products as consumed.	The ML does not apply to canned berries and other small fruits. Relevant Codex commodity standards are CODEX STAN 242-2003, CODEX STAN 254-2007, CODEX STAN 78-1981, CODEX STAN 159-1987, CODEX STAN 42-1981, CODEX STAN 99-1981.	The 9th CCCF noted that the ML also applied to canned mixed fruits. (REP 15/CF, para. 39)

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Canned berries and other small fruits	0.1	4		CF	The ML applies to the products as consumed.	Relevant Codex commodity standards are CODEX STAN 242-2003, CODEX STAN 254-2007, CODEX STAN 78-1981, CODEX STAN 159-1987, CODEX STAN 42-1981, CODEX STAN 99-1981.	CX/CF 16/10/7 The 10th CCCF is recommended to consider including in canned fruits.
Canned raspberries	1	Adopted	CS 60-1981	PFV		Relevant Codex commodity standard is CODEX STAN 60-1981.	CX/CF 16/10/7 The 10th CCCF is recommended to revoke this ML.
Canned strawberries	1	Adopted	CS 62-1981	PFV		Relevant Codex commodity standard is CODEX STAN 62-1981.	CX/CF 16/10/7 The 10th CCCF is recommended to revoke this ML.
Jam (fruit preserves) and Jellies	1	Adopted	CS 79-1981	PFV		Relevant Codex commodity standard is CODEX STAN 296-2009 (for jams and jellies only).	
Jam (fruit preserves) and Jellies	0.1	4		CF		Relevant Codex commodity standard is CODEX STAN 296-2009	CX/CF 16/10/7 The 10th CCCF is recommended that the Committee should reconsider whether marmalades should be included in this category.
Mango chutney	1	Adopted	CS 160-1987	PFV		Relevant Codex commodity standard is CODEX STAN 160-1987.	CX/CF 16/10/7 The 10th CCCF is recommended to maintain the current ML, pending new data. If insufficient data are available to consider mango chutney as a unique category in 2017, combine mango chutney with jams and jellies in the GSCTFF.

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Canned vegetables	0.1	Adopted	2015	CF	The ML applies to the products as consumed.	The ML does not apply to canned brassica vegetables, canned leafy vegetables and canned legume vegetables. Relevant Codex commodity standard is CODEX STAN 297-2009 (except annexes on canned green beans and canned wax beans and canned green peas).	The 9th CCCF noted that the ML also applied to canned mixed vegetables.(REP 15/CF, para. 42)
Canned leafy and legume vegetables	0.1	4		CF	The ML applies to the products as consumed.		CX/CF 16/10/7, The 10th CCCF is recommended to consider including in the canned vegetables category.
Preserved tomatoes	1	Adopted	CS 13-1981	PFV		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.	
Preserved tomatoes	0.05	4		CF		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.	CX/CF 16/10/7
Table olives	1	Adopted	CS 66-1981	PFV		Relevant Codex commodity standard is CODEX STAN 66-1981.	

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Table olives	0.4	4		CF		Relevant Codex commodity standard is CODEX STAN 66-1981.	CX/CF 16/10/7 The 10th CCCF is recommended to reevaluate table olives in the future when more data are available.
Canned green beans and canned wax beans	1	Adopted	CS 16-1981	PFV		Relevant Codex commodity standard is CODEX STAN 297-2009.	CX/CF 16/10/7 The 10th CCCF is recommended to revoke this ML.
Canned green peas	1	Adopted	CS 58-1981	PFV		Relevant Codex commodity standard is CODEX STAN 297-2009.	CX/CF 16/10/7 The 10th CCCF is recommended to revoke this ML.
Pickled cucumbers (cucumber pickles)	1	Adopted	CS 115-1981	PFV		Relevant Codex commodity standard is CODEX STAN 115-1981.	
Pickled cucumbers (cucumber pickles)	0.1	4		CF		Relevant Codex commodity standard is CODEX STAN 115-1981.	CX/CF 16/10/7
Processed tomato concentrates	1.5	Adopted	CS 57-1981	PFV		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.	
Processed tomato concentrates	0.05	4		CF		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	CX/CF 16/10/7

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
						soluble solids, the reference value being 4.5 for fresh fruit.	
Canned chestnuts and canned chestnuts puree	1	Adopted	CS 145-1985	PFV		Relevant Codex commodity standard is CODEX STAN 145-1985.	CX/CF 16/10/7 The 10th CCCF is recommended to maintain this ML pending new data for reconsideration. If insufficient data are available to consider canned chestnuts and chestnut puree as a unique category in 2017, combine canned chestnuts and chestnut puree with canned fruits in the GSCTFF.
Fruit juicesand nectars, ready to drink	0.03	Adopted	2015	CF	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	The ML does not apply to juices exclusively from berries and other small fruit. The ML does not apply to passion fruit juice and nectar. Relevant Codex commodity standard is CODEX STAN 247-2005.	The 9th CCCF agreed to exclude passion fruit juices and nectars from the ML and wait until the 10th CCCF to make a final decision on this matter based on the recommendation of the EWG. (REP 15/CF, para. 36)
Passion fruit juice and nectar	0.03	4		CF	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	Relevant Codex commodity standard is CODEX STAN 247-2005.	CX/CF 16/10/7 The 10th CCCF is recommended to consider including in the fruit juices category.
Fruit juices exclusively from berries and other small fruits	0.05	Adopted	2015	CF	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	Relevant Codex commodity standard is CODEX STAN 247-2005.	Original ML of 0.05 mg/kg for fruit juices and nectars was retained for this category (REP 15/CF, para. 38)
Juices and nectars from berries and other small fruits	0.3 or	4		CF		Relevant Codex commodity standard is CODEX STAN 247-2005.	CX/CF 16/10/7

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
	0.4						The 10th CCCF is recommended to postpone the decision on juices and nectars from berries and other small fruits to 2017 to allow submission of new data.
Cereal grains	0.2	Adopted	2001	FAC	Whole commodity	The ML does not apply to buckwheat cañihua and quinoa.	GC 0081
Meat of cattle, pigs and sheep	0.1	Adopted	2001	FAC	Whole commodity (without bones)	The ML also applies to the fat from meat.	MM 0097
Meat and fat of poultry	0.1	Adopted	2001	FAC	Whole commodity (without bones)		PM 0110 PF 0111
Cattle, Edible offal of	0.5	Adopted	2001	FAC	Whole commodity.		MO 0812
Pig, Edible offal of	0.5	Adopted	2001	FAC	Whole commodity.		MO 0818
Poultry, Edible offal of	0.5	Adopted	2001	FAC	Whole commodity.		PO 0111
Edible fats and oils	0.1	Adopted	CS 19-1981,	FO	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 and CODEX STAN 211-1999.	OC 0172 OR 0172
Fat spreads and blended spreads	0.1	Adopted	CS 256-2007	FO		Relevant Codex commodity standard is CODEX STAN 256-2007.	1)

Metals

Lead

Commodity / Product Name	Maximum Level(ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Milk	0.02	Adopted	2001	FAC	Whole commodity	Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing. A concentration factor applies to partially or wholly dehydrated milks.	ML 0106 The previous footnote "For dairy products, an appropriate concentration factor should apply" was changed by the 26th CAC.
Secondary milk products	0.02	Adopted	2001	FAC	Whole commodity	The ML applies to the food as consumed.	
Infant formula, Formula for special medical purposes intended for infants and Follow-up formula	0.01	Adopted	2014	CF	Whole commodity	Relevant Codex commodity standards are CODEX STAN 72-1981 and CODEX STAN 156-1987. The ML applies to formula as consumed.	
Fish	0.3	Adopted	2006	FAC	Whole commodity (in general after removing the digestive tract)		
Natural mineral waters	0.01	Adopted	CS 108-1981	NMW, CF		Relevant Codex commodity standard is CODEX STAN 108-1981. The ML is expressed in mg/l.	2)
Salt, food grade	2	Adopted	CS 150-1985	NFSDU		Relevant Codex commodity standard is CODEX STAN 150-1985.	
Wine	0.2	Adopted	2001	FAC			3)

1) The Standard for fat spreads and blended spreads contain the following wording for the mentioned contaminant MLs: "The products covered by the provisions of this Standard shall comply with MLs being established by the CAC but in the meantime the following limits will apply." (only applying to Pb and As).

2) The Standard for Natural Mineral Waters contains the level in the Section 3.2 "Health-related limits for certain substances". The 2nd CCCF (2008) temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41, para. 23-27). After establishment of an EWG by CCCF4, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, para 89-90).

3) The OIV requested special consideration to be given to levels of lead in wines that had been stored for long periods of time (ALINORM 01/41, para.123).

Metals

Lead

The 32nd CAC (2001) requested reevaluation of the lead MLs in milk and milk fat (ALINORM 01/41, para. 121); see also ALINORM 03/12 paras. 135-137. The 35th CCFAC (2004) discussed the issue of the necessity of an ML for milk, as milk was not a major contributor to the intake of lead. However, in view of opinions that milk is a major contributor to the exposure of infants and young children, the ML for milk was maintained. The Committee decided to inform the CAC that the current level for lead in milk fat (0.1 mg/kg) should be revoked (no documentation of such a decision is found in the CAC 2003 report however). The 35th CCFAC (2005) agreed to retain the current ML for milk.

The 4th CCCF (2010) noted that the Committee on Processed Fruits and Vegetables had elaborated several general standards for groups of canned fruits and vegetables thereby replacing individual standards for canned fruits and vegetable which were revoked by the Commission on adoption of the general standards. It was further noted that the scope of these general standards had also been expanded to include other commodities for which individual standards had not previously existed. These general standards contained the general statement on contaminants from the Procedural Manual. At the same time, several MLs for lead for canned fruits and vegetables from the revoked standards were listed in the GSCTFF. The Committee therefore considered whether the levels for lead applied to the more general standards with particular regard to whether these levels could also be extended to those commodities now included in these general standards for which levels had not previously been established.
The Committee agreed to not take action until the 73rd JECFA in June 2010 had completed its evaluation (ALINORM 10/33/41, paras. 18-22).

The 73rd JECFA (2010) re-evaluated lead and concluded that the effects on neurodevelopment and systolic blood pressure provided the appropriate bases for dose–response analyses. Based on the dose–response analyses, the Committee estimated that the previously established PTWI of 25 µg/kg bw was associated with a decrease of at least 3 IQ points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults, which were considered important effects when viewed on a population level. The Committee therefore withdrew the PTWI as it could no longer be considered health protective. Because the dose–response analyses did not provide any indication of a threshold for the key effects of lead, the Committee concluded that it was not possible to establish a new PTWI that would be considered to be health protective. The Committee concluded that the conducted dose–response Analyses should be used to identify the magnitude of effect associated with identified levels of dietary lead exposure in different populations.
The mean dietary exposure estimates for children aged about 1–4 years ranged from 0.03 to 9 µg/kg bw per day and for adults from 0.02 to 3 µg/kg bw per day. The higher end of the exposure range for children was deemed by the Committee to be a concern, as it was higher than the level of 1.9 µg/kg bw per day calculated by the Committee to be associated with a population decrease of 3 IQ points. For adults, the higher end of the exposure range, a population increase of approximately 2 mmHg (0.3 kPa) in systolic blood pressure would be expected to occur.
An increase of this magnitude had been associated, in a large meta-analysis, with modest increases in the risks of ischaemic heart disease and cerebrovascular stroke. The Committee considered the expected effects in children of more concern than the effects in adults. The Committee stressed that other (than dietary) sources of exposure to lead needed also to be considered. Also, The Committee concluded that, in populations with prolonged dietary exposures to lead that are at the higher end of the ranges identified above, measures should be taken to identify major contributing sources and foods and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

The 5th CCCF (2011) agreed to establish an electronic Working Group, led by the United States of America and working in English only, to: (i) reconsider the existing MLs with a focus on foods important for infants and children and also on the canned fruits and vegetables and (ii) reconsider if other existing maximum levels should be addressed.

The 6th CCCF (2012) agreed to start new work on the revision of the MLs for lead in fruit juices, milk and secondary milk products, infant formula, canned fruits and vegetables, fruits and cereal grains (except buckwheat, cañihua and quinoa). It was noted that where possible follow-up formula could be taken into account during this work because the data that was used for infant formula could also apply to this product. The Committee also agreed to establish an electronic working group lead by the United States of America to revise the MLs for lead for comments at Step 3 and consideration at the 7th session (REP12/CF, paras. 126-127 and Appendix VIII).

Metals

Lead

The 35th CAC (2012) approved the new work (REP12/CAC, Appendix VI).

The 7th CCCF (2013) agreed to retain the current MLs of 0.02 mg/kg for milks and 0.2 mg/kg for cereals. The Committee noted that the ML for milk might be reviewed in future when new data became available and might be revised in light of the review of the MLs for milk products and also noted that if different MLs would be considered for cereal grains in future, stricter MLs could be applied to certain cereal grains in light of available data (REP 13/CF, paras 28-29)., The Committee agreed to retain the ML of 0.05 mg/kg for juices and nectars from berries and other small fruits, ready-to-drink, and noted that in future, there might be a need for different MLs for fruit juices depending on the outcome of discussions on the ML for lead in fruit(REP 13/CF, paras 31-32).
The Committee agreed to advance the proposed draft ML of 0.03 mg/kg for fruit juices and nectars, ready-to-drink (excluding juices from berries and other small fruits); the proposed draft ML of 0.1 mg/kg for canned fruits, including canned mixed fruits (excluding canned berry and other small fruits); and the proposed draft ML of 0.1 mg/kg for canned vegetables, including canned mixed vegetables (excluding canned brassica vegetables, canned leafy vegetables and canned legume vegetables) to the 36th Session of CAC for adoption at Step 5/8.
Following this decision, the Committee agreed to request the Commission to revoke the MLs for lead for the individual standards for canned fruits (i.e. canned fruit cocktail, canned tropical fruit salad, canned grapefruit, canned mandarin oranges, canned mangoes, canned pineapples, canned raspberries and canned strawberries) and to revoke the MLs for lead for the individual standards for canned vegetables (i.e. canned asparagus, canned carrots, canned green beans and canned wax beans, canned green peas, canned mature processed peas, canned mushrooms, canned palmito (palm hearts), canned sweet corn, canned tomatoes and table olives) (REP13/CF, para.41-43 and APPENDIX II).

The Committee agreed to continue with the review of MLs for lead in fruits, vegetables, milk products and infant formula, follow-up formula and formula for special medical purposes for infants. The Committee therefore agreed to re-establish the EWG led by the United States of America and working in English to continue with the review of the MLs for lead for the above-mentioned commodities in the GSCTFF (REP13/CF, para. 39-40).

The 36th CAC (2013) agreed to adopt the MLs at Step 5 with the understanding that countries that had intervened commit to submit data to GEMS/Food database within a year, to allow CCCF to further consider the revision of the MLs in 2015 for submission to the 38th Session of the Commission. Following this decision, the Commission did not revoke MLs for the individual standards for canned fruits and vegetables (REP13/CAC, para. 79 and 102).

The 8th CCCF (2014) noted wide support for the retention of the current MLs in the GSCTFF for “assorted (sub)tropical fruits, edible peel”, “assorted(sub)tropical fruits, inedible peel”, “citrus fruits”, “pome fruits”, “stone fruits”, “bulb vegetables”, “leafy vegetables”, “root and tuber vegetables” and “secondary milk products” and therefore no further action needed to be taken in regard to these MLs. The Committee noted that retention of these MLs implied that the relevant accompanying explanatory notes should be retained (REP 14/CF, para. 21).
The Committee noted that for the commodity group “berries and other small fruits” the proposed lower ML may be acceptable when applied to the occurrence data of this group as a whole. However, when the data are split into the individual species or varieties of berries and small fruits, the proposed reduction may be problematic for some berries such as cranberries, currants, elderberries and strawberry tree. Therefore, it was advisable to postpone the discussion of this ML until the 9th CCCF to allow interested countries to submit new or additional data to GEMS/Food for analysis on the understanding that if no data were made available, the Committee would accept the proposed lower ML for adoption at its 9th session. The Committee recalled that this approach was similar to the one taken on infant formula at its 7th Session (REP 14/CF, para. 22).
The Committee agreed to request the EWG to also undertake the review of the data submitted on lead contamination in fruit juices and nectars, canned fruits and canned vegetables in reply to CL 2013/23-CF, with a view to facilitating their discussion and finalization at the 9th CCCF. The Committee further agreed that the EWG would be led by the United States of America and would be working in English only (REP 14/CF, paras. 26-27).
The Committee agreed to forward the proposed draft ML of 0.01 mg/kg for lead in infant formula and formula for special medical purposes intended for infants and follow up formula (as consumed) to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th Session of the Commission. The Delegations of the European Union and Norway expressed their reservation to this decision.

Metals

Lead

In taking this decision, the Committee further agreed to request the Commission to revoke the current ML of 0.02 mg/kg for lead in infant formula in the GSCTFF and to request the Committee on Nutrition and Foods for Special Dietary Uses to remove this ML from the section on contaminants in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) and instead to make reference to the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995, REP 14/CF, paras. 32-34. Appendix II).

The 37th CAC (2014) adopted the revised ML of 0.01 mg/kg for lead in Infant Formula and Formula for Special Medical Purposes and for Follow-Up Formula as proposed by the CCCF. The Delegations of the European Union, Egypt, Malaysia and Norway expressed their reservation (REP 14/CAC, para. 74, Appendix III). The CAC agreed to revoke the Maximum Level for Lead in Infant Formula in the GSCTFF (REP 14/CAC, para. 94, Appendix V).

The 9th CCCF (2015) agreed to reduce the ML for lead in fruit juices and nectars, ready-to-drink from 0.05 to 0.03 mg/kg. The Committee also agreed to retain the ML of 0.05 mg/kg for juices and nectars from berries and other small fruit at 0.05 mg/kg, and agreed that exclusion for juices from berries and other small fruits should be limited to juices that were “exclusively” prepared from berries and other small fruits. The Committee also agreed to exclude passion fruit juice from the ML for fruit juices and nectars and wait until the 10th Session of CCCF to make a final decision on this matter based on the recommendation of the EWG (REP 15/CF, paras. 36-38).

The Committee agreed to reduce the ML for canned fruits (excluding berries and other small fruits) from 1mg/kg to 0.1 mg/kg. The Committee noted that the ML also applied to canned mixed fruits. Following this decision, the Committee agreed to make consequential amendments to the MLs for lead in the GSCTFF by revocation of MLs of corresponding fruits. The Committee agreed to retain the MLs for canned raspberries and canned strawberries at 1mg/kg for consideration at the 10th CCCF based on the recommendation of the EWG (REP 15/CF, paras. 39-40).
The Committee agreed to reduce the ML for berries and other small fruits from 0.2 mg/kg to 0.1 mg/kg and to exclude certain types of berries i.e. cranberry, currant, elderberry and to retain the existing ML of 0.2 mg/kg for these fruits (REP 15/CF, para. 41).

The Committee agreed to reduce the ML for canned vegetables (excluding canned brassica, leafy and legume vegetables) from 1mg/kg to 0.1 mg/kg. The Committee noted that the ML also applied to canned mixed vegetables. The Committee agreed to make consequential amendments to the MLs for lead in the GSCTFF by revocation of MLs of corresponding vegetables and noted that MLs for canned brassica vegetables, canned leafy vegetables and canned legume vegetables would be considered by the EWG (REP 15/CF, paras. 42-44).
The Committee agreed with the following: (i) reduce the ML for brassica vegetables from 0.3 mg/kg to 0.1 mg/kg; (ii) reduce the ML for legume vegetables from 0.2 mg/kg to 0.1 mg/kg; (iii) reduce the ML for fruiting vegetables, cucurbits from 0.1 mg/kg to 0.05 mg/kg; and (iv) reduce the ML for fruiting vegetables, other than cucurbits from 0.1 mg/kg to 0.05 mg/kg (excluding fungi and mushrooms). The Committee noted a proposal to exclude sweet corn from the ML for fruiting vegetables, other than cucurbits, however data in support of this reduction came mainly from one region while global GEMS/Food data supported inclusion of canned sweet corn under the ML for fruiting vegetables, other than cucurbits. The Committee also noted that in view of the exclusion of fungi and mushrooms from the ML for fruiting vegetables, other than cucurbits, MLs for these commodities would be considered by the EWG (REP 15/CF, paras. 45-47).

Consequently, the Committee agreed to forward draft MLs for fruit juices and nectars (excluding juices exclusively from berries and other small fruits and passion fruit), ready-to-drink at 0.03 mg/kg, canned fruits (excluding berries and other small fruits) at 0.1 mg/kg and canned vegetables (excluding canned brassica, leafy and legume vegetables) at 0.1 mg/kg to the 38th CAC for adoption at Step 8, and proposed draft MLs for berries and other small fruits (excluding cranberry, currant and elderberry) at 0.1 mg/kg; cranberries at 0.2 mg/kg; currant at 0.2 mg/kg; elderberry at 0.2 mg/kg; brassica vegetables at 0.1 mg/kg; legume vegetables at 0.1 mg/kg; fruiting vegetables, cucurbits at 0.05 mg/kg; and fruiting vegetables, other than cucurbits at 0.05 mg/kg (excluding fungi and mushrooms) to the 38th CAC for adoption at Step 5/8.
The Committee also agreed to recommend revocation of the following MLs by the 38th CAC: canned grapefruit, canned mandarin oranges, canned mangoes, canned pineapples, canned fruit cocktail, canned tropical fruit salad, canned asparagus, canned carrots, canned mature processed peas, canned mushrooms, canned palmito (palm hearts) and canned sweet corn. (REP 15/CF, paras. 49-51)

Metals

Lead

The Committee also agreed to re-establish the EWG, chaired by USA to continue to work on outstanding issues related to the review of MLs for lead in fruits and vegetables in the GSCTFF namely review of MLs for passion fruit juice; juices and nectars from berries and other small fruits; canned berries and other small fruits; jams (fruit preserves) and jellies; mango chutney; canned chestnuts and canned chestnuts puree; canned brassica vegetables; canned leafy vegetables; canned legume vegetables; pickled cucumbers (cucumber pickles); preserved tomatoes; processed tomato concentrates; table olives; fungi and mushrooms (REP 15/CF, para. 48).

The 38th CAC (2015) adopted the draft and proposed draft MLs for lead at step 8 and 5/8 (REP15/CAC, para. 13, Appendix III).

Exposure to lead can occur from many sources but usually arises from industrial use. Lead and its compounds can enter the environment during mining, smelting, processing, use, recycling, or disposal. The main uses of lead are in batteries, cables, pigments, plumbing, gasoline, solder and steel products, food packaging, glassware, ceramic products, and pesticides. The main exposure of the general non-smoking adult population is from food and water. Airborne lead may contribute significantly to exposure, depending on such factors as use of tobacco, occupation, and proximity to sources such as motorways and lead smelters. Food, air, water, and dust or soil are the main potential sources of exposure of infants and young children.

The rate of absorption of lead after ingestion can range from 3% to 80%. It is heavily influenced by food intake, much higher rates of absorption occurring after fasting than when lead is ingested with a meal. Absorption is also affected by age, the typical absorption rates in adults and infants being 10% and 50%, respectively. Up to 50% of the inhaled lead compound may be absorbed. After its absorption and distribution in blood, lead is initially distributed to soft tissues throughout the body. Eventually, bone accumulates lead over much of the human life span and may serve as an endogenous source of lead. The half-life for lead in blood and other soft tissues is about 28-36 days, but it is much longer in the various bone compartments. The percentage retention of lead in body stores is higher in children than adults. Inorganic lead is not metabolized. Lead that is not distributed is mainly excreted through the kidney.

Lead is a classical chronic or cumulative poison. In humans, lead can result in a wide range of biological effects depending upon the level and duration of exposure. Health effects are generally not observed after a single exposure. Many of the effects that have been observed in laboratory animals have also been observed in humans, including hematological effects, neurological and behavioral effects, renal effects, cardiovascular effects, and effects on the reproductive system. In addition, lead has been shown to have effects on bone and on the immune system in laboratory animals. Children are more vulnerable to the effects of lead than adults. Lead has been shown to be associated with impaired neurobehavioral functioning in children. Impaired neurobehavioral development and increase in systolic blood pressure were considered to be the most critical effect (JECFA73, 2010).

Inorganic lead compounds are classified by the IARC as probably carcinogenic to humans (Group 2A; Vol. 87, 2006)

Metals

Mercury

Reference to JECFA:	10 (1966), 14 (1970), 16 (1972), 22 (1978), 72 (2010)
Toxicological guidance value:	PTWI 4 µg/kg bw for inorganic mercury (2010)
Contaminant definition:	Mercury, Total
Synonyms:	Hg
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Natural mineral waters	0.001	Adopted	CS 108-1981	NMW, CF		Relevant Codex commodity standard is Codex STAN 108-1981. The ML is Expressed in mg/l	1)
Salt, food grade	0.1	Adopted	CS 150-1985	NFSDU		Relevant Codex commodity standard is Codex STAN 150-1985.	

1) The Standard for Natural Mineral Waters contains the level in the Section 3.2 “Health-related limits for certain substances”. The 2nd CCCF (2008) temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41 para. 23-27). After establishment of an EWG by CCCF4, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, para 89-90).

No CCFAC/CCCF position document was available about mercury.

The 72nd JECFA in February 2010 considered that, based on the toxicological database for mercury (II) chloride, that there was limited evidence for carcinogenicity of inorganic mercury, but that direct DNA damage was not demonstrated, and that therefore setting a health-based guidance value was appropriate. The lowest $BMDL_{10}$ for relative kidney weight increase in male rats was calculated to be 0.11 mg/kg bw per day as mercury(II) chloride. This corresponds to 0.06 mg/kg bw per day as mercury, adjusted from a 5 day per week dosing schedule to an average daily dose and for the percent contribution of inorganic mercury to dose. After application of a 100-fold uncertainty factor, the Committee established a PTWI for inorganic mercury of 4 µg/kg bw. The previous PTWI of 5 µg/kg bw for total mercury, established at the sixteenth meeting, was withdrawn.
The new PTWI for inorganic mercury was considered applicable to dietary exposure to total mercury from foods other than fish and shellfish. For dietary exposure to mercury from these foods the previously established PTWI for methyl mercury should be applied. The upper limits of estimates of average dietary exposure to total mercury from foods other than fish and shellfish for adults (1 µg/kg bw per week) and for children (4 µg/kg bw per week) were at or below the PTWI for inorganic mercury.

The 72nd JECFA noted that there was a lack of quantitative data on methylmercury in non-fish products and on inorganic mercury in foods in general.

Mercury is a naturally occurring metallic element which can be present in foodstuffs by natural causes; elevated levels can also occur due to e.g. environmental contamination by industrial or other uses of mercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products.

Metals

Methylmercury

Reference to JECFA: 22 (1978), 33 (1988), 53 (1999), 61 (2003), 67 (2006)
Toxicological guidance value: PTWI 0.0016 mg/kg bw (2003; confirmed in 2006)
Contaminant definition: Methylmercury
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks	Notes for CCCF
Fish	0.5	Adopted	1991	FAC, FFP	Whole commodity (in general after removing the digestive tract)	The GL does not apply to predatory fish. The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade. a)	
Predatory fish	1	Adopted	1991	FAC, FFP	Whole commodity (in general after removing the digestive tract)	Predatory fish such as shark, swordfish, tuna, pike and others. The guideline levels intended for methylmercury in fresh or processed fish and fish products moving in international trade. a)	1)

a) Lots should be considered as being in compliance with the guideline levels if the level of methylmercury in the analytical sample, derived from the composite bulk sample, does not exceed the above levels. Where these Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction and what recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women.

1) The GLs for methylmercury in fish were adopted by the CAC-19 in 1991 (ALINORM 91/40, para. 202), on the understanding that the levels would be kept under review by the CCFAC as well as the CCFFP, especially as to the identification of predatory species of fish to which the higher GL applies.

The 24th CCFAC (1992) informed the CAC and the CCFFP that the recommended GLs for mercury in fish referred to total mercury rather than methylmercury. The 20th CAC (1993) decided to maintain the GLs for methylmercury in fish as previously adopted, while recommending that the establishment of corresponding GLs for total mercury in fish be considered by the CCFAC at its next meeting. The 26th CCFAC (1994) noted that analysis of total mercury was generally adequate to ensure that GLs for methylmercury were not exceeded and decided that the establishment of GLs for total mercury in fish was not necessary. The 29th CCFAC (1997) noted that the 43rd CXEXEC (1996) had recommended that the CCFAC initiate a new risk analysis on methylmercury. It was decided to defer any decision on the question of GLs based on methylmercury or total mercury until JECFA had performed the risk assessment.

The 53rd JECFA (1999) calculated the human exposure to methylmercury in regional diets to range from 0.3-1.5 µg/kg bw/week. Nationally reported dietary exposures are in the range 0.1 –2.0 µg/kg bw/week. The 53rd JECFA maintained the PTWI of 3.3 µg bw for methylmercury set in the previous meetings of the JECFA and recommended that methylmercury be re-evaluated in 2002 when new information on the cohort in one of the studies could be assessed and possibly other new relevant data could be available. The JECFA also recommended that the nutritional benefits of fish consumption are weighted against the possibility of harm when limits on methylmercury concentrations in fish or on fish consumption are being considered.
The 32nd CCFAC (2000) took note of these recommendations made by the 53rd JECFA.

Metals

Methylmercury

The 37th CCFAC (2005) agreed that the revision of the GLs requires more comprehensive consideration by CCFAC in order to take into account all factors related to the consumption of fish, in particular, risks and benefits. In the meantime, the existing GLs can be retained with the understanding that enforcement can be performed by determination of total mercury as a screening method (for facilitating control/monitoring). Methylmercury needs only be determined for verification purposes (ALINORM 05/28/12, para. 202).

The 38th CCFAC (2006) agreed: to forward a request to the CAC for an FAO/WHO expert consultation on health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and health benefits of fish consumption; to postpone consideration on the need to revise the guideline levels for methylmercury in fish pending the outcome of the requested FAO/WHO consultation and to retain the current Codex guideline levels; not to start compiling data on the ratio of methylmercury to total mercury in different fish species; and to postpone discussion on the risk communication aspects of methylmercury in fish (ALINORM 06/29/12, paras 191-194).

The 67th JECFA (2006) confirmed the PTWI of 1.6 µg/kg bw, set in 2003, based on the most sensitive toxicological end-point (developmental neurotoxicity) in the most susceptible species (humans). However, the Committee noted that life-stages other than the embryo and fetus may be less sensitive to the adverse effects of methylmercury. The Committee considered that intakes of up to about two times higher than the existing PTWI would not pose any risk of neurotoxicity in adults, except for women of childbearing age in order to protect the embryo and fetus. Concerning infant and children up to about 17 years no firm conclusions could be drawn; it is clear that they are not more sensitive than the embryo or fetus, but may be more sensitive than adults because significant development of the brain continues in infancy and childhood. Therefore, no level of intake higher than the existing PTWI could be identified of infants and children.

The 67th JECFA recommended that:
- Known benefits of fish consumption need to be taken in consideration in any advice aimed at different populations, since fish make an important contribution to nutrition, especially in certain regional and ethnic diets. Risk managers may wish to consider whether specific advice should be given concerning children and adults after weighing the potential risks and benefits.
- Setting of guideline levels for methyl mercury in fish may not be an effective way of reducing exposure for the general population, however advice to population subgroups that may be at risk may provide an effective method for lowering the number of individuals with exposures greater than the PTWI.

The First CCCF (2007) was informed by the WHO Representative that JECFA's conclusion with respect to guideline levels must be considered in relation to the fact that guidelines already in place in some national jurisdictions had already influenced the range of observed mercury concentrations by eliminating fish containing high concentrations of mercury from the market. The First CCCF reaffirmed the decision made by the 38th Session of the CCFAC to postpone consideration of the need to revise the guideline levels for methylmercury in fish pending the outcomes of a joint FAO/WHO expert consultation on health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption and to retain the current Codex guideline levels for the time being (ALINORM 07/30/41, paras 34-35).

The 30th Commission (2007) recalled that its 29th Session had requested FAO and WHO for scientific advice on the health risks associated with methylmercury and dioxins and dioxin-like PCBs in fish and the health benefits of fish consumption. The Representative of FAO, speaking on behalf of FAO and WHO, informed the Commission that a step-wise preparatory process was being taken, given the complex nature of the issue and the need for innovative principles and methodology. The Representative indicated that, possibly at a first stage, FAO and WHO would consider conducting qualitative risk-benefit assessment of fish consumption, specifically addressing issues related to the impact of methylmercury exposure on women of child-bearing age and at a later stage, conducting quantitative assessment including the intake of dioxin and dioxin-like PCBs, taking into account consumption of fatty fish, considered as a significant source of beneficial fatty acids (ALINORM 07/30/REP, para. 192).

Metals

Methylmercury

FAO and WHO organized an expert consultation on the risks and benefits of fish consumption, taking into consideration the health risks associated with methylmercury (MeHg), dioxin and dioxin-like PCBs (DLC) and the nutritive and health benefits of eating fish, in response to the request of the 29th session of the Commission (ALINORM 09/32/41, para. 24). The Expert Consultation was held in January 2010. It was concluded that consumption of fish provides energy, protein, and a range of other important nutrients, including the long-chain n-3 poly unsaturated fatty acids (LC n-3 PUFA), that eating fish was part of the cultural traditions of many peoples and that in some populations fish was a major source of food and essential nutrients. The Consultation concluded that among the general adult population, consumption of fish, particularly oily fish, lowers the risk of coronary heart disease (CHD) mortality and that probable or convincing evidence of CHD risks of MeHg was absent. When considering benefits of LC n-3 PUFA vs. risks of MeHg among women of childbearing age: maternal fish consumption lowered the risk of suboptimal neurodevelopment in their offspring compared to women not eating fish in most circumstances evaluated. Among infants, young children, and adolescents, the available data were insufficient to derive a quantitative framework of health risks and benefits of eating fish. However, the Consultation stated that healthy dietary patterns that include fish and are established early in life influence dietary habits and health during adult life. To minimize risks in target populations, the Consultation recommended a series of steps that member states should take to better assess and manage the risks and benefits of fish consumption and more effectively communicate with their citizens.

The 5th CCCF (2011) agreed to consider the need to review the existing GLs for methylmercury in fish and predatory fish when the full report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption becomes available.

The 6th CCCF (2012) agreed to the development of a discussion paper on the review of the guideline level for methylmercury in fish and predatory fish through an EWGled by Norway and co-chaired by Japan for consideration and discussion at the 7th session with the view of identification of possible actions or new work on this issue (REP 12/CF, para. 174).

The 7th CCCF (2013) agreed that consumer advice should not be developed at the international level and that such guidance was more appropriate at the national level. It was agreed to review the GLs with a view to their revision or conversion to MLs. The Committee therefore re-established the EWG, led by Japan and co-chaired by Norway, to prepare a discussion paper; collect data on total mercury and methylmercury in fish species important in international trade in order to review the current GLs; and explore the possibility of revising the GLs or their conversion to MLs and to identify the fish for which the level or levels could apply (REP 13/CF, paras. 125,126).

The 8th CCCF (2014) noted that there was wide support for establishment of an ML for methylmercury, and agreed that this would be the approach with the use of total mercury for screening purposes, but that further consideration was needed on an appropriate level or levels; and the fish classification would have to be further developed as proposed by the chair of the EWG. The Committee further noted that this decision did not preclude the usefulness of consumer advice and confirmed the decision of the last session of the Committee that consumer advice should be developed at the national or regional level as the advice would vary between countries because of the risk of mercury exposure from the diet would depend on, amongst others, the patterns of consumption of fish and the types of fish consumed; and that no further work would be done at the international level. The Committee agreed to re-establish the EWG, led by Japan and co-chaired Norway to develop a discussion paper to provide proposals for ML(s) for methylmercury, to express to which fish species these should apply, and to include a project document for a new work proposal for consideration by the 9th session of the Committee (REP 14/CF, paras. 113-114).

The 9th CCCF (2015) noted that the continued support for an ML for methylmercury and agreed that further work on this should continue through the development of another discussion paper to consider expanding the ML to fish species that can accumulate high methylmercury concentrations, other than tuna and that consideration should be given to narrowing down the ML ranges. It was recognised that development of this paper would require additional data and that an exposure assessment based on different MLs should be conducted.
The Committee agreed to re-establish the EWG, chaired by Japan and co-chaired by New Zealand to prepare a discussion paper with proposals for ML for methylmercury, including a project document for consideration by the next session. (REP 15/CF, paras. 125-126)

Methylmercury

Methylmercury is the most toxic form of mercury and is formed in aquatic environments. Methylmercury therefore is found mainly in aquatic organisms. It can accumulate in the food chain; the levels in large predatory fish species are therefore higher than in other species and fish is the predominant source of human exposure to methylmercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products.

In all experimental animal species evaluated, methylmercury was readily absorbed (up to 95%) after oral exposure. Methylmercury crossed both the blood–brain barrier and the placenta effectively, resulting in higher concentrations of mercury in the brain of the fetus than of the mother. Methylmercury is eliminated mainly via the bile and faeces, neonatal animals having a lower excretory capacity than adults. Methylmercury is toxic to the nervous system, kidney, liver and reproductive organs, neurotoxicity being the most sensitive end-point (WHO Food additives Series 52; 2004).

Metals

Tin

Reference to JECFA:	10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26(1982), 33(1988), 55 (2000), 64 (2005)
Toxicological guidance value:	PTWI 14 mg/kg bw (1988, Expressed as Sn; includes tin from food additive uses; maintained in 2000)
Contaminant definition:	Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification
Synonyms:	Sn
Related code of practice:	Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods (CAC/RCP 60-2005) Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Canned foods (other than beverages)	250	Adopted	2007	FAC, CF		The ML does not apply to non-tinplate canned cooked cured chopped meat,cooked cured ham, cooked cured pork shoulder, corned beef and luncheon meat. Relevant Codex commodity standards include CODEX STAN 62-1981, CODEX STAN 254-2007, CODEX STAN 296-2009, CODEX STAN 242-2003, CODEX STAN 297-2009, CODEX STAN 78-1981, CODEX STAN 159-1987, CODEX STAN 42-1981, CODEX STAN 60-1981, CODEX STAN 99-1981, CODEX STAN 160-1987, CODEX STAN 66-1981, CODEX STAN 13-1981, CODEX STAN 115-1981, CODEX STAN 57-1981, CODEX STAN 145-1981, CODEX STAN 98-1981, CODEX STAN 96-1981, CODEX STAN 97-1981, CODEX STAN 88-1981, CODEX STAN 89-1981.	
Canned beverages	150	Adopted	2007	FAC, CF		Relevant Codex commodity standards include CODEX STAN 247-2005.	
Cooked cured chopped meat	50	Adopted	CS 98-1981	PMPP		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 98-1981.	
Cooked cured ham	50	Adopted	CS 96-1981	PMPP		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 96-1981.	

Metals

Tin

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Cooked cured pork shoulder	50	Adopted	CS 97-1981	PMPP		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 97-1981.	
Corned beef	50	Adopted	CS 88-1981	PMPP		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 88-1981.	
Luncheon meat	50	Adopted	CS 89-1981	PMPP		The ML applies to products in containers other than tinplate containers. Relevant Codex commodity standard is CODEX STAN 89-1981.	

In previous JECFA meetings it was noted that inorganic tin compounds generally have low systemic toxicity in animals, because of limited absorption from the gastrointestinal tract, low accumulation in tissues, and rapid passage through the gastrointestinal tract. Insoluble tin compounds are less toxic than soluble tin salts.

The 33rd JECFA (1988) established a PTWI for inorganic tin of 14 mg/kg bw.

At the 55th JECFA (2000), it was concluded that the acute toxicity of inorganic tin in animals and humans results from irritation of the mucosa of the gastrointestinal tract, which may lead to vomiting, diarrhea, anorexia, depression, ataxia, and muscular weakness. There was insufficient data available to establish an ARfD for inorganic tin. The committee did not consider studies on organic tin compounds, since it had concluded at the 22nd JECFA (1978), that these compounds differ considerably from inorganic tin compounds with respect to toxicity and should be considered separately.

The 55th JECFA maintained the existing PTWI and reiterated that limited human data available indicated that concentrations of 150mg/kg tin in canned beverages and 250 mg/kg in other canned foods may produce acute manifestations of gastric irritation in certain individuals. This is considered to be a reversible effect however, which may occur in a limited number of sensitive subject only.

Following the discussions in the 34th CCFAC (2002) and in the 35th CCFAC (2003) (ALINORM 03/12, para.146 and ALINORM 03/12A, para.160), the proposed MLs were repeatedly returned to step 3. The 35th CCFAC changed the terminology of the commodities to which the proposed draft MLs apply, which previously was “liquid canned foods resp. solid foods”, to “canned beverages” and “canned foods other than beverages”. The Committee decided to ask JECFA to evaluate current tin level in canned foods and to determine an acute reference dose; it was noted that new data would become available. The 36th CCFAC (2004) decided to hold the proposed MLs and reconsider these MLs in the light of the 64th JECFA re-evaluation (ALINORM 04/27/12, para.171).

The 64th JECFA (2005) concluded that the data available indicated that it is inappropriate to establish and ARfD for inorganic tin since whether or not irritation of gastrointestinal tract occur after ingestion of a food containing tin depends on the concentration and nature of in the product, rather than on the dose ingested on a body-weight basis.

Metals

Tin

The 37th CCFAC (2005) agreed to circulate the proposed MLs for comments at Step 3 (ALINORM 05/28/12, para.163). The 38th CCFAC (2006) forwarded the proposed draft MLs to step 5(ALINORM 06/29/12 para.183). The 29th CAC adopted the proposed draft MLs and advanced it to step 6 (ALINORM 06/29/41 para.106).

The First CCCF (2007) agreed to forward the draft MLs to the 30th Commission for adoption at Step 8 and noted that the adoption of the ML for tin in canned foods (other than beverages) would result in consequential changes to MLs for tin in certain canned products (i.e. products in tin-layered cans), currently included in Schedule 1 (ALINORM 07/30/41, para. 81).

The 30th Commission adopted these MLs at Step 8 with the understanding that the existing MLs for tin in certain canned foods included in Schedule I of the GSCTF would be replaced by the adopted MLs (ALINORM 07/30/REP).

Tin is mainly used in tinplated containers, but it is also extensively used in solders, in alloys including dental amalgams. Inorganic tin compounds, in which the element may be present in the oxidation states of +2 or +4, are used in a variety of industrial processes for the strengthening of glass, as a base for colours, as catalysts, as stabilizers in perfumes and soaps, and as dental anticariogenic agents. On the whole, contamination of the environment by tin is only slight. Food is the main source of tin for man. Small amounts are found in fresh meat, cereals, and vegetables. Larger amounts of tin may be found in foods stored in plain cans and, occasionally, in foods stored in lacquered cans. Some foods such as asparagus, tomatoes, fruits, and their juices tend to contain high concentrations of tin if stored in unlaquered cans (Environmental health criteria for tin; International Programme on Chemical Safety (IPCS); 1980). Inorganic tin is found in food in the +2 and +4 oxidation states; it may occur in a cationic form (stannous and stannic compounds) or as inorganic anions (stannites or stannates).

Mycotoxins

Aflatoxins, Total

Reference to JECFA: 31 (1987), 46 (1996), 49 (1997), 68 (2007)
Toxicological guidance value: Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible.)
Contaminant definition: Aflatoxins total (B_1 +B_2 + G_1 + G_2)
Synonyms: Abbreviations, AFB, AFG, with numbers, to designate specific compounds
Related code of practice: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004)
Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005)
Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feeding stuffs for Milk Producing Animals (CAC/RCP 45-1997)
Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (CAC/RCP 65-2008)
Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Almonds	15	Adopted	2008	CF	Whole commodity after removal of shell.	The ML applies to almonds intended for further processing (*). For sampling plan, see Annex 2.	TN 0660
Almonds	10	Adopted	2008	CF	Whole commodity after removal of shell.	The ML applies to almonds “ready-to-eat” (**). For sampling plan, see Annex 2.	TN 0660
Brazil nuts	15	Adopted	2010	CF	Whole commodity	The ML applies to shelled Brazil nuts intended for further processing (*). For sampling plan, see Annex 2.	
Brazil nuts	10	Adopted	2010	CF	Whole commodity	The ML applies to shelled Brazil nuts ready-to-eat (**). For sampling plan, see Annex 2.	
Hazelnuts	15	Adopted	2008	CF	Whole commodity after removal of shell.	The ML applies to hazelnuts, also known as filberts, intended for further processing (*). For sampling plan, see Annex 2.	TN 0666
Hazelnuts	10	Adopted	2008	CF	Whole commodity after removal of shell.	The ML applies to hazelnuts, also known as filberts, “ready-to-eat” (**). For sampling plan, see Annex 2.	TN 0666
Peanuts	15	Adopted	1999	FAC	Unless specified, seed or kernels, after removal of shell or husk.	The ML applies for peanuts, also as known as groundnuts, intended for further processing (*). For sampling plan, see Annex 1.	SO 0697

Mycotoxins

Aflatoxins, Total

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Peanuts	10	4		CF	Unless specified, seed or kernels, after removal of shell or husk.	The ML applies for peanuts, also as known as groundnuts, "ready-to-eat" (**). For sampling plan, see Annex 1.	The ML does not apply to mixed preparations of RTE peanuts. Held at Step 4 pending the outcome of the JECFA exposure assessment (REP 15/CF, paras. 97 and 100)
Pistachios	15	Adopted	2008	CF	Whole commodity after removal of shell.	The ML applies to pistachios intended for further processing (*).For sampling plan, see Annex 2.	TN 0675
Pistachios	10	Adopted	2008	CF	Whole commodity after removal of shell.	The ML applies to pistachios "ready-to-eat" (**). For sampling plan, see Annex 2.	TN 0675
Dried figs	10	Adopted	2012	CF	Whole commodity	The ML applies to dried figs "ready-to-eat" (**) For sampling plan see Annex 3.	DF 0297

(*) "destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by colour sorting, and sorting by specific gravity and colour (damage). There is some evidence that roasting reduces aflatoxins in pistachios but for other nuts the evidence is still to be supplied.
(**) "ready-to-eat" means "not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as ingredient in foodstuffs, otherwise processed or offered for human consumption.

The 23rd CCFAC (1991) decided to discontinue the development of a ML for aflatoxins in foods in general, and to discuss the problems on a commodity basis.

The CCCPL in 1994 decided not to proceed with the proposed GL for processed peanuts and to advance the proposed GL for raw peanuts (intended for further processing), associated with a specific sampling plan because the contamination is usually very inhomogeneous in a lot. It is assumed that raw peanuts are the major commodity in international trade.

It is acknowledged that for primary plant products the aflatoxin contamination is often not homogeneous and a sampling plan is necessary to assure reasonable application of MLs. A general position paper on aflatoxins in food and feeds (CX/FAC 97/16) was presented to the 29th CCFAC (1997).

- Maize was included in a Technical Consultation on sampling plans for aflatoxins in commodities. See FAO Food and nutrition Paper 55 (Rome, 1993).

- The 26th CCFAC (1994) decided to discontinue the establishment of GLs for AFB1 in supplementary feedingstuffs for milk-producing animals (previously proposed at the level of 5 µg/kg), based on the assumption that the relationship between aflatoxins in milk and feeds is not (completely) clear and that there is not much international trade in (composite) supplementary feedingstuffs. International trade mostly is in the form of individual commodities which can be used as feed components in various quantities, directed to other feed uses than milk producing animals, or to other uses in general, or

Aflatoxins, Total

be decontaminated etc. Therefore, a Code of Practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals was developed and adopted as RCP 045-1997.

The 35th CCFAC (2003) agreed to the elaboration of MLs for aflatoxins in almonds, hazelnuts and pistachios, based on the ALARA principle and with the understanding that related sampling plans need to be established (ALINORM 03/12A para.129). The 37th CCFAC (2005) advanced the ML for unprocessed almonds, hazelnuts and pistachios while the Committee decided to circulate for comments at step 3 the ML for processed almonds, hazelnuts and pistachios(ALINORM 05/28/12 para.141). The 38th CCFAC (2006) agreed to rename “processed” and “unprocessed” tree nuts to as “ready-to-eat” and tree nuts “for further processing” respectively and to hold at step 7 the ML in tree nuts for further processing and to advance to step 5 the ML in ready-to-eat tree nuts(ALINORM 06/29/12 para.132). The 29th CAC (2006) adopted ML for ready-to-eat tree nuts at Step 5.

The 38th CCFAC (2006) agreed to request JECFA to conduct a dietary exposure assessment on ready-to-eat tree nuts and impact on exposure taking into account hypothetical levels of 4, 8, 10 and 15 µg/kg, putting in the context of exposure from other sources and previous exposure assessments on maize and groundnuts. The Committee decided to expand the discussion paper on the aflatoxin level in ready-to-eat tree nuts, considering I) the detailed data on distribution on aflatoxins between lots, ii) consumer health risk assessment of different levels of aflatoxin in ready-to-eat tree nuts, iii) sampling plan for tree nuts, iv) effect of code of practice and v) terminology of “ready-to-eat” and “for further processing” for consideration at the 1st session of CCCF (ALINORM 06/29/12 paras 129-130).
The 38th CCFAC agreed to further elaborate the proposed draft sampling plan once a ML had been established by Committee and to include considerations on the draft sampling plan for tree nuts in the discussion paper on total aflatoxin levels in processed tree-nuts (ALINORM 06/29/12 para.125).

The 1st CCCF (2007) agreed that the proposed draft Sampling Plan for Aflatoxin Contamination in Almonds, Brazil Nuts, Hazelnuts and Pistachios be returned to Step 2 for redrafting by an EWG, with a view to circulation at Step 3 and consideration at Step 4 at the next session of the CCCF. It was also agreed that the working document to be considered at the next session of the CCCF incorporate a revised proposed draft Sampling Plan as well as an explanatory text in support of the consideration of the Sampling Plan (ALINORM 07/30/41, para. 62).

The 68th JECFA (2007) concluded that consumption of almonds, Brazil nuts, hazelnuts, pistachios and dried figs contributes to more than 5% of the total aflatoxin dietary exposure in only five of the 13 GEMS/Food cluster diets (clusters B, C, D, E and M). Setting an ML of 20 µg/kg for these products would only have an impact on the relative contribution to aflatoxin dietary exposure in these clusters (including the high-level consumers of tree nuts). This can solely be attributed to the elevated aflatoxin level in pistachios. For the tree nuts other than pistachios, as well as dried figs, setting an ML has no effect on aflatoxin dietary exposure. Also, enforcing an ML of 4, 8, 10 or 15 µg/kg has little further impact on the overall dietary exposure to aflatoxin compared to an ML of 20 µg/kg.

The 2nd CCCF (2008) forwarded the MLs for Total Aflatoxins in Almonds, Hazelnuts and Pistachios “For further processing” and “Ready-to-eat” to CAC31 for adoption at Step 8 and the Sampling Plans for Aflatoxin Contamination in Ready-to-eat Treenuts and Treenuts Destined for Further Processing: Almonds, Hazelnuts and Pistachios for adoptionat Step 5/8 (ALINORM 08/31/41, para. 127 and142, and Appendix VIII and IX). The 31st CAC (2008) adopted the MLs as such (ALINORM 08/31/REP, Appendix VII).

The 8th CCCF (2014) agreed to amend the definition for tree nuts “ready-to-eat” and dried figs “ready-to-eat” to provide further clarification on the description of the products they apply to and that this definition would also apply to peanuts (REP 14/CF, para. 91). The Committee also agreed to add the assessments of aflatoxins, already evaluated by JECFA, to the priority list. An update of the risk assessment of aflatoxins may be desirable in view of additional data that have become available since the last full assessment by JECFA. The Committee agreed that the risk assessment of aflatoxins would not be a high priority. (REP 14/CF, paras 129-130, Appendix XIII)

Mycotoxins

Aflatoxins, Total

Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts – Brazil Nuts

The 38th CCFAC agreed to forward the proposed draft Appendix to the Codex Code of Practice for the Prevention and Reduction of Aflatoxins Contamination in Tree Nuts – Additional Measures for the Prevention and Reduction of Aflatoxins in Brazil nuts to the 29th CAC for adoption at at Step 5/8 (ALINORM 06/29/12 para. 123). The 29th CAC endorsed this decision (ALINORM 06/29/41, Appendix IV).

The 3rd CCCF noted that after the completion of the Standards and Trade Development Facility (STDF) project SafeNut which addressed the factors causing aflatoxin contamination in the Brazil nut production chain and the methods of control available, it appeared that an updating of the provisions on Brazil nuts in the Code of Practice was necessary in order to take into account the findings of the project. The Committee agreed to initiate new work on the revision of the Code to incorporate additional measures for the prevention and reduction of aflatoxin contamination in Brazil nuts. It was further agreed that the Proposed Draft Revision prepared by the Delegation of Brazil would be circulated for comments at Step 3 and consideration at the next session (ALINORM 09/32/41, para. 121 and 123, Appendix IX). The proposal of new work was subsequently endorsed by the Commission at its 32nd Session (ALINORM 09/32/REP, Appendix VI).

The 4th CCCF (2010) agreed to forward the proposed draft revision to the 33rd Session of the Codex Alimentarius Commission (2010) for adoption at Step 5/8 (with omission of Steps 6 and 7). The 33rd CAC adopted these revisions at Step 8 (ALINORM 10/33/REP, Appendix III).

Maximum Levels in Brazil Nuts

The 1st CCCF agreed that the discussion paper on aflatoxin contamination in Brazil nuts would be updated by the Delegation of Brazil, incorporating additional data that would become available on the contribution of the shell to aflatoxin contamination of Brazil nuts, for consideration at the next session of the Committee (ALINORM 07/30/41, para. 66).

The 2nd CCCF (2008) agreed to start new work on a Maximum Level for Total Aflatoxins in Brazil Nuts (ALINORM 08/31/41, para. 147).

The 3rd CCCF (2009) agreed to return the Proposed Draft Maximum Levels to Step 2/3 for redrafting by the Delegation of Brazil for comments and consideration by the next session (ALINORM 09/32/41, para. 78).

The 4th CCCF (2010) agreed to forward the proposed MLs for Shelled, ready to eat Brazil Nuts and Shelled, destined for further processing Brazil Nuts (including sampling plans) to the 33rd Session of the Codex Alimentarius Commission for adoption at Step 5/8 with omission of Steps 6 and 7 and not to set any maximum level for in-shell Brazil nuts (ALINORM 10/33/41, para. 74 and 76, Appendix V). The 33rd CAC adopted the MLs at Step 5/8 (ALINORM 10/33/REP, Appendix III).

Code of Practice for dried figs

The 1st CCCF (2007) agreed to forward the project document proposing new work on a Code of Practice aflatoxins in dried figs to the 59th Executive Committee for critical review and for approval by the 30th Commission.
It was also agreed to establish an EWG to prepare a draft proposed code of practice on the prevention and reduction of aflatoxin contamination in dried figs at Step 2, with a view to its circulation for comments at Step 3 and its consideration at Step 4 at the second session, pending the formal approval of new work by the Commission (ALINORM 07/30/41, paras 120-121). The 30th Commission (2007) approved the above new work (ALINORM 07/30/REP, Appendix VII).

The 2nd CCCF (2008) agreed to forward the Proposed Draft Code of Practice to the 31st Session of the Codex Alimentarius Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (ALINORM 08/31/41, para. 163 and Appendix XI). The 31st CAC adopted the Code at Step 5/8 (ALINORM 08/31/REP, Appendix VII).

Mycotoxins

Aflatoxins, Total

Maximum levels in dried figs

The 4th CCCF (2010) agreed to initiate new work on maximum levels for total aflatoxins in dried figs. Subject to approval by the Commission, the Committee agreed that the proposed draft maximum levels would be developed by an electronic Working Group led by Turkey, working in English, for comments at Step 3 and consideration at the 5th session of the Committee (ALINORM 10/33/41, para. 114, Appendix IX). The 33rd CAC approved this new work (ALINORM 10/33/REP, Appendix VI).

The 5th CCCF (2011) agreed to return the Proposed Draft maximum levels for total aflatoxins in dried figs to Step 2/3 so that the sampling plans according to the proposed ML of 10 µg/kg can be developed for consideration by the 6thsession of the Committee (REP11/CF, para. 50). The 6th CCCF (2012) agreed to forward the Proposed Draft ML of 10 µg/kg for Dried Figs including the sampling plan to the 35th CAC for adoption at Step 5/8 with omission of Steps 6 and 7 (REP12/CF, para. 72 and Appendix VI). The 35th CAC (2012) adopted the draft ML at Step 5/8 (REP12/CAC, Appendix III).

Aflatoxins in sorghum

The 6th CCCF (2012) agreed to initiate new work on the development of an annex for the management of aflatoxins and ochratoxin A in sorghum to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003, COP). The Committee agreed to establish an EWG to prepare the proposed draft annex for comments at Step 3 and consideration at the 7th session. (REP12/CF, para. 136 and Appendix IX). The 35th CAC (2012) approved the new work (REP12/CAC, Appendix VI).

The 7th CCCF (2013) agreed to return the proposed draft Annex to Step 2/3 for further development by the EWG, circulation for comments and further consideration by the 8th session of the Committee (REP13/CF, para. 74).

The 8th CCCF (2014) agreed that in view of the considerable progress made on the annex that it would be advanced for adoption, with the understanding that the annex would be integrated into the COP and its annexes in the new work on the revision of the COP. The Committee agreed to forward the proposed draft Annex to Step 5/8 (with the omission of Steps /7) for adoption by the 37th CAC (REP 14/CF, paras. 76-77, Appendix V). The 37th CAC adopted the annex at Step 5/8 (REP 14/CAC, para 47, Appendix III).

Aflatoxins in cereals

The 6th CCCF (2012) agreed to the development of a discussion paper on aflatoxins in cereals through an EWG for consideration and discussion at the 7th session with the view of identification of possible actions or new work on this issue (REP12/CF, para. 175).

The 7th CCCF (2013) agreed that the JECFA Secretariat would put out a public call for data; that this data would be submitted to GEMS/Food; and that the re-established EWG would review and analyze the data and provide a report and recommendations on how to proceed with aflatoxins in cereals for consideration by the 8th session of the Committee (REP13/CF, para. 140).

The 8th CCCF (2014) noted that there was general support that rice should remain the focus of work until more data became available on other cereals, but that priority should be given to the revision of the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, noting that an annex on aflatoxins would take into account measures for control aflatoxins in rice and other cereals, rather than on establishing an ML for aflatoxins in rice. The committee agreed that countries would submit data, especially for wheat, maize and sorghum, to GEMS/Food and no further work would be undertaken on the establishment of MLs for aflatoxins in cereals for the time being (REP 14/CF, paras. 102-103).

Aflatoxins in ready-to-eat (RTE) peanuts

Mycotoxins

Aflatoxins, Total

In the 7th CCCF (2013), a new work on the establishment of a maximum level for total aflatoxins in ready-to-eat peanuts and associated sampling plan was proposed. The Committee agreed to establish an EWG to prepare a discussion paper for consideration at the 8th session that defines the issue, identifies the available data and specifies data requirements for establishing the ML (REP13/CF, para. 149-151).

The 8th CCCF (2014) agreed to forward the proposal to initiate new work on MLs for total aflatoxins in RTE peanuts for approval by the 37th CAC (Appendix X). The Delegation of the Russian Federation expressed its reservation to this decision. The Committee agreed to establish an EWG led by India to prepare proposals for MLs for total aflatoxins in RTE peanuts, for comments at Step 3 and consideration at the 9th session of the Committee (REP 14/CF, paras. 119-120).
The 37th CAC adopted the new work (REP 14/CAC, para. 96. Appendix VI).

The 9th CCCF (2015) agreed to request JECFA to conduct an exposure assessment for health impact and calculate violation rates based on the hypothetical MLs of 4, 8, 10 and 15 µg/kg for total aflatoxins in RTE peanuts and agreed that work on the ML for aflatoxins in RTE would be undertaken when the results of the JECFA impact assessment became available. It was clarified that the RTE peanuts include several categories of peanuts, such as raw shelled peanuts, raw-in-shell peanuts, roasted in shell peanuts, roasted/blanched shelled peanuts, fried shelled peanuts with or without skin, coated peanuts in all types of packing (consumer or bulk), and any other products having preparation of more than 20% of peanuts. The Committee noted that the definition for RTE peanuts had been included in the GSCTFF. Noting that the ML should be established for RTE peanuts, the Committee agreed to remove mixed preparations from the list of RTE peanuts.The Committee agreed to hold the proposed draft ML and sampling plan at Step 4 pending the outcome of the JECFA exposure assessment for health impact (REP 15/CF, paras. 96-100).

<u>Aflatoxins in spices</u>
The 8th CCCF (2014) discussed proposals for new work on MLs for aflatoxins in spices and total aflatoxins and aflatoxin B1 in nutmeg, and associated sampling plans. The Committee had a general discussion on how best to approach the establishment of MLs in spices and considered a proposal by the Chairperson that a review of mycotoxins in spices first be conducted to allow the Committee to understand which mycotoxins to address and in which spices. Such a study could allow for a possible prioritisation of the work on spices for the Committee. The Committee agreed to establish an EWG, led by India and co-chaired by the European Union and Indonesia, and working in English only, to prepare a discussion paper as outlined in the proposal by the Chairperson for consideration at the next session (REP 14/CF, paras. 134 and 137).

In view of the interest to continue with work on MLs in spices, but the need for further clarity on which mycotoxin/spice(s) combination to establish MLs and the rationale for this, as well as further need for prioritisation of the work, the 9th CCCF (2015) agreed to re-establish the EWG, led by India and co-chaired by Indonesia and EU to prepare a new discussion paper and project document for establishment of ML for spices. The discussion paper should also include proposals for possible MLs to assist the next session of the Committee to take a decision on new work (REP 15/CF, paras 138-139).

The Committee agreed to request the CAC to approve new work on the COP for the Prevention and Reduction of mycotoxin contamination in spices and to forward the project document to the Executive Committee for critical review (Appendix VIII). The Committee also agreed to establish the EWG, chaired by Spain and co-chaired by India and The Netherlands to prepare, subject to approval by the Commission, a proposed draft of COP for circulation for comments at Step 3 and consideration at its next session. The EWG would also prepare a discussion paper to outline the development of possible annexes for mycotoxin/individual spices or groups of spices combinations (REP 15/CF, paras 143-144).

The 38th CAC approved the new work (REP15/CAC Appendix VI).

Mycotoxins

Aflatoxins, Total

Aflatoxins are a group of highly toxic mycotoxins produced by fungi of the genus *Aspergillus*. The four main aflatoxins found in contaminated plant products are B1, B2, G1 and G2 and are a group of structurally related difuranocoumarin derivatives that usually occur together in varying ratios, AFB1 usually being the most important one. These compounds pose a substantial hazard to human and animal health. IARC (1992) classified aflatoxin B1 in Group 1 (human carcinogen) and aflatoxin M in Group 2B (probable human carcinogen). The liver is the primary target organ.

A wide range of foods may be contaminated with aflatoxins; they are most commonly found in groundnuts (peanuts), dried fruit, tree nuts (such as almonds, pecans, walnuts, pistachio and Brazil nuts), spices, figs, crude vegetable oils, cocoa beans, maize, rice, cottonseed and copra. Aflatoxin B1 present in animal feed can partly be transferred to milk in the form of the metabolite aflatoxin M1 (mostly 1-2%, but higher percentages are found at low contamination levels in high producing animals.) Aflatoxin contamination is responsible for considerable economic losses and efforts are being made to reduce contamination of food and feedingstuff.

Aflatoxins, Total

Annex 1

SAMPLING PLAN FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING

INTRODUCTION

1. The sampling plan calls for a single 20 kg laboratory sample of shelled peanuts (27 kg of unshelled peanuts) to be taken from a peanut lot (sub-lot) and tested against a maximum level of 15 micrograms per kilogram (μg/kg) total aflatoxins.

2. This sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments of peanuts traded in the export market. To assist member countries in implementing the Codex sampling plan, sample selection methods, sample preparation methods and analytical methods required to quantify aflatoxin in bulk peanut lots are described in this document.

A. DEFINITIONS

Lot	An identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.
Sublot	Designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	Is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the codex maximum limit.
Incremental sample	A quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples taken from the lot or sublot. The aggregate sample has to be at least as large as the 20 kg laboratory sample.
Laboratory sample	The smallest quantity of peanuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenization as possible.
Test portion	Portion of the comminuted laboratory sample. The entire 20 kg laboratory sample should be comminuted in a mill. A portion of the comminuted 20 kg sample is randomly removed for the extraction of the aflatoxin for chemical analysis. Based upon grinder capacity, the 20 kg aggregate sample can be divided into several equal sized samples, if all results are averaged.

B. SAMPLING

Material to be sampled

3. Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The subdivision can be done following provisions laid down in Table 1 below.

4. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

Table 1: Subdivision of large lots into sublots for sampling

Commodity	Lot weight – tonne (T)	Weight or number of sublots	Number of incremental samples	Laboratory sample weight (kg)
Peanuts	≥ 500	100 tonnes	100	20
	>100 and <500	5 sublots	100	20
	≥ 25 and ≤ 100	25 tonnes	100	20
	>15 and <= 25	--1 sublot	100	20

Aflatoxins, Total

Number of incremental samples for lots of less than 15 tonnes

5. The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100. The figures in the following Table 2 may be used to determine the number of incremental samples to be taken. It is necessary that the total sample weight of 20 kg is achieved.

Table 2: Number of incremental samples to be taken depending on the weight of the lot

Lot weight tonnes – (T)	N° of incremental samples
T≤ 1	10
1 <T ≤ 5	40
5< T ≤ 10	60
10<T < 15	80

Incremental sample selection

6. Procedures used to take incremental samples from a peanut lot are extremely important. Every individual peanut in the lot should have an equal chance of being chosen. Biases will be introduced by the sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

7. Since there is no way to know if the contaminated peanut kernels are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small portions or increments of the product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

Static lots

8. A static lot can be defined as a large mass of peanuts contained either in a single large container such as a wagon, truck, or railcar or in many small containers such as sacks or boxes and the peanuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because the container may not allow access to all peanuts.

9. Taking an aggregate sample from a static lot usually requires the use of probing devices to select product from the lot. The probing devices used should be specially designed for the type of container. The probe should (1) be long enough to reach all product, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small increments of product taken from many different locations throughout the lot.

10. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

    Equation 1: SF = (LT x IS)/(AS x IP).

    The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic lots

11. True random sampling can be more nearly achieved when selecting an aggregate sample from a moving stream of peanuts as the lot is transferred, for example, by a conveyor belt from one location to another. When sampling from a moving stream, take small increments of product from the entire length of the moving stream; composite the peanuts to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample, then blend and subdivide the aggregate sample to obtain the desired size laboratory sample.

12. Automatic sampling equipment such as cross-cut samplers are commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic equipment is not available, a person can be assigned to manually pass a cup though the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, small increments of peanuts should be collected and composited at frequent and uniform intervals throughout the entire time peanuts flow past the sampling point.

13. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about three times the largest dimensions of the items in the lot.

Aflatoxins, Total

14. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

    Equation 2: S = (D x LT) / (T x V).

    D is the width of the diverter cup opening (in cm), LT is the lot size (in kg), T is interval or time between cup movement through the stream (in seconds), and V is cup velocity (in cm/sec).

15. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup is:

    Equation 3: SF = (S x V) / (D x MR).

16. Equation 2 can also be used to compute other terms of interest such as the time between cuts (T). For example, the required time (T) between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 30,000 kg lot where the diverter cup width is 5.08 cm (2 inches), and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,

    T = (5.08 cm x 30,000 kg)/(20 kg x 30 cm/sec) = 254 sec

17. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 60 minutes and only 14 cuts (14 incremental samples) will be made by the cup through the lot. This may be considered too infrequent, in that too much product passes through the sampler between the time the cup cuts through the stream.

    Weight of the incremental sample

18. The weight of the incremental sample should be approximately 200 grams or greater, depending on the total number of increments, to obtain an aggregate sample of 20kg.

    Packaging and transmission of samples

19. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample which might arise during transportation or storage.

    Sealing and labelling of samples

20. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

C. SAMPLE PREPARATION

Precautions

21. Daylight should be excluded as much as possible during the procedure, since aflatoxin gradually breaks down under the influence of ultra-violet light.

Homogenization – Grinding

22. As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared - and especially homogenized - with extreme care. All laboratory sample obtained from aggregate sample is to be used for the homogenization/grinding of the sample.

23. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenization as possible.

24. The use of a hammer mill with a #14 screen (3.1 mm diameter hole in the screen) has been proven to represent a compromise in terms of cost and precision. A better homogenization (finer grind – slurry) can be obtained by more sophisticated equipment, resulting in a lower sample preparation variance.

Aflatoxins, Total

Test portion

25. A minimum test portion size of 100 g taken from the laboratory sample.

D. ANALYTICAL METHODS

Background

26. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specified method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation, reproducibility coefficient of variation, and the percent recovery necessary for various statutory limits. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

Performance criteria for methods of analysis

Table 3: Specific requirements with which methods of analysis should comply

Criterion	Concentration Range	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	-
Recovery-Aflatoxins Total	1 - 15 μg/kg	70 to 110%	
	> 15 μg/kg	80 to 110%	
Precision RSD_R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD_r may be calculated as 0.66 times Precision RSD_R at the concentration of interest			

- The detection limits of the methods used are not stated as the precision values are given at the concentrations of interest;
- The precision values are calculated from the Horwitz equation, i.e.:

  $RSD_R = 2^{(1-0.5\log C)}$

  where:

  - RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions [(s_R / $\bar{x}$) x 100]
  - C is the concentration ratio (i.e. 1 = 100 g/100 g, 0.001 = 1,000 mg/kg)

27. This is a generalized precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

Annex 2

SAMPLING PLANS FOR AFLATOXIN CONTAMINATION IN READY-TO-EAT TREENUTS AND TREENUTS DESTINED FOR FURTHER PROCESSING: ALMONDS, HAZELNUTS, PISTACHIOS AND SHELLED BRAZIL NUTS

DEFINITION

Lot	An identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	Designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	It is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the codex maximum level.
Incremental sample	The quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	The smallest quantity of tree nuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.
Test portion	A portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.
Ready-to-eat treenuts	Nuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption.
Treenuts destined for further processing	Nuts, which are intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by color sorting, and sorting by specific gravity and color (damage). There is some evidence that roasting reduces aflatoxins in pistachios but for other nuts the evidence is still to be supplied.
Operating characteristic (OC) Curve	A plot of the probability of a accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers may commercially classify treenuts as either "ready-to-eat" (RTE) or "destined for further processing" (DFP). As a result, maximum levels and sampling plans are proposed for both commercial types of treenuts. Maximum levels need to be defined for treenuts destined for further processing and ready-to-eat treenuts before a final decision can be made about a sampling plan design.
2. Treenuts can be marketed either as inshell or shelled nuts. For example, pistachios are predominately marketed as inshell nuts while almonds are predominately marketed as shelled nuts.
3. Sampling statistics, shown in Annex I, are based upon the uncertainty and aflatoxin distribution among laboratory samples of shelled nuts. Because the shelled nut count per kg is different for each of the three treenuts, the laboratory sample size is expressed in number of nuts for statistical purposes. However, the shelled nut count per kg for each treenut, shown in Annex I, can be used to convert laboratory sample size from number of nuts to mass and vice versa.

Aflatoxins, Total

4. Uncertainty estimates associated with sampling, sample preparation, and analysis, shown in Annex I, and the negative binomial distribution[7],[8],[9] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans (Annex II).

5. In Annex, the analytical variance reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data[10]. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for the three treenuts. The within laboratory analytical uncertainty for each treenut can be found at the website http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[7].

6. The issue of correcting the analytical test ns for the range of acceptable recoverresult for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestioy rates.

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

7. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the proposed maximum level and the aflatoxin test procedure are given below in this section.

8. The maximum levels for total aflatoxins in treenuts (almonds, hazelnuts, pistachios and shelled Brazil nuts) “ready-to-eat” and “destined for further processing” are 10 and 15 µg/kg, respectively.

9. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the proposed aflatoxin sampling plans use a 20 kg aggregate sample for all three treenuts.

10. The two sampling plans (RTE and DFP) have been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of treenuts traded in the export market.

Treenuts destined for further processing

Maximum level – 15 µg/kg total aflatoxins

Number of laboratory samples – 1

Laboratory sample size - 20 kg
Almonds – shelled nuts
Hazelnuts – shelled nutsPistachios – inshell nuts (equivalent to about 10 kg shelled nuts that is calculated on the basis of the actual edible portion in the sample)
Brazil nuts-shelled nuts

Sample preparation – sample shall be finely ground and mixed thoroughly using a process, e.g., dry grind with a vertical cutter mixer type mill, that has been demonstrated to provide the lowest sample preparation variance. Preferably, Brazil nuts should be ground as slurry.

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxins, then accept the lot. Otherwise, reject the lot.

The operating characteristic curve describing the performance of the sampling plan for the three treenuts destined for further processing is shown in Annex II.

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[7] Whitaker, T., Dickens, J., Monroe, R., and Wiser, E. 1972. Comparison of the negative binomial distribution of aflatoxin in shelled peanuts to the negative binomial distribution. J. American Oil Chemists’ Society, 49:590-593.
[8] Thompson, M. 2000. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. J. Royal Society of Chemistry, 125:385-386.
[9] CONFORCAST. Ferramentas Analíticas para Capacitação do Brasil na Garantia da Conformidade da Castanha-Do-Brasil (Bertholletia Excelsa) quanto ao Perigo aflatoxina. Projeto nº 1.265/05, Aprovado pela FINEP na Chamada Pública, “Ação Transversal - TIB - 06/2005 - Linha 1”. MAPA. Minist~erio da Agricultura, pecuária e do Abasteciento. Secretaria de Defesa Agropecuária - DAS, Departamento de Inspeção de Produtos de Origem Vegetal – DIPOV. Coordenação-Geral de Apoio Laboratorial – CGAL, Laboratório Nacional Agropecuário – LANAGRO/MG, United States Department of Agriculture (Thomas Whitaker and Andy Slate).

Mycotoxins

Aflatoxins, Total

Ready-to-eat treenuts

Maximum level – 10 µg/kg total aflatoxins

Number of laboratory samples – 2

Laboratory sample size - 10 kg
Almonds – shelled nuts
Hazelnuts – shelled nuts
Pistachios – inshell nuts (equivalent to about 5 kg shelled nuts per test sample that is calculated on the basis of the actual edible portion in the sample)
Brazil nuts-shelled nuts

Sample preparation – sample shall be finely ground and mixed thoroughly using a process, e.g., dry grind with a vertical cutter mixer type mill, that has been demonstrated to provide the lowest sample preparation variance. Preferably, Brazil nuts should be ground as slurry.

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxin in both test samples, then accept the lot. Otherwise, reject the lot.

The operating characteristic curve describing the performance of the sampling plan for the three ready-to-eat treenuts is shown in Annex II.

11. To assist member countries implement these two Codex sampling plans, sample selection methods, sample preparation methods, and analytical methods required to quantify aflatoxin in laboratory samples taken from bulk treenut lots are described in the following sections.

SAMPLE SELECTION

MATERIAL TO BE SAMPLED

12. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a sublot should not exceed 25 tonnes. The minimum lot weight should be 500 kg.

13. Taking into account that the weight of the lot is not always an exact multiple of 25 tonne sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 25%.

14. Samples should be taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date. Any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative should be avoided. For example do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby.

15. In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

INCREMENTAL SAMPLE SELECTION

16. Procedures used to take incremental samples from a treenut lot are extremely important. Every individual nut in the lot should have an equal chance of being chosen. Biases will be introduced by sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

17. Since there is no way to know if the contaminated treenut kernels are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

NUMBER OF INCREMENTAL SAMPLES FOR LOTS OF VARYING WEIGHT

18. The number and size of the laboratory sample(s) will not vary with lot (sublot) size. However, the number and size of the incremental samples will vary with lot (sublot) size.

Mycotoxins

Aflatoxins, Total

19. The number of incremental samples to be taken from a lot (sublot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes below 25 tonnes. The number of incremental samples varies from a minimum of 10 and to a maximum of 100.

Table 1. Number and size of incremental samples composited for an aggregate sample of 20 kg[a] as a function of lot (or sublot) weight

Lot or sublot weight[b] (T in tonnes)	Minimum number of incremental samples	Minimum incremental sample size[c] (g)	Minimum aggregate sample size (kg)
T<1	10	2 000	20
1≤T<5	25	800	20
5≤T<10	50	400	20
10≤T<15	75	267	20
15≤T	100	200	20

a / Minimum aggregate sample size = laboratory sample size of 20 kg
b / 1 Tonne = 1 000 kg
c / Minimum incremental sample size = laboratory sample size (20 kg) / minimum number of incremental samples,
i.e. for 0.5<T< 1 tonne, 2 000 g = 20 000/10

WEIGHT OF THE INCREMENTAL SAMPLE

20. The suggested minimum weight of the incremental sample should be approximately 200 g for lots of 25 metric tonnes (25 000 kg). The number and/or size of incremental samples will have to be larger than that suggested in Table 1 for lots sizes below 25 000 kg in order to obtain an aggregate sample greater than or equal to the 20 kg laboratory sample.

STATIC LOTS

21. A static lot can be defined as a large mass of treenuts contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the nuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or sublot may not be accessible.

22. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

23. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

Equation 1: SF= (LT x IS) / (AS x IP).

24. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

DYNAMIC LOTS

25. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of treenuts as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

26. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the nuts flow past the sampling point.

27. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

28. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

Equation 2: S = (D x LT) / (T x V),

where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

29. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.

Equation 3: SF = (S x V) / (D x MR).

30. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 20 000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,

T = (5.0 cm x 20 000 kg) / (20 kg x 20 cm/sec) = 250 sec.

31. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2 400 sec) and only 9.6 cuts (9 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (2 083.3 kg) passes through the sampler between the time the cup cuts through the stream.

PACKAGING AND TRANSPORTATION OF SAMPLES

32. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

SEALING AND LABELLING OF SAMPLES

33. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

PRECAUTIONS

34. Sunlight should be excluded as much as possible during sample preparation, since aflatoxin gradually breaks down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and aflatoxin formation.

HOMOGENIZATION - GRINDING

35. As the distribution of aflatoxin is extremely non-homogeneous, laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

36. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation (Annex I) approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

37. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction[11]. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance[12].

TEST PORTION

38. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 grams. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 50 g of nut mass.

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[11] Ozay, G., Seyhan, F., Yilmaz, A., Whitaker, T., Slate, A., and Giesbrecht, F. 2006. Sampling hazelnuts for aflatoxin: Uncertainty associated with sampling, sample preparation, and analysis. J. Association Official Analytical Chemists, Int., 89:1004-1011.

[12] Spanjer, M., Scholten, J., Kastrup, S., Jorissen, U., Schatzki, T., Toyofuku, N. 2006. Sample comminution for mycotoxin analysis: Dry milling or slurry mixing, Food Additives and Contaminants, 23:73-83.

Aflatoxins, Total

39. Procedures for selecting the 50 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 50 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 50 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.
40. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

BACKGROUND

41. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS

42. A list of criteria and performance levels are shown in Table 2. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 2: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range (ng/g)	Recommended value	Maximum Permitted Value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 110%	n/a
	>15	80 to 110%	n/a
Precision or Relative Standard Deviation RSD_R (Reproducibility)	1 to 120	Equation 4 by Thompson	2 x value derived from Equation 4
	>120	Equation 5 by Horwitz	2 x value derived from Equation 5
Precision or Relative Standard Deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	>120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

43. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values are calculated from equations 4 and 5 developed by Thompson[2] and Horwitz and Albert[13], respectively.

Equation 4: $RSD_R = 22.0$ (for $C \leq 120$ ng/g or $c \leq 120x10^{-9}$)

Equation 5: $RSD_R = 2^{(1-0.5\log c)}$ (for $C > 120$ ng/g or $c > 120x10^{-9}$)

where:

- RSD_R = the relative standard deviation calculated from results generated under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = 0.66 RSD_R
- c = the aflatoxin concentration ratio (i.e. 1 = 100 g/100 g, 0.001 = 1 000 mg/kg)
- C = aflatoxin concentration or mass of aflatoxin to mass of treenuts (i.e. µg/kg)

44. Equations 4 and 5 are generalized precision equations, which have been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.
45. Results should be reported on the edible portion of the sample.

[13] Horwitz, W. and Albert, R. 2006. The Horwitz ratio (HorRat): A useful index of method performance with respect to precision. J. Association of Official Analytical Chemists, Int., 89:1095-1109.

Aflatoxins, Total

Annex I

Uncertainty, as measured by the variance, associated with sampling, sample preparation, and analytical steps of the aflatoxin test procedure used to estimate aflatoxin in almonds, hazelnuts, pistachios and shelled Brazil nuts.

Sampling data for almonds, hazelnuts, pistachios and shelled Brazil nuts were supplied by the United States, Turkey, and Iran, respectively.

Variance estimates and the negative binomial distribution[1] were used to compute operating characteristic curves for each treenut in Annex II. Sampling, sample preparation, and analytical variances associated with testing almonds, hazelnuts, pistachios and shelled Brazil nuts are shown in Table 1 below.

Because of the computational complexities associated with use of the negative binomial distribution to compute operational characteristic (OC) curves for various sampling plan designs, the effect of various laboratory sample sizes, various numbers of laboratory samples, and various maximum levels on the performance (OC curves) of sampling plan designs is provided at the website address http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[7].

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Table 1. Variances[a] associated with the aflatoxin test procedure for each treenut.

Test Procedure	Almonds	Hazelnuts	Pistachios	Shelled Brazil nuts
Sampling[b,c]	S^2_s = (7,730/ns)5.759$C^{1.561}$	S^2_s = (10,000/ns)4.291$C^{1.609}$	S^2_s = (8,000/ns)7.913$C^{1.475}$	S^2_s = (1,850/ns)4.8616$C^{1.889}$
Sample Prep[d]	S^2_{sp} = (100/nss)0.170$C^{1.646}$	S^2_{sp} = (50/nss)0.021$C^{1.545}$	S^2_{sp} = (25/nss)2.334$C^{1.522}$	S^2_{sp} = (50/nss)0.0306$C^{0.632}$
Analytical[e]	S^2_a = (1/na)0.0484$C^{2.0}$	S^2_a = (1/na)0.0484$C^{2.0}$	S^2_a = (1/na)0.0484$C^{2.0}$	experimental S^2_a = (1/n)0.0164$C^{1.117}$ or FAPAS S^2_a = (1/n)0.0484$C^{2.0}$
Total variance	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

a/ Variance = S^2 (s, sp, and a denote sampling, sample preparation, and analytical steps, respectively, of aflatoxin test procedure)
b/ ns = laboratory sample size in number of shelled nuts, nss =test portion size in grams, na = number of aliquots quantified by HPLC, and C = aflatoxin concentration in ng/g total aflatoxin.
c/ Shelled nut count/kg for almonds, hazelnuts, pistachios and Brazil nuts is 773, 1 000, and 1 600, respectively.
d/ Sample preparation for almonds, hazelnuts, and pistachios reflect Hobart, Robot Coupe, and Marjaan Khatman type mills, respectively. Laboratory samples were dry ground into a paste for each treenut except for Brazil nut that were prepared as a slurry Brazil nuts/water 1/1 w/w.
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson[2] (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the three treenuts.

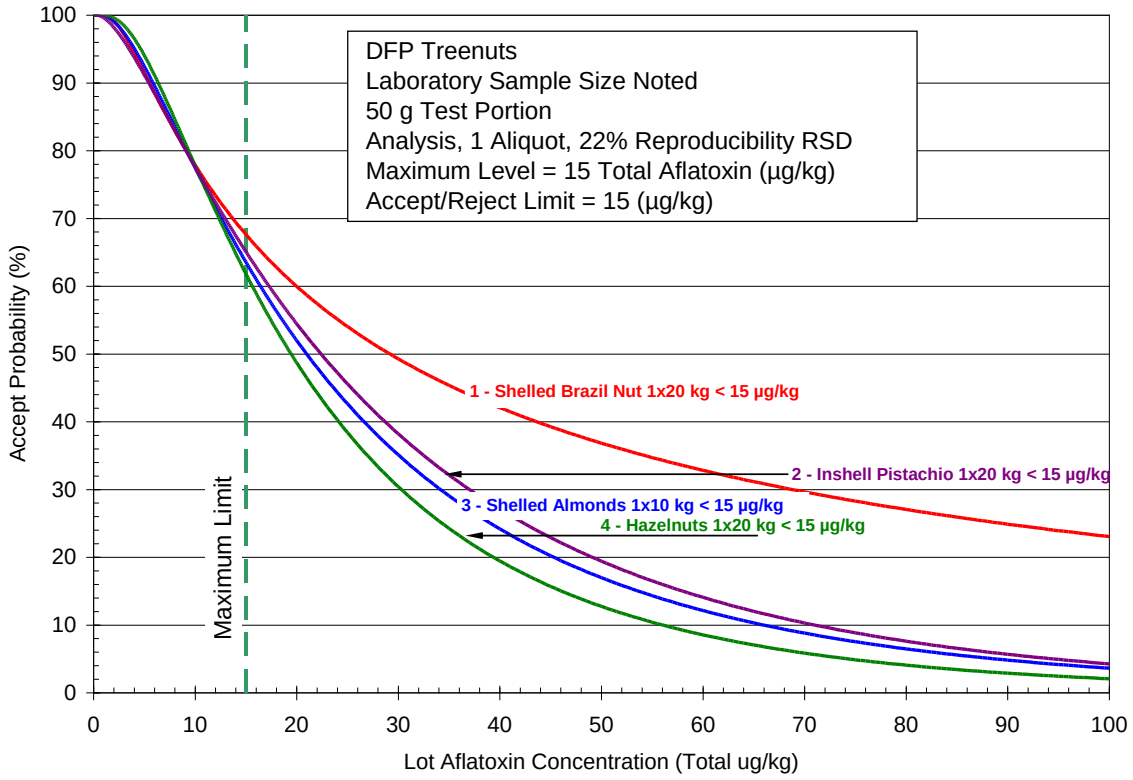
Aflatoxins, Total

Annex II

Operating Characteristic Curves describing the performance of draft aflatoxin sampling plans for almonds, hazelnuts, pistachios and shelled Brazil nuts.

Treenuts Destined for Further Processing

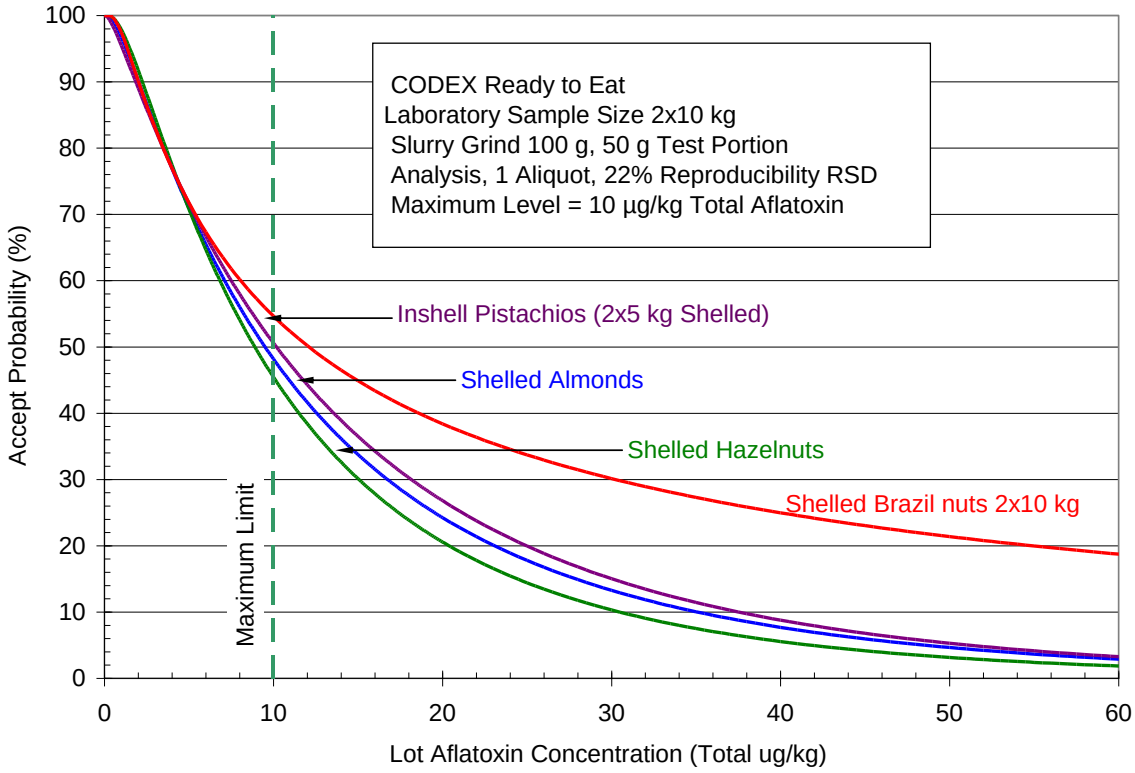
Operating Characteristic curve describing the performance of the aflatoxin sampling plan for almonds, hazelnuts, pistachios and shelled Brazil nuts destined for further processing using a single laboratory sample of 20 kg and a maximum level of 15 ng/g for total aflatoxins. The operating characteristic curve reflects uncertainty associated with a 20 kg laboratory sample of shelled nuts for almonds hazelnuts and shelled Brazil nuts and a 20 kg laboratory sample of inshell nuts (about 10kg shelled nuts) for pistachios, dry grind with a vertical cutter mixer type mill almonds, hazelnuts, pistachio and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



Aflatoxins, Total

Ready-to-Eats Treenuts

Operating Characteristic curve describing the performance of the aflatoxin sampling plan for ready-to-eat almonds, hazelnuts, pistachios and shelled Brazil nuts using two laboratory samples of 10 kg each and a maximum level of 10 ng/g for total aflatoxins, dry grind with a vertical cutter mixer type mill almond, hazelnuts, pistachios and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



Annex 3

SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN DRIED FIGS

DEFINITION

Lot	An identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	Designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	It is defined by an aflatoxin test procedure and an accept/reject level. An aflatoxin test procedure consists of three steps: sample selection of sample(s) of a given size, sample preparation and aflatoxin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level.
Incremental sample	The quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	The smallest quantity of dried figs comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.
Test portion	A portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.
Ready-to-eat dried figs	Dried figs, which are not intended to undergo an additional processing/treatment that have proven to reduce levels of aflatoxin before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption.
Operating characteristic (OC) curve	A plot of the probability of accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve also provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers commercially classify dried figs mostly as "ready-to-eat" (RTE). As a result, maximum levels and sampling plans are proposed for only ready-to-eat dried figs.

2. The performance of the proposed draft sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots. Because the dried fig count per kg is different for different varieties of dried figs, the laboratory sample size is expressed in number of dried figs for statistical purposes. However, the dried fig count per kg for each variety of dried figs can be used to convert laboratory sample size from number of dried figs to mass and vice versa.

3. Uncertainty estimates (variances) associated with sampling, sample preparation, and analysis and the negative binomial distribution[14] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans for dried figs.

4. The analytical variance measured in the sampling study reflects within laboratory variance and was replaced with an estimate of analytical variance that reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is

[14] Whitaker, T., Dickens, J., Monroe, R., and Wiser, E. 1972. Comparison of the negative binomial distribution of aflatoxin in shelled peanuts to the negative binomial distribution. J. American Oil Chemists' Society, 49:590-593. are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans for dried figs.

based upon Food Analysis Performance Assessment Scheme (FAPAS) data[15]. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for dried figs.

5. The issue of correcting the analytical test result for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestions for the range of acceptable recovery rates.

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

6. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the proposed maximum level and the aflatoxin test procedure are given below in this section.

7. The maximum level for "ready-to-eat" dried figs is 10 µg/kg total aflatoxins.

8. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the proposed aflatoxin sampling plan uses three 10 kg aggregate samples of dried figs.

9. The RTE sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of dried figs traded in the export market.

   Maximum level – 10 µg/kg total aflatoxins

   Number of laboratory samples – 3

   Laboratory sample size - 10 kg

   Sample preparation – water-slurry grind and a test portion that represents 55 g mass of dried figs

   Analytical method – performance based (see Table 2)

   Decision rule – If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxins for all three 10 kg laboratory samples, then accept the lot. Otherwise, reject the lot.

   The operating characteristic curve describing the performance of the sampling plan for the ready-to-eat dried figs is shown in paragraph 46 at the end of this Annex.

10. To assist member countries implement the above Codex sampling plan, sample selection methods, sample preparation methods, and analytical methods required to quantify aflatoxin in laboratory samples taken from bulk dried fig lots are described in the following sections.

SAMPLE SELECTION

MATERIAL TO BE SAMPLED

11. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 15 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 15 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 15 tonnes. It is recommended that a lot or a sublot should not exceed 15 tonnes.

12. Taking into account that the weight of the lot is not always an exact multiple of 15 tonnes, the weight of the sublot may exceed the mentioned weight by a maximum of 25%.

13. Samples should be taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date. Any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative should be avoided. For example do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby.

14. In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

INCREMENTAL SAMPLE SELECTION

15. Procedures used to take incremental samples from a dried fig lot are extremely important. Every individual fig in the lot should have an equal chance of being chosen. Biases will be introduced by sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

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[15] Thompson, M. 2000. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. J. Royal Society of Chemistry, 125:385-386.

Aflatoxins, Total

16. Since there is no way to know if the contaminated figs are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

17. For lots less than 10 tonnes, the size of the aggregate sample is reduced so that the aggregate sample size doesn't exceed a significant portion of the lot or sublot size.

NUMBER AND SIZE OF INCREMENTAL SAMPLES FOR LOTS OF VARYING WEIGHT

18. The number of incremental samples to be taken from a lot (sublot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes. The number of incremental samples varies from 10 to 100 for lots or sublots of various sizes.

Table 1. Number and size of incremental samples composited for an aggregate sample of 30kg [a] as a function of lot (or sublpt) weight

Lot or Sublot Weight [b] (T in Tonnes)	Minimum Nubmer of Incremental Samples	Minimum Incremental Sample Size [c] (g)	Minimum Aggregate Sample Size (kg)	Laboratory Sample Size (kg)	Number of Laboratory Samples
15.0 ≥ T > 10.0	100	300	30	10	3
10.0 ≥ T > 5.0	80	300	24	8	3
5.0 ≥ T > 2.0	60	300	18	9	2
2.0 ≥ T > 1.0	40	300	12	6	2
1.0 ≥ T > 0.5	30	300	9	9	1
0.5 ≥ T > 0.2	20	300	6	6	1
0.2 ≥ T > 0.1	15	300	4.5	4.5	1
0.1 ≥ T	10	300	3	3	1

a/ Minimum aggregate sample size = laboratory sample size of 30 kg for lots above 10 tonnes

b/ 1 Tonne = 1000 kg

c/ Minimum incremental sample size = laboratory sample size (30 kg)/minimum number of incremental samples, i.e. for 10 < T ≤ 15 tonne, 300 g = 30000 g/100

19. The suggested minimum weight of the incremental sample is 300 grams for lots and sublots of various sizes.

STATIC LOTS

20. A static lot can be defined as a large mass of dried figs contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the dried figs are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or sublot may not be accessible.

21. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

22. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

Equation 1: SF= (LT x IS) / (AS x IP).

23. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

DYNAMIC LOTS

24. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of dried figs as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental

samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

25. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the figs flow past the sampling point.

26. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

27. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

    Equation 2: S = (D x LT) / (T x V),

    where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

28. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.

    Equation 3: SF = (S x V) / (D x MR).

29. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 30 kg aggregate sample from a 20 000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 20 cm/sec. Solving for T in Equation 2,

    T = (5.0 cm x 20 000 kg) / (30 kg x 20 cm/sec) = 167 sec.

30. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2 400 sec) and only 14.4 cuts (14 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (1 388.9 kg) passes through the sampler between the time the cup cuts through the stream.

PACKAGING AND TRANSPORTATION OF SAMPLES

31. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

SEALING AND LABELLING OF SAMPLES

32. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

Aflatoxins, Total

SAMPLE PREPARATION

PRECAUTIONS

33. Sunlight should be excluded as much as possible during sample preparation, since aflatoxin gradually breaks down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and aflatoxin formation.

HOMOGENIZATION – GRINDING

34. As the distribution of aflatoxin is extremely non-homogeneous, the laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

35. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

36. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction[16]. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance[17].

TEST PORTION

37. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 grams. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 50 g of fig mass.

38. Procedures for selecting the 50 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 50 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 50 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

39. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

BACKGROUND

40. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific analytical method. The performance criteria established for analytical methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS

41. A list of criteria and performance levels are shown in Table 2. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

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[16] Ozay, G., Seyhan, F., Yilmaz, A., Whitaker, T., Slate, A., and Giesbrecht, F. 2006. Sampling hazelnuts for aflatoxin: Uncertainty associated with sampling, sample preparation, and analysis. J. Association Official Analytical Chemists, Int., 89:1004-1011.

[17] Spanjer, M., Scholten, J., Kastrup, S., Jorissen, U., Schatzki, T., Toyofuku, N. 2006. Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?, Food Additives and Contaminants, 23:73-83.

Aflatoxins, Total

Table 2: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range (ng/g)	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 110%	n/a
	> 15	80 to 110%	n/a
Precision or Relative Standard Deviation RSD_R (Reproducibility)	1 to 120	Equation 4 by Thompson	2 x value derived from Equation 4
	> 120	Equation 5 by Horwitz	2 x value derived from Equation 5
Precision or Relative Standard Deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	> 120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

42. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values (expressed as a%) are calculated from equations 4 and 5 developed by Thompson[15] and Horwitz and Albert[18], respectively.

Equation 4: $RSD_R = 22.0$

Equation 5: $RSD_R = 45.25C^{-0.15}$ where:

- RSD_R = the relative standard deviation calculated from results generated
- under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = $0.66RSD_R$
- C = aflatoxin concentration or mass of aflatoxin to mass of dried figs (i.e. ng/g)

43. Equations 4 and 5 are generalized precision equations, which have been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

44. Results should be reported on the sample.

UNCERTAINTY, AS MEASURED BY THE VARIANCE, ASSOCIATED WITH THE SAMPLING, SAMPLE PREPARATION, AND ANALYTICAL STEPS OF THE AFLATOXIN TEST PROCEDURE USED TO DETECT AFLATOXIN IN DRIED FIGS

45. The sampling, sample preparation, and analytical variances associated with the aflatoxin test procedure for dried figs are shown in Table 3.

Table 3.Variancesa associated with the aflatoxin test procedure for each dried figs

Test Procedure	Variances for Dried Figs
Sampling[b,c]	$S^2_s = (590/ns)2.219C^{1.433}$
Sample Prep[d]	$S^2_{sp} = (55/nss)0.01170C^{1.465}$
Analytical[e]	$S^2_a = (1/na)0.0484C^{2.0}$
Total	$S^2_t = S^2_s + S^2_{sp} + S^2_a$

a / Variance = S^2 (t, s, sp, and a denote total, sampling, sample preparation, and analytical steps, respectively, of aflatoxin test procedure)

[18] Horwitz, W. and Albert, R. 2006. The Horwitz ratio (HorRat): A useful index of method performance with respect to precision. J. Association of Official Analytical Chemists, Int., 89:1095-1109.

Aflatoxins, Total

b / ns = laboratory sample size in number of dried figs, nss =test portion size in grams of fig mass, na = number of aliquots quantified by HPLC, and C = aflatoxin concentration in ng/g total aflatoxins.

c / Count/kg for dried figs averaged 59/kg.

d / Sample preparation variance reflects a water-slurry method and a test portion that reflects 55 g fig mass.

e / Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson2 (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the three dried figs.

OPERATING CHARACTERISTIC CURVE DESCRIBING THE PERFORMANCE OF THE DRAFT AFLATOXIN SAMPLING PLAN FOR READY-TO-EAT DRIED FIGS

46. The operating characteristic curve describing the performance of draft aflatoxin sampling plan for ready-to-eat dried figs is shown in Figure 1.

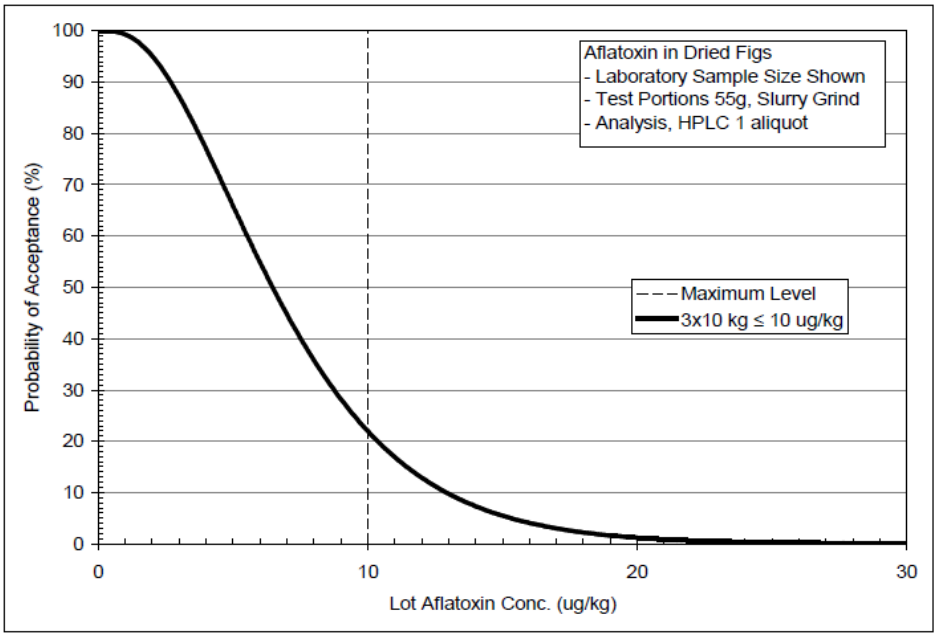

Figure 1. Operating characteristic (OC) curve describing the performance of the aflatoxin sampling plan for ready-to-eat dried figs using three laboratory samples of 10 kg each and a maximum level of 10 µg/kg total aflatoxins, water-slurry comminution method, test portion that reflects 55 g fig mass, and quantification of aflatoxin in a the test portion by HPLC.

Mycotoxins

Aflatoxin M_1

Reference to JECFA:	56 (2001)
Toxicological guidance value:	Cancer potency estimates at specified residue levels (2001, Using worst-case assumptions, the additional risks for liver cancer predicted with use of proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small. The potency of aflatoxin M1 appears to be so low in HBsAg-individuals that a carcinogenic effect of M1 intake in those who consume large quantities of milk and milk products in comparison with non-consumers of these products would be impossible to demonstrate. Hepatitis B virus carriers might benefit from a reduction in the aflatoxin concentration in their diet, and the reduction might also offer some protection in hepatitis C virus carriers.)
Contaminant definition:	Aflatoxin M_1
Synonyms:	AFM_1
Related Code of Practice:	Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CAC/RCP 45-1997)

Commodity / Product Name	Maximum Level(ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Milks	0.5	Adopted	2001	FAC	Whole commodity	Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing. A concentration factor applies to partially or wholly dehydrated milks.	ML0106

The 24th CCFAC (1993) decided to stop the development of a specific standard for aflatoxin M1 in milk destined for use in baby foods. The CCFAC has discussed 2 options for a standard for aflatoxin M1 in milk: 0.05 µg/kg and 0.5 µg/kg. At the request of the 32nd CCFAC (2000), the 56th JECFA (2001) examined exposure to aflatoxin M1 and conducted a quantitative risk assessment to compare the consequences of setting the maximum level in milk at 0.05 µg/kg and 0.5 µg/kg. The estimates of the potency of aflatoxin M1 were combined with estimates of intake from the GEMS/Food European regional diet. JECFA noted that the calculation showed that, with worst case assumptions, the projected risks for liver cancer at the proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small. As a result, 0.5 µg/kg was forwarded to the 24th CAC by 33rd CCFAC (2001) which adopted this draft ML at Step 8, noting that data supporting the lower level, if and when available, could be examined by the CCFAC at a future meeting when necessary. It is acknowledged that the aflatoxin M1 level in milk is related to the aflatoxin B1 level in the animal feed. See notes under Aflatoxins, total.

Mycotoxins

Deoxynivalenol

Reference to JECFA:	56 (2001), 72 (2010)
Toxicological guidance value:	Group PMTDI 0.001 mg/kg bw (2010, for DON and its acetylated derivates) Group ARfD 0.008 mg/kg bw (2010, for DON and its acetylated derivates)
Contaminant definition:	Deoxynivalenol
Synonyms:	Vomitoxin; Abbreviation, DON
Related code of practice:	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Cereal grains (wheat, maize and barley) destined for further processing	2	Adopted	2015	CF		"Destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce levels of DON before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels. *For sampling plan, see Annex.*	CX/CF 15/9/2
Flour, meal, semolina and flakes derived from wheat, maize or barley	1	Adopted	2015	CF		*For sampling plan, see Annex.*	CX/CF 15/9/2
Cereal-based foods for infants and young children	0.2	Adopted	2015	CF	ML applies to the commodity on a dry matter basis.	All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months). *For sampling plan, see Annex.*	CX/CF 15/9/2

The PMTDI is based on a chronic dietary study with mice, applying a safety factor of 100. An intake at the level of the PMTDI is not expected to result in effects of DON on the immune system, growth or reproduction, which are the most critical effects. JECFA in 2001 recommended that toxic equivalency factors relative to DON be developed for the other trichothecenes commonly occurring in cereal grains, if sufficient data become available.

The JECFA estimated that the PMTDI for DON could be exceeded in 4 out of 5 GEMS/Food regional diets.

The situation regarding deoxynivalenol has been reviewed in a discussion paper (last version CX/FAC 03/35); the 35th CCFAC (2003) discontinued the consideration of this discussion paper and agreed to commence work on the elaboration of MLs for DON (ALINORM 03/12A, paras 180-182).

The 26th CAC (2003) approved the development of maximum levels for DON as new work (ALINORM 03/41, Appendix VIII).

Mycotoxins

Deoxynivalenol

The 36th CCFAC (2004) agreed to discontinue the consideration of maximum levels for deoxynivalenol for the time being. Instead, it agreed to request information on: the occurrence of deoxynivalenol in cereals; the influence of processing, decontamination, sorting, etc. to lower the level of DON in a lot; national levels or guideline levels for DON; sampling procedures and methods of analysis; etc. for consideration by the 37th Session of the Committee (ALINORM 04/27/12, paras 156-158).

The 37th CCFAC (2005) noted that many data on the occurrence of DON in cereals and processed cereal products were already available or would soon be made available on a more global basis. The Committee therefore decided to ask JECFA to conduct an exposure assessment based on the new data. In this regard, the Committee reconfirmed the importance to take into account processed foods and the effects of processing on the level of DON. The Committee decided to establish an electronic Working Group to develop a discussion paper to provide comprehensive relevant data, including the occurrence of deoxynivalenol and the effects of processing on the levels of DON, for consideration at the 38th session (ALINORM 05/28/12, paras 148-150).

The 38th CCFAC (2006) agreed to endorse the recommendation of the ad hoc Working Group on Contaminants and Toxins in Foods to update the Discussion Paper on DON with: more data from regions where data on DON levels are missing or inadequate; additional data, especially on DON levels in maize; information on the effect on levels of seasonal variation; and information on the effect of processing on DON levels in foods (ALINORM 06/29/12, paras 137-138). The Committee also endorsed the recommendations of the Working Group on the Priority List of substances for evaluation by JECFA to maintain the request for evaluation of DON in the Priority List and to add a question regarding the potential toxicity of 3-acetyl and 15-acetyl deoxynivalenol to the existing request (ALINORM 06/29/12, paras 205-206).

The 1st CCCF (2007) agreed, in view of the need for more occurrence data, including regional data on incidence and levels of DON in cereals over a period of several years, and for adequate information on consumption patterns for various countries as a pre-requisite to developing international standards, to discontinue consideration of this item for the time being and to encourage countries to submit data on DON contamination to GEMS/Food Databases electronically and in the prescribed format (ALINORM 07/30/41, para. 108). The Committee noted that sufficient data on DON occurrence in food and fate at processing would not be available before the end of 2008 and that no information was provided on the availability of toxicological data. It agreed that DON remain on the priority list (ALINORM 07/30/41, para. 126).

The 2nd CCCF (2008) agreed to maintain the high priority for DON in evaluation by JECFA and noted that occurrence data from ongoing surveys would be made available by the end of 2008 and that some data had already been submitted to the GEMS/Food data base (ALINORM 08/31/41, paras 173 and 174).

The 72nd JECFA in February 2010 decided to convert the provisional maximum tolerable daily intake (PMTDI) for DON to a group PTMDI of 1 µg/kg bw for DON and its acetylated derivatives (3-Ac-DON and 15-Ac-DON), as 3-acetyl-deoxynivalenol (3-Ac-DON) is converted to deoxynivalenol (DON) in vivo and therefore contributes to the total DON-induced toxicity. In this regard, the Committee considered the toxicity of the acetylated derivatives equal to that of DON. The Committee concluded that, at this time, there was insufficient information to include DON-3- glucoside in the group PMTDI.

The Committee derived a group acute reference dose (ARfD) of 8 µg/kg bw for DON and its acetylated derivatives, using the lowest lower limit on the benchmark dose for a 10% response ($BMDL_{10}$) of 0.21 mg/kg bw per day for emesis in pigs dosed with DON via the diet and application of an uncertainty factor of 25. Limited data from human case reports indicated that dietary exposures to DON up to 50 µg/kg bw per day are not likely to induce emesis.

The Committee concluded that all of the mean estimates of national exposure to DON were below the group PMTDI of 1 µg/kg-bw. Estimation of dietary exposure was made using data from 42 countries, representing 10 of the 13 Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) consumption cluster diets, and was therefore considered to be more globally representative than the previous evaluation.

Mycotoxins

Deoxynivalenol

National reports showed dietary exposures that were above 1 µg/kg-bw per day in only a few cases, only for children at upper percentiles. For acute dietary exposure, the estimate of 9 µg/kg-bw per day, based on high consumption of bread and a regulatory limit for DON of 1 mg/kg food, was close to the group ARfD. The acetylated derivatives have not been included in the estimates of dietary exposure to DON but the Committee noted that, in general, they are found at levels less than 10% of those for DON, and inclusion would not be expected to significantly change the estimates of dietary exposure to DON. DON-3-glucoside was also not included in the dietary exposure estimates.

The 72nd JECFA noted that data were limited on the occurrence of DON-3-glucoside, which might be an important contributor to dietary exposure.

During the 5th CCCF (2011) it was proposed that the Committee proceed with MLs, but that the Committee first focus on MLs for DON together with associated sampling plans before proceeding with MLs for its acetylated derivatives due to the lack of complete data and availability of analytical methods (REP11/CF, para. 38). The Committee agreed to return the proposed draft Maximum Levels for DON to Step2/3 for further development the electronic Working Group led by Canada, circulation for comments and further consideration by the 6th session of the Committee (REP11/CF, para. 43), and that it would at the 8th Session of the Committee consider the extension of the ML to acetylated derivatives of DON (REP11/CF, para. 41).

The 6th CCCF (2012) agreed to return the proposed draft MLs for DON to Step 2/3 for further development by the electronic Working Group, circulation for comments and further consideration by the 7th session of the Committee (REP12/CF, para. 77).

The 7th CCCF (2013) agreed to the ML of 2 mg/kg for raw cereals (maize, wheat and barley) prior to sorting and removal of damaged kernels with the associated sampling plan with sample size of 5 kg for maize and 1 kg for wheat and barley. For flour, semolina, meal and flakes derived from wheat, maize or barley, the Committee agreed to establish a ML of 1 mg/kg. For cereal-based foods for infants and young children, the Committee agreed to establish the ML of 0.2 mg/kg and that this ML would apply to cereal-based foods as consumed. The Committee agreed to forward the proposed draft MLs for raw cereal grains including sampling plans, and for flour, semolina, meal and flakes from wheat, maize or barley to Step 5 and the proposed draft ML for cereal-based foods for infants and young children to Step 5/8 for adoption by the 36th CAC (REP13/CF, para. 64-66, 70 and APPENDIX III).

With regard to MLs for bran products, the Committee agreed to encourage members to collect and submit occurrence data for DON in wheat and corn brans for possible future work. (REP13/CF, para. 67)
The Committee recalled its earlier decision taken at the 5th Session of the Committee that it would consider the extension of the MLs for DON to its acetylated derivatives at the 8th Session of the Committee and agreed that an EWG led by Canada and Japan, working in English, would prepare a discussion paper and proposals for the extension of MLs for DON to its acetylated derivatives for consideration at the 8th session of the Committee (REP13/CF, para. 68).

The 36th CAC noted that clarification was needed on whether the ML should apply to cereal-based foods for infants and young children “as consumed” or to the “dry matter” and therefore agreed to adopt the proposed draft ML at Step 5 for further consideration in CCCF. The Commission also adopted the draft maximum levels for DON in raw cereal grains (maize, wheat and barley) and associated sampling plan and in flour, semolina, meal and flakes from wheat, maize or barley at Step 5 (REP13/CAC, para. 80, APPENDIX IV).

The 8th CCCF (2014) noted that it was not possible to reach agreement on the MLs for raw cereal grains (wheat, maize and barley); flour, meal, semolina and flakes derived from wheat, maize or barley, nor for the ML for cereal-based foods for infants and young children and agreed to hold the MLs and associated sampling plans at Step 7 for consideration at the 9th session of the Committee in light of a discussion paper on additional ways of developing MLs, such as phasing in of lower MLs over a defined period of time, to be developed by FAO, WHO and the Codex Secretariat. The Committee agreed that the ML for cereal-based foods for infants and young children should be set on a “dry matter basis”. (REP 14/CF, paras. 57-59, Appendix XII).

Mycotoxins

Deoxynivalenol

The Committee, noting the decision taken on MLs for DON and the conclusions of the EWG, agreed that it was premature to continue with work on the extension of the MLs for DON in cereals and cereal products to its acetylated derivatives. The Committee encouraged members to continue collecting and submitting data on occurrence of acetylated DON to GEMS/Food and noted the need for development of an internationally validated method for analysis of acetylated DON. The Committee agreed that no further consideration would be given to acetylated derivatives of DON as a separate item, but that when further information became available, it could be considered as part of the discussion on the MLs for DON in cereals and cereal-based products (REP 14/CF, paras. 61-62).

The 9th CCCF (2015) discussed the note for cereal grains to which the ML applies and agreed to refer to cereal grains "destined for further processing" and to qualify that it meant that additional processing or treatments proven to reduce levels of DON could be applied and that Codex members could define the processes that have been shown to reduce levels. The Committee agreed that the MLs, 2 mg/kg for cereal grains (wheat, maize and barley) for further processing, 1 mg/kg for flour, meal, semolina and flakes derived from wheat, maize or barley, and 0.2 mg/kg on dry matter basis for cereal-based foods for infants and young children, respectively, and agreed to advance the MLs and the associated sampling plans to theCAC for adoption at Step 8. The sampling plans and performance criteria for methods of analysis (aligned with fumonisins) being subject to endorsement by CCMAS. The Russian Federation expressed their reservation to all the MLs, while EU and Norway expressed their reservations to the ML for flour, meal, semolina and flakes (REP 15/CF, paras 76-91, Appendix VI).

The 38th CAC adopted the MLs at Step 8 subject to endorsement of the sampling plans and performance criteria for methods of analysis by CCMAS, as recommended by CCEXEC70. The Commission noted the reservations of the Russian Federation to the ML for cereal-based foods for infants and young children and the reservations of the European Union, Norway, Jordan and the Russian Federation to the ML for flour, meal, semolina and flakes derived from wheat, maize or barley (REP 15/CAC, para. 36).

The 37th CCMAS (2016) endorsed the sampling plans and performance criteria for methods of analysis as revised by 9th CCCF with an amendment to the title to read "Sampling plans and method performance criteria for deoxynivalenol (DON) in cereal-based foods for infants and young children in flour, meal, semolina and flakes derived from wheat, maize or barley and in cereal grains (wheat, maize and barley) destine for further processing"(REP 16/MAS, para 25 and Appendix II)

Deoxynivalenol (DON) is the major compound of a group of chemically related mycotoxins called type B trichothecenes (which are epoxy-sesquiterpenoid compounds) and is produced by certain Fusarium species, which are pathogens of several cereal grains. Closely related compounds are e.g. nivalenol and several acetyl-DON derivatives. DON is water-soluble and chemically very stable under most normal food processing conditions. DON contamination is commonly found in various cereals and cereal products. It undergoes rapid metabolism and elimination in livestock species and the transfer from feed to animal products is probably negligible. Maximum levels in feed are not needed to product public health, but are useful for the protection of animal health and productivity. Especially pigs are vulnerable.
In animals, decreased feed consumption, diarrhea and vomiting have been observed as acute effects. JECFA recognized that DON can lead to outbreaks of acute illness in humans.

Deoxynivalenol

ANNEX

SAMPLING PLANS AND METHOD PERFORMANCE CRITERIA FOR DEOXYNIVALENOL (DON) IN CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN IN FLOUR, MEAL, SEMOLINA AND FLAKES DERIVED FROM WHEAT, MAIZE OR BARLEY AND IN CEREAL GRAINS (WHEAT, MAIZE AND BARLEY) DESTINE FOR FURTHER PROCESSING

Cereal grains (wheat, cereal and barley) destined for further processing

Maximum level	2000 µg/kg DON
Increments	increments of 100 g, depending on the lot weight (≥ 0.5 tonnes)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm - 20 mesh)
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the DON-sample test result for the laboratory samples is equal or less than 2000 µg/kg, accept the lot. Otherwise, reject the lot.

Cereal-based foods for infants and young children

Maximum level	200 µg/kg DON
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the DON sample test result is equal or less than 200 µg/kg, accept the lot. Otherwise, reject the lot.

Flour, semolina, meal and flakes derived from wheat, cereal or barley

Maximum level	1000 µg/kg DON
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the DON sample test result is equal or less than 1000 µg/kg, accept the lot. Otherwise, reject the lot.

Mycotoxins

Deoxynivalenol

DEFINITION

Lot - an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.

Sublot - designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by a DON test procedure and an accept/reject level. A DON test procedure consists of three steps: sample selection, sample preparation and analysis or DON quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

Incremental sample – the quantity of material taken from a single random place in the lot or sublot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample – the smallest quantity of shelled cereal comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample in such a way to ensure that the laboratory sample is still representative of the sublot sampled.

Test portion – a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the DON for chemical analysis.

SAMPLING PLAN DESIGN CONSIDERATIONS

Material to be sampled

1. Each lot of cereal, which is to be examined for DON, must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot should be subdivided into sublots according to Table 1.

Table 1. Subdivision of cereal sublots according to lot weight

Lot weight (t)	Maximum Weight or minimum number of sub lots	Number of incremental sample	Minimum laboratory Sample Weight (kg)
≥ 1500	500 tonnes	100	1
> 300 and < 1500	3 sublots	100	1
≥ 100 and ≤ 300	100 tonnes	100	1
≥ 50 and < 100	2 sublots	100	1
< 50	-	3-100*	1

* see table 2

2. Taking into account that the weight of the lot is not always an exact multiple of the weight of sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

Incremental Sample

3. The suggested minimum weight of the incremental sample should be 100 grams for lots ≥ 0.5 tonnes.

4. For lots less than 50 tonnes, the sampling plan must be used with 3 to 100 incremental samples, depending on the lot weight. For very small lots (≤ 0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg. Table 2 may be used to determine the number of incremental samples to be taken.

Mycotoxins

Deoxynivalenol

Table 2. Number of incremental samples to be taken depending on the weight of the lot of

Lot weight (t)	Number of incremental sample	Minimum Laboratory Sample Weight (kg)
≤ 0.05	3	1
> 0.05 - ≤ 0.5	5	1
> 0.5 - ≤ 1	10	1
> 1 - ≤ 3	20	1
> 3 - ≤ 10	40	1
> 10 - ≤ 20	60	1
> 20 - < 50	100	1

Static Lots

5. A static lot can be defined as a large mass of shelled cereal contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the cereal is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or sublot may not be accessible.

6. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

7. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

   SF = (LT x IS)/(AS x IP).

8. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

9. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of shelled cereal as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

10. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the cereal flow past the sampling point.

11. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot..

12. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

    S=(D x LT) / (T x V),

where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

13. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed as a function of S, V, D, and MR.

    SF = (S x V) / (D x MR).

Packaging and Transportation of Samples

14. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

15. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

SAMPLE PREPARATION

16. Sunlight should be excluded as much as possible during sample preparation, since DON may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favour mould growth and DON formation.

17. As the distribution of DON is extremely non-homogeneous, laboratory samples should be homogenised by grinding the entire laboratory sample received by the laboratory. Homogenisation is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

18. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenisation as possible. Complete homogenisation implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent DON cross-contamination.

Test portion

19. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g

20. Procedures for selecting the test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminuting process, the test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the test portion should be the accumulation of several small portions selected throughout the laboratory sample.

21. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

22. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. A list of possible criteria and performance levels are shown in Table 3). Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Deoxynivalenol

Table 3. Proposed method criteria for DON in cereals.

Commodity	ML (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	Precision on HorRat	Minimum applicable range (mg/kg)	Recovery
Cereal grains (wheat, cereal and barley) destined for further processing	2.0	≤ 0.2	≤ 0.4	≤ 2	1-3	80 - 110%
Cereal-based foods for infants and young children	0.2	≤ 0.02	≤ 0.04	≤ 2	0.1 – 0.3	80 – 110%
Flour, semolina, meal and flakes derived from wheat, cereal or barley	1.0	≤ 0.1	≤ 0.2	≤ 2	0.5 – 1.5	80 – 110%

Mycotoxins

Diacetoxyscirpenol

Reference to JECFA:	-
Toxicological guidance value:	-
Contaminant definition:	-
Synonyms:	Abbreviation: DAS
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Maximum Level(ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
	No ML						

DAS has been detected with a high prevarence in sorghum samples analysed in the FAO/WHO Mycotoxins in Sorghum Project. This mycotoxin has not been assessed by JECFA and a full safety assessment may be warranted to facilitate the interpretation of the analytical results. The 8th CCCF (2014) agreed to add a full risk assessment of DAS in the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA. (REP 14/CF, paras. 125-130 and Appendix XIII)

Diacetoxyscirpenol (DAS) is a trichothecene mycotoxin produced by certain species of *Fusarium*, such as *F. poae*, *F. semitectum*, *F. moniliforme*, *F. sporotrichioides* etc. DAS was discovered in 1961 as a phytotoxic compound from a culture of F. equiseti and Gibberella intricans and its chemical properties and structure have been characterized. According to chemical classification of trichothecenes, DAS as well as T-2 and HT-2 toxins, belongs to group A which is characterized by the absence of a ketone on C-8 position and the absence of a macrocyclic ring. Particularly, it is included in the scirpentriol subgroup which comprises a family of type A trichothecene toxins: scirpentriol, the parent alcohol and its seven acetylated derivatives such as DAS, monoacetoxyscirpenol and triacetoxyscirpenol. Among trichothecenes produced by Fusarium spp., DAS is one of the most toxic. The presence of DAS in animal feeds and human foods is a possible health threat to humans and animals in some parts of the world, as historically documented by studies on a variety of animal toxicosis, human alimentary toxic aleukia, Msleni joint disease, and more recently evidenced by studies on human toxicoses and bone and joint disease in China. The toxic effects of DAS in humans and animals are similar and include vomiting, diarrhea, hypotension, and myelosuppression.

Mycotoxins

Ergot alkaloids

Reference to JECFA:	-
Toxicological guidance value:	-
Contaminant definition:	-
Synonyms:	abbreviation: EAs
Related code of practice:	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
	No ML						

The 34th CCFAC (2002) agreed to add ergot alkaloids for full evaluation to the priority list of food additives, contaminants and naturally occurring toxicants proposed for evaluation by JECFA. (ALINORM 03/12, paras 164-169)

The 38th CCFAC (2006) agreed to delete ergot alkaloids from the priority list for evaluation by JECFA (details are not noted in the report of the session).

The 9th CCCF (2015) noted that a proposal had been made for an additional annex on ergot alkaloids to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003) but that further information was needed on which the Committee could take a decision on the inclusion of such an annex. The Delegation of Germany agreed to develop a discussion paper for consideration by the next session of the Committee. (REP 15/CF, para.103)

"Ergot" is the term used for the solidified mycelium of the fungus *Claviceps purpurea, africana, fusiformis, sorghi* and related species, which can afflict grasses and cereals of all kinds and may contain ergot alkaloids. A dark, sometimes white ergot (sclerotium) is formed instead of a grain in the ears of cereal infected via the plant's blossom. These bodies usually differ significantly from the cereal as an overall entity in terms of their shape, colour and composition. The main types of cereal affected are rye and triticale (*Claviceps purpurea*), sorghum (*Claviceps africana, sorghi, sorghicola*) and pearl millet (*Claviceps fusiformis*). In spring seasons with longer moist and cool periods, wheat and barley might also be affected. A contamination of the harvested product with ergot and the toxic compounds – ergot alkaloids (EA) – can occur. Out of 40 known ergot alkaloids the most relevant are ergocornine, ergocristine, ergocryptine, ergometrine, ergosine, ergotamine and their epimers. Moreover, in sorghum ergot also dihydro-ergosine and related alkaloids are relevant components. Sclerotia contain different amounts of EAs, depending on the fungi species, the host, the weather conditions and the geographical region. The total alkaloid content in a single sclerotium varies and can reach up to 0.5%. A total ergot alkaloid mean of 0.08% in ergot bodies has been reported based on European data.

Intoxication induced by ergot alkaloids is commonly known as ergotism or "St. Anthony's fire", which was ubiquitous in the middle Ages. Local epidemics have occurred also in more recent years in France, India and Ethiopia, respectively. There are two symptomatic forms of ergotism: gangrenous and convulsive. In the gangrenous form, tingling effects are felt in peripheral tissues finally leading to the loss of limbs, whereas in convulsive ergotism the tingling is followed by hallucinations, delirium and epileptic-type seizures. "Chronic intake of moderate quantities of ergot alkaloid can have a negative impact on reproduction (e.g. trigger miscarriage, lower birth weight, deficient lactation). Chronic oral ingestion of large quantities of ergot alkaloids result in symptoms which correspond to acute ingestion of high quantities of ergot alkaloids. This is known from observations of unwanted effects where certain ergot alkaloids were used as active ingredients in medicines or where, following ingestion of cereal products containing high levels of ergot, people became ill." (Ref. CX/CF 16/10/13)

Mycotoxins

Fumonisins (B_1+B_2)

Reference to JECFA: 56 (2001), 74 (2011)
Toxicological guidance value: PMTDI 0.002 mg/kg bw (2001, 2011)
Contaminant definition: Fumonisins (B_1+B_2)
Synonyms: (Several related compounds have been described, notably fumonisin B_1, B_2 and B_3 (abbreviation: FB_1 etc.))
Related code of practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Raw Maize grain	4000	Adopted	2014	CF	Whole commodity	*For sampling plan, see Annex.*	CX/CF 15/9/2
Maize flour and maize meal	2000	Adopted	2014	CF	Whole commodity	*For sampling plan, see Annex.*	CX/CF 15/9/2

A position paper has been prepared for fumonisins (last version CX/FAC 00/22). The 32nd CCFAC (2000) asked the USA to finalize the position paper as a potential basis for future work (ALINORM 01/12 paras 106-109). No MLs have been proposed.

The Representative of WHO, speaking on behalf of the JECFA Secretariats, clarified at the 1st CCCF (2007) that there was no plan for JECFA to update the risk assessment conducted by the 56th JECFA meeting and that an updated risk assessment could be conducted only when new data became available (ALINORM 07/30/41, para. 135).

The 2nd CCCF (2008) agreed to establish an electronic working group to prepare a discussion paper, which should include an overview of available data and scope of the problem of fumonisin contamination for consideration at its next session (ALINORM 08/31/41, para. 177).

The 3rd CCCF(2009) agreed to initiate work on establishing maximum levels and developing a sampling plan for fumonisins in maize and maize-based products subject to approval by the 32nd Session of the Commission. It was further agreed to request JECFA to review the available toxicology and occurrence data in order to carry out a re-evaluation on fumonisins in maize and maize products and that, based on the outcome of JECFA re-evaluation, the maximum level might be revised. It was noted that work would be completed by 2012 noting that JECFA could only consider fumonisins at the earliest at its meeting in 2011 (ALINORM 09/32/41, para. 101). The proposal of new work was subsequently by the Commission at its 32nd Session (ALINORM 09/32/REP, Appendix VI).

The 4th CCCF (2010) agreed to retain the proposed draft ML and sampling plans, as contained in Annex I and Annex Ⅱ of CX/ CF 10/4/8 respectively, at Step 4 until further advice was provided by JECFA (ALINORM 10/33/41, para. 95). Although occurrence of FB3 was well documented and that JECFA in 2001 had allocated a PMTDI of 2 µg/kg/ bw/day for FB1, FB2 and FB3 alone or in combination, it was noted that FB3 made up only 10% of total intake; that the routine laboratory testing for FB3 was expensive and that not all countries tested for FB3, but that consideration could be given to their inclusion in the standard (ALINORM 10/33/41, para. 90- 91).

The 74th JECFA (2011) evaluated fumonisins and reviewed all relevant studies performed since 2001. Studies suitable for dose-response analysis have been conducted with rodents employing either purified FB1 or F. verticillioides culture material containing FB1. Although naturally contaminated corn would probably be more representative of actual human dietary exposure than either purified FB1 or culture material, no suitable studies were identified that used naturally contaminated corn as test material.

Mycotoxins

Fumonisins (B_1+B_2)

For culture material, the lowest identified $BMDL_{10}$ using FB1 as a marker was 17 µg/kg bw per day for renal toxicity in male rats. The Committee chose not to establish a health-based guidance value for culture material because its composition was not well characterized and may not be representative of natural contamination. For pure FB1, the lowest identified $BMDL_{10}$ was 165 µg/kg bw per day for megalocytic hepatocytes in male mice. Using an uncertainty factor of 100 for intraspecies and interspecies variation, the Committee derived a PMTDI of 2 µg/kg bw. As this was the same value as the previous established group PMTDI, this group PMTDI for FB1, FB2, and FB3, alone or in combination, was retained.
It was estimated that the dietary exposure to FB1 for the general population ranges from 0.12 x 10-3 to 7.6 µg/kg bw per day (95th percentile: up to 33.3 µg/kg bw per day). Dietary exposure to total fumonisins for the general population would range, for a consumer with average consumption, from 0.087 x 10-3 to 10.6 µg/kg bw per day, whereas for consumers with high consumption, exposure would be up to 44.8 µg/kg bw per day. Maize was found to be the predominant source of exposure to FB1 and total fumonisins. Comparison of the estimated dietary exposure with the group PMTDI indicated that the group PMTDI is exceeded at the population level in some regions within some countries. The Committee concluded that adverse effects from fumonisin exposure may occur and that reduction of exposure is highly desirable, particularly in areas of the world where maize is a major dietary staple food and where high contamination can occur.
As fumonisins do not carry over from feed to animal products in significant amounts, the occurrence of fumonisins in feed was considered not to be a human health concern.

The 74th JECFA concluded that implementation of the MLs proposed by CCCF could significantly reduce exposure (by more than 20%) to total fumonisins in six GEMS/Food consumption clusters (A, D, G, B, K, F). The main contribution to reduction was due to the proposed Codex ML for the category “Corn/maize grain, unprocessed”. The Committee also noted that the national estimates of exposure to fumonisins show that the exceedance of the PMTDI occurs only in limited regions presenting high maize consumption levels and highly contaminated maize. The Committee concluded that no or little effect was noticed on the international exposure estimates resulting from the implementation of MLs higher than those proposed by CCCF.

The 74th JECFA recommended that, to be able to fully assess the toxic potential of culture material or naturally contaminated food, characterization and quantification of their mycotoxin content are necessary. Also, to obtain a realistic representation of the effects of “real life” exposure, and in order to compare its toxic potential with the studies used for the final evaluation, naturally contaminated feed should be tested in dose–response studies in animals. In addition, further studies must be performed to elaborate more appropriate analytical methods to obtain additional occurrence data and information on the effects of processing. As dietary exposure to fumonisins may occur together with exposure to other mycotoxins, such as aflatoxins, well-designed laboratory and epidemiological studies are needed to assess interactions. For evaluation of the co-occurrence, in food and feed, of fumonisins with other mycotoxins, levels of fumonisins and other mycotoxins must be provided at the level of the individual analytical sample (i.e. not aggregate data).
Additional data on fumonisin distribution in corn Commodity / Product Names should be collected in order to establish appropriate sampling procedures. To validate the potential candidate urinary FB1 level for a human biomarker of short-term exposure, large-scale human studies that indicate a well characterized dose–response relationship between urinary FB1 level and dietary fumonisin exposures are needed. A biomarker for long-term exposure is also needed. To investigate the association of fumonisin exposure with oesophageal cancer risk, child growth impairment and NTDs in humans, studies on fumonisin exposure and incidence of these conditions in individuals (such as a cohort or case–control study) are needed using a validated fumonisin exposure biomarker and controlling for confounders and for known risk factors.

The 6th CCCF (2012) noted that there was agreement for the need for MLs on raw maize/corn grains and corn/maize flour, but that there was no agreement on the actual MLs and the further proposal to develop a code of practice for fumonisins in maize, the Committee agreed to develop a discussion paper to identify the gaps in the Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals and the need for a separate code of practice for fumonisins in maize and whether there are any other measures to control fumonisins in maize. The Committee agreed to establish an electronic working group lead by Brazil and co-chaired by the United States of America and working to develop the discussion paper for consideration by the next session and to suspend development of the proposed draft MLs for fumonisins until the consideration of the discussion paper by the electronic working group at the 7th Session (REP12/CF paras. 92, 93 and 95).

Mycotoxins

Fumonisins (B_1+B_2)

The 7th CCCF (2013) agreed that it was too early to start new work on the revision of the COP and that it needed more information on the nature of the revision and agreed to re-establish the EWG, led by Brazil and co-chaired by the United States of America, working to further develop the discussion paper based on the discussions at the 7th session and, if possible, to prepare a proposed draft revision of the COP for consideration by the 8th session. (REP13/CF para 132). It agreed that the proposed draft MLs for fumonisins in maize and maize products and associated sampling plans previously discussed at the 6th Session of the Committee (CX/CF 12/6/18) would be circulated for comments and a revised proposal for proposed draft MLs for fumonisins in maize and maize products and associated sampling plans would be prepared by Brazil for comments and consideration by the 8th session (REP13/CF para 133).

The 8th CCCF (2014) agreed that the ML of 4 000 µg/kg for raw cereal grains and 2 000 µg/kg for maize flour and maize meal were ready for adoption by the Commission. In relation to the ML for maize flour and maize meal, the Committee agreed that these would be advanced for adoption with the understanding that exposure and impact assessment should be undertaken by JECFA within three years for reconsideration of the levels. The Committee agreed to forward the proposed draft MLs with associated sampling plans to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th Session of the Commission. The sampling plans would be sent for endorsement by CCMAS. (REP14/CF, paras. 71-72, Appendix IV). The Committee also agreed to add the assessments of fumonisins already evaluated by JECFA, to the priority list. An updated exposure assessment for fumonisins shall be performed by JECFA after three years once more occurrence data from countries where limited data are available have been collected. (REP 14/CF, paras 129-130, Appendix XIII)

The 37th CAC (2014) adopted the adopted the MLs and sampling plans at Step 5/8 while noting that sampling plans should be endorsed by CCMAS. The Delegation of Egypt, supported by the Delegation of Jordan, expressed a reservation that lower MLs would be desirable considering the impact of these mycotoxins on human health, and in particular their cumulative effect in the human body and their carry-over from feed to food. (REP 14/CAC, paras. 83 and 85, Appendix III).

The 36th CCMAS (2015) did not endorse the sampling plans noting that there were several inconsistencies between the tables and text in the sampling plans. The Committee agreed to request CCCF to consider removing the inconsistencies and to present a revised version to the next session of CCMAS. (REP15/MAS, paras 17-20)

The 9th CCCF (2015) agreed to send the sampling plans and performance criteria for methods of analysis, revised by in-session WG, to CCMAS for endorsement. (REP 15/CF, paras 11-13, Appendix III)
The 37th CCMAS (2016) endorsed the sampling plans and performance criteria for methods of analysis as revised by 9th CCCF with an amendment to the title to read “Sampling plans and method performance criteria for fumonisins (FB1 + FB2) in maize grain and maize flour and maize meal”. (REP 16/MAS, para 25 and Appendix II)

Fumonisins are a class of recently identified mycotoxins that are produced mainly by certain *Fusarium* species, especially *F. moniliforme* which is a pathogen of corn (*Zea mays*). Fumonisins are a structurally related group of diesters of propane-1,2,3-tricarboxylic acid and various 2-amino-12,16-dimethylpolyhydroxyeicosanes. There are at least 12 fumonisin analogues identified, classified into series A, B, F and P. The B-series, consisting mainly of fumonisin B1 and fumonisin B2, is believed to be the most abundant and most toxic group. A typical ratio between these analogues is B1:B2:B3 as 10:3:1. The worldwide occurrence of fumonisins in corn and corn-based products is well documented: sporadic natural occurrence in sorghum, rice and navy beans has been reported. Fumonisins are heat-stable, so cooking and other heat processes do not substantially reduce their levels in foods. Processing involving treatment of wet milling fractions may, however, lead to elimination of most fumonisin. The human exposure via food can vary to a large extent because of the large range of fumonisin contents found in practice. Fumonisins undergo rapid metabolism and elimination in livestock species and the transfer from feed to animal products is probably negligible. Maximum levels in feed are not needed to protect public health but are useful for the protection of animal health and productivity. In animals, various adverse effects have been observed.

Mycotoxins

Fumonisins (B_1+B_2)

The horse appears to be the most sensitive species, and equine leukoencephalomalacia (ELEM) is the most frequently encountered disease. Fumonisins are also associated with liver damage, often also kidney lesions and changes in certain lipid classes, especially sphingolipids, in all animals studied. Carcinogenic effects have been observed in animals exposed to high dietary levels. Nephrotoxicity, observed in several strains of rat, was considered by JECFA to be the most sensitive toxic effect. On the basis of the NOEL for renal toxicity and a safety factor of 100, the PMTDI was established. National estimates for the mean or median intake were generally much lower than the PMTDI (the highest being 0.2 µg/kg bw).

Mycotoxins

Fumonisins (B_1+B_2)

ANNEX

SAMPLING PLANS AND METHOD PERFORMANCE CRITERIA FOR FUMONISINS (FB1 + FB2) IN MAIZE GRAIN AND MAIZE FLOUR AND MAIZE MEAL

Maize grain, unprocessed

Maximum level	4 000 µg/kg FB_1 + FB_2
Increments	increments of 100 g, depending on the lot weight (≥ 0.5 tonnes)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm - 20 mesh)
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result for the laboratory samples is equal or less than 4 000 µg/kg, accept the lot. Otherwise, reject the lot.

Maize flour and maize meal

Maximum level	2 000 µg/kg FB_1 + FB_2
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result is equal or less than 2000 µg/kg, accept the lot. Otherwise, reject the lot.

DEFINITION

Lot - an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.

Sublot - designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by a fumonisin test procedure and an accept/reject level. A fumonisin test procedure consists of three steps: sample selection, sample preparation and analysis or fumonisin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

Incremental sample - the quantity of material taken from a single random place in the lot or sublot.

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample - the smallest quantity of shelled maize comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample in such a way to ensure that the laboratory sample is still representative of the sublot sampled.

Test portion - a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the fumonisin for chemical analysis.

Mycotoxins

Fumonisins (B_1+B_2)

SAMPLING PLAN DESIGN CONSIDERATIONS

Material to be sampled

1. Each lot of maize, which is to be examined for fumonisin, must be sampled separately. Lots larger than 50 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 50 tonnes, the lot should be subdivided into sublots according to Table 1.

Table 1. Subdivision of maize sublots according to lot weight

Lot weight (t)	Maximum Weight or minimum number of sub lots	Number of incremental sample	Minimum laboratory Sample Weight (kg)
≥ 1500	500 tonnes	100	1
> 300 and < 1500	3 sublots	100	1
≥ 100 and ≤ 300	100 tonnes	100	1
≥ 50 and < 100	2 sublots	100	1
< 50	-	3-100*	1

* see table 2

2. Taking into account that the weight of the lot is not always an exact multiple of the weight of sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20%.

Incremental Sample

3. The suggested minimum weight of the incremental sample should be 100 grams for lots ≥0.5 tonnes.

4. For lots less than 50 tonnes, the sampling plan must be used with 3 to 100 incremental samples, depending on the lot weight. For very small lots (≤0.5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg. Table 2 may be used to determine the number of incremental samples to be taken.

Table 2. Number of incremental samples to be taken depending on the weight of the lot

Lot weight (t)	Number of incremental sample	Minimum Laboratory Sample Weight (kg)
≤ 0.05	3	1
> 0.05 - ≤ 0.5	5	1
> 0.5 - ≤ 1	10	1
> 1 - ≤ 3	20	1
> 3 - ≤ 10	40	1
> 10 - ≤ 20	60	1
> 20 - < 50	100	1

Mycotoxins

Fumonisins (B_1+B_2)

Static Lots

5. A static lot can be defined as a large mass of shelled maize contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the maize is stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or sublot may not be accessible.

6. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

7. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

   SF = (LT x IS)/(AS x IP).

8. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

9. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of shelled maize as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

10. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the maize flow past the sampling point.

11. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

12. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is: S=(D x LT) / (T x V),

    where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

13. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed as a function of S, V, D, and MR.

    SF = (S x V) / (D x MR).

Packaging and Transportation of Samples

14. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample, which might arise during transportation or storage. Samples should be stored in a cool dark place.

15. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

Mycotoxins

Fumonisins (B_1+B_2)

SAMPLE PREPARATION

16. Sunlight should be excluded as much as possible during sample preparation, since fumonisin may gradually break down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and fumonisin formation.

17. As the distribution of fumonisin is extremely non-homogeneous, laboratory samples should be homogenised by grinding the entire laboratory sample received by the laboratory. Homogenisation is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

18. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenisation as possible. Complete homogenisation implies that particle size is extremely small and the variability associated with sample preparation approaches zero. After grinding, the grinder should be cleaned to prevent fumonisin cross-contamination.

Test portion

19. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 25 g

20. Procedures for selecting the test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminuting process, the test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the test portion should be the accumulation of several small portions selected throughout the laboratory sample.

21. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

22. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. A list of possible criteria and performance levels are shown in Table 3). Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

Table 3. Performance criteria for Fumonisin B_1+ B_2.

Maize Grain

Analyte	ML (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	RSD_R	Recovery (%)
FB_1 + FB_2	4.0	-	-	-	-
FB_1		≤ 0.3*	≤ 0.6*	HorRat ≤ 2 (< 27%)	80 - 110
FB_2		≤ 0.15*	≤ 0.3*	HorRat ≤ 2 (< 32%)	80 - 110

* - The LOD and LOQ were derived based upon typical B_1:B_2 ratio of 5:2 in naturally-contaminated samples

Maize Flour/Meal

Analyte	ML (mg/kg)	LOD (mg/kg)	LOQ (mg/kg)	RSD_R	Recovery (%)
FB_1 + FB_2	2.0	-	-	-	-
FB_1		≤ 0.15*	≤ 0.3*	HorRat ≤ 2 (< 30%)	80 – 110
FB_2		≤ 0.06*	≤ 0.15*	HorRat ≤ 2 (< 34%)	80 – 110

* - The LOD and LOQ were derived based upon typical B_1:B_2 ratio of 5:2 in naturally-contaminated samples

Mycotoxins

Ochratoxin A

Reference to JECFA: 37 (1990), 44 (1995), 56 (2001), 68 (2007)
Toxicological guidance value: PTWI 0.0001mg/kg bw (2001)
Contaminant definition: Ochratoxin A
Synonyms: (The term "ochratoxins" includes a number of related mycotoxins (A, B, C and their esters and metabolites), the most important one being ochratoxin A)
Related code of practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)
Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (CAC/RCP 63-2007)
Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee (CAC/RCP 69-2009)
Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Cocoa (CAC/RCP 72-2013)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Barley	5	Adopted	2008	CF	Whole commodity	The ML applies to raw barley..	GC 0640
Rye	5	Adopted	2008	CF	Whole commodity	The ML applies to raw rye.	GC 0650
Wheat	5	Adopted	2008	CF	Whole commodity	The ML applies to raw common wheat, raw durum wheat, raw spelt and raw emmer.	GC 0654

The situation regarding ochratoxins has been reviewed in a position paper (last version CX/FAC 99/14).

The draft ML of 5 µg/kg for ochratoxin A in raw wheat, barley and rye and derived products was forwarded for adoption at step 8 by the 34th CCFAC (2002) (ALINORM 03/12, paras 111-114), on the basis of the assumption that this level was ALARA. The 26th CAC (2003) discussed this proposal (ALINORM 03/41, paras 45-47). Many delegations were of the opinion that this proposed ML was too low and, taking account of the evaluation of the 56th JECFA (2001), noted that a ML of 20 µg/kg could be adequate in terms of public health and safety. The CAC concluded that there was a lack of consensus both regarding the appropriate ML and regarding the reference to derived products and returned the standard to step 6 for further work by the CCFAC. The 36th CCFAC (2004) noted that given the wide range of derived products and that many of them were of little or no importance in international trade, the maximum level should be limited to raw wheat, barley, and rye. The Committee agreed to hold the maximum level of 5 µg/kg for Ochratoxin A in raw wheat, barley, and rye at Step 7. The Committee also agreed, depending upon the available data, that JECFA should perform a comprehensive risk assessment by 2006, so that the Committee might reconsider this issue in the light of the outcome of the JECFA evaluation at its Session in 2007 (ALINORM 04/27/12, paras 132-137).

The ad hoc working group of the 38th CCFAC (2006) agreed to forward to the CAC for approval of new work, the project document "Code of practices for the prevention and reduction of Ochratoxin A contamination in wine", and agreed that MLs for ochratoxin A in wine might be considered in future, pending collection of data on levels in wine and the outcomes of the elaboration of the Code. The Committee agreed to endorse the recommendation of the ad hoc Working Group on Contaminants and Toxins in Foods to start new work on the elaboration of the Code and clarified that the scope of this work should be limited to wine only. The Committee also agreed that the proposed draft Code would be circulated for comments at Step 3 and considered at the next session of the Committee. The 29th CAC (2006) approved the development of the Code as a new work (ALINORM 06/29/12, paras 139-142).

Mycotoxins

Ochratoxin A

The 38th CCFAC agreed with the recommendations of the ad hoc Working Group to establish two electronic Working Groups to prepare separate discussion papers on ochratoxin A in coffee and ochratoxin A in cocoa, respectively, for circulation, comments and consideration at its next Session that might allow the Committee to decide if the development of Codes of Practice was appropriate (ALINORM 06/29/12, paras 143-145).

The 1st CCCF (2007) agreed to retain the draft MLs at Step 7 and to inform the Executive Committee that work on this item would be completed by 2009 (ALINORM 07/30/41, para. 50).

The 68th JECFA (2007) retained the PTWI of 100 ng/kg bw. The estimated overall dietary exposure to Ochratoxin A from cereals (mainly European data) was adjusted to 8-17 ng/kg bw/week (processed cereals), compared with the 25 ng/kg bw/week (raw cereals) in the previous assessment. This is well below the PTWI. Moreover, contamination levels in the majority of raw cereal samples were below 5 µg/kg and only a few samples were above the highest proposed limit of 20 µg/kg. The 68th JECFA concluded that it would be unlikely that an ML of 5 or 20 µg/kg has an impact on dietary exposure to Ochratoxin A. The committee was unable to reach a conclusion regarding developing countries due to the lack of adequate data to consider.

The 2nd CCCF (2008) agreed to forward the Draft Maximum Level of 5 µg/kg for OTA in RawWheat, Barley and Rye to the 31st Session of the Codex Alimentarius Commission for adoption at Step 8 and subsequent inclusion in the General Standard for Contaminants and Toxins in Foods (ALINORM 08/31/REP, para. 112 and Appendix VII). The 31st CAC adopted the draft ML at Step 8 (ALINORM 08/31/REP, para. 26 and Appendix VII).

<u>OTA in coffee</u>
The 1st CCCF (2007) decided to establish an electronic working group, to be chaired by Brazil, to prepare a revised discussion paper for consideration at the second session. The revised discussion paper should incorporate new data and other relevant information including those submitted to the first session, and be accompanied by a project document proposing new work and possibly an outline of the proposed draft code of practice (ALINORM 07/30/41, para. 113).

The 2nd CCCF (2008) agreed to to establish an electronic working group to prepare a draft proposed Code of Practice on the Prevention and Reduction of Ochratoxin A contamination in Coffee at Step 2, with a view to its circulation for comments at Step 3 and its consideration at Step 4 at the next session of the Committee, pending the formal approval of new work by the Codex Alimentarius Commission (ALINORM 08/31/41, para. 168). The 31st CAC approved this work (ALINORM 08/31/REP, para. 101).

The 3rd CCCF (2009) agreed to forward the Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Coffee at Step 5/8 (ALINORM 09/32/41, para. 95 and Appendix VI). The 32nd CAC approved the proposed draft Code at Step 5/8 (ALINORM 09/32/REP, Appendix III).

<u>OTA in cocoa</u>
The 1st CCCF decided to establish an EWG to be chaired by Ghana to update the discussion paper with new data and other relevant information, and taking into account the comments made at the first session, for consideration at the second session (ALINORM 07/30/41, para. 117).

The 2nd CCCF (2008) agreed to suspend the consideration of this matter with the understanding to re-consider OTA contamination in cocoa in light of the new data available in the near future (ALINORM 08/31/41, para. 170).

Mycotoxins

Ochratoxin A

The 5th CCCF (2011) agreed to re-establish the EWG, working in English, led by Ghana, to update the discussion paper with a view to the development a code of practice in cocoa, for consideration by the 6th session of the Committee (REP11/CF, para. 75).

The 6th CCCF (2012) agreed to initiate a new work on the development of a code of practice for the prevention and reduction of OTA in cocoa. The Committee agreed that the proposed code of practice would be developed by an EWGled by Ghana for comments at Step 3 and consideration at the 7th session (REP12/CF, para. 141 and Appendix X). The 35th CAC (2012) approved the new work (REP12/CAC, Appendix VI).

The 7th CCCF (2013) agreed to forward the proposed draft Code to Step 5/8 for adoption by the 36th CAC (REP13/CF, para. 79, Appendix IV). The 36th CAC approved the draft Code at Step 5/8 (REP13/CAC, Appendix III).

OTA in sorghum

The 6th CCCF (2012) agreed to initiate a new work on the development of an annex for the management of aflatoxins and OTA in sorghum to the *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003, COP), subject to approval by the 35th Session of the Commission. The Committee agreed to establish an EWG led by Nigeria and co-chaired by Sudan to prepare the proposed draft annex for comments at Step 3 and consideration at the 7th session (REP12/CF, para. 136 and Appendix IX). The 35th CAC (2012) approved the new work (REP12/CAC, Appendix VI).

The 7th CCCF (2013) agreed to return the proposed draft Annex to Step 2/3 for further development by the EWG, circulation for comments and further consideration by the 8th session of the Committee (REP13/CF, para. 74).

The 8th CCCF agreed that in view of the considerable progress made on the annex that it would be advanced for adoption, with the understanding that the annex would be integrated into the COP and its annexes in the new work on the revision of the COP. The Committee agreed to forward the proposed draft Annex to Step 5/8 (with the omission of Steps /7) for adoption by the 37th CAC (REP 14/CF, para. 76-77, Appendix V). The 37th CAC adopted the annex at Step 5/8 (REP 14/CAC, para. 47, Appendix III).

OTA in paprika

In 8th CCCF (2014), a proposal for new work on a code of practice for the prevention and reduction of OTA in paprika was discussed. The Committee agreed that a more general approach should also be taken for this COP, similar to the Code of Practice for Prevention and Reduction of Mycotoxin Contamination in Cereals; and that consideration could be given to development of annexes for specific mycotoxin-spice combinations. The Committee agreed to establish an EWG, led by Spain and co-chaired by the Netherlands, to prepare a discussion paper on the feasibility for a code of practice for mycotoxins in spices with specific annexes for consideration at the 9th session (REP 14/CF, paras. 138-140).

Ochratoxin A is the major compound of a group of chemically related mycotoxins produced by species of the genera *Aspergillus* and *Penicillium*. Ochratoxin A contamination is commonly found in various cereals, some pulses, coffee, cocoa, figs, grapes, wine, nuts and coconut products. It can also be transferred through the feed to animal products and concentrates especially in the kidney, but may also be found in meat and milk. Most ochratoxin A is, however, converted to the less harmful ochratoxin-alpha in the rumen of ruminants. Ochratoxin A is a nephrotoxic mycotoxin, which is carcinogenic to rodents and has also teratogenic, immunotoxic and possibly neurotoxic properties. It has been associated with Balkan Endemic Nephropathy.

Mycotoxins

Patulin

Reference to JECFA: 35 (1989), 44 (1995)
Toxicological guidance value: PMTDI 0.0004 mg/kg bw (1995)
Contaminant definition: Patulin
Related code of practice: Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (CAC/RCP 50-2003)

Commodity / Product Name	Maximum Level (ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Apple juice	50	Adopted	2003	FAC	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration.	Relevant Codex commodity standard include CODEX STAN 247-2005 (apple product only). The ML applies also to apple juice used as an ingredient in other beverages.	

The situation regarding patulin was reviewed in a position paper (last version CX/FAC 99/16).

The 26th CAC in 2003 adopted the ML. The possible reduction of the ML from 50 to 25 µg/kg will be reconsidered by the CCFAC once the Code of Practice has been implemented (i.e., after 4 years). More data are requested on the level of patulin in apple juice and apple juice ingredients for other beverages.

The First CCCF (2007) agreed to take patulin out of the priority list, noting that there was an existing maximum level and this topic was no longer considered a high priority (ALINORM 07/30/41, para. 127).

Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera Aspergillus, Penicillium and Byssochlamys. The major sources of patulin contamination are apples with brown rot and blue mould. Because patulin does not spread much from spoilt tissue, the main human exposure can be expected from processed products, like apple juice and apple sauce, in which the contamination is not visible. Because fermentation destroys patulin, it is not normally present in cider and perry, unless unfermented apple juice has been added after fermentation. Patulin may also be a contaminant of soft fruits, some vegetables, barley, wheat and corn.

Potential health problems related to patulin are connected to cytotoxic, immunotoxic, neurotoxic, gastrointestinal and other effects observed in animals. Patulin is mostly eliminated within a few days after ingestion.

The PMTDI was set by applying a safety factor of 100 to the lowest NOAEL of 43 µg/kg bw/day in rats.

Sterigmatocystin

Reference to JECFA:	-
Toxicological guidance value:	-
Contaminant definition:	-
Synonyms:	Abbreviation: STC
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Maximum Level(ML) (µg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
	No ML						

STC has been detected with a high prevarence in sorghum samples analysed in the FAO/WHO Mycotoxins in Sorghum Project. This mycotoxin has not been assessed by JECFA and a full safety assessment may be warranted to facilitate the interpretation of the analytical results. The 8th CCCF (2014) agreed to add a full risk assessment of STC in the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA. (REP 14/CF, paras. 125-130 and Appendix XIII)

Sterigmatocystin (STC) is a polyketide mycotoxin that is produced by more than 50 fungal species, including *Aspergillus flavus*, *A. parasiticus*, *A. versicolor* and *A. nidulans*, of which *A. versicolor* is the most common source. STC shares its biosynthetic pathway with aflatoxins. *A. nidulans* and *A. versicolor* are apparently unable to biotransform STC into O-methylsterigmatocystin, the direct precursor of aflatoxin B_1 and G_1. Consequently, substrates colonised by these fungi can contain high amounts of STC, while substrates invaded by *A. flavus* and *A. parasiticus* contain only low amounts of STC as most is converted into aflatoxins. STC can occur in grains and grain-based products due to fungal infestation at the post-harvest stage.
The IARC (1976 and 1978) has assessed the carcinogenic potential of STC and concluded that STC produced lung tumours in mice and liver tumours in rats following oral administration. The IARC noted that in rats, STC induced skin and liver tumours following its administration to the skin and sarcomas at the site of its subcutaneous injection. No case reports or epidemiological studies were available for evaluation by IARC and it was concluded that STC is possibly carcinogenic to humans (group 2B).

Mycotoxins

T2 and HT-2 Toxin

Reference to JECFA:	56 (2001)
Toxicological guidance value:	PMTDI 0.00006 mg/kg bw (2001, Group PMTDI for T-2 and HT-2 toxins, alone or in combination)
Related code of practice:	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Level (µg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
	No ML					

No further action on T-2 and HT-2 toxin has been recommended by the 33rd CCFAC (2001), probably based on the understanding that the (limited) information available suggested that intakes would not exceed the PMTDI (ALINORM 01/12A, para. 16).

T-2 and HT-2 toxin are closely related compounds belonging to a group of chemically related mycotoxins called type A trichothecenes (which are epoxy-sesquiterpenoid compounds) and are produced by certain *Fusarium* species, which are pathogens of several cereal grains. The most important producer is *F. sporotrichioides*, a saprophyte which only will grow at high water activities. As a consequence, T-2 and HT-2 toxins are not normally found in grain at harvest, but result from water damage when it remains wet for longer periods in the field or after harvest. T-2 and HT-2 toxin undergo rapid metabolism and elimination in livestock species and the transfer from feed to animal products is probably negligible. Maximum levels in feed are not needed to protect public health, but are useful for the protection of animal health and productivity. Especially pigs are vulnerable. In animals, decreased feed consumption, diarrhea and vomiting have been observed as acute effects.

T-2 toxin is a potent inhibitor of protein synthesis, both in vivo and in vitro. T-2 toxin is linked to outbreaks of acute poisoning of humans, in which the adverse effects reported include nausea, vomiting, pharyngeal irritation, abdominal pain, diarrhea, bloody stool, dizziness and chills. Co-occurrence of T-2 toxin with other trichothecenes in these cases is likely. T-2 toxin is also associated with food-related poisoning incidents in 1931- 1947 referred to as alimentary toxic aleukia, in the former Soviet Union.

The PMTDI is based on a 3-week dietary study with pigs, applying a safety factor of 500 to a LOEL for changes in white and red cell counts. The average intake of T-2 and HT-2 toxin via the human diet was estimated by JECFA as 8 resp. 9 ng/kg bw, which is lower than the group PMTDI. An intake at the level of the PMTDI is not expected to result in effects of T-2 and HT-2 toxin on the immune system and to haematotoxicity, which are considered critical effects after short-term intake. JECFA recommended that toxic equivalency factors relative to DON be developed for the other trichothecenes commonly occurring in cereal grains, if sufficient data become available.

Mycotoxins

Zearalenone

Reference to JECFA:	53 (1999)
Toxicological guidance value:	PMTDI 0.0005 mg/kg bw (1999, The total intake of zearalenone and its metabolites (including alpha-zearalenol (zeranol)) should not exceed the PMTDI.)
Synonyms:	(Zearalenone is the most important of a group of related mycotoxins and relevant metabolites. Abbreviation: ZEN. Its metabolite, alpha-zearalenol (zeranol) is used as veterinary drug.)
Related code of practice:	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CAC/RCP 51-2003)

Commodity / Product Name	Level (µg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
	No ML					

The situation regarding ZEN has been reviewed in a position paper (last version CX/FAC 00/19).

Preliminary intake calculations indicate values well below the PMTDI. It is mentioned however that further action seems required to reduce the levels of ZEN in risk products (especially maize containing products) for especially children with a high intake of these products.

The 31st CCFAC (1999) agreed that, recognizing that there were no identified trade problems with ZEN, Codex MLs were not necessary for the time being. The MRLs for zearalenol (ZAL) in cattle liver and muscle have been established by Codex (CCRVDF) because of recognized use of zeranol in cattle; they are relevant for the CCFAC in so far that feed contamination with ZEN can lead to residues of both ZEN and ZAL (and other metabolites) in cattle liver and muscle.

Zearalenone (ZEN) is the most important of a group of resorcyclic acid lactone mycotoxins, produced by several species of *Fusarium* moulds. It is found worldwide in a number of cereal crops and also in derived products like beer. It has been implicated in numerous incidents of mycotoxicosis in farm animals, especially pigs. ZEN is rapidly metabolized in and excreted from animals; residues of this mycotoxin in animal products are probably not significant from a health point of view. A metabolite of ZEN, alpha-zearalenol (zeranol, abbreviated here as ZAL) is, however, relevant relating to its potential use as a veterinary drug. Also beta-zearalenol (taleranol) has hormonal activity. Besides these substances which can be used as anabolic growth promoters, also alpha- and beta-zearalenol (ZAL) and zearalenone (ZEN) are mentioned as possibly occurring metabolites of or co-occurring substances with ZEN.

The PMTDI for ZEN was set by applying a safety factor of 100 from the lowest NOAEL, related to the estrogenic effect in pigs. ZAL has an ADI of 0.5 µg/kg bw (ref. JECFA 26, 27 and 32).

Residues of ZEN and ZAL together in an animal product may be regarded as evidence that the animal feed was contaminated with ZEN. In order to distinguish between contamination of the feed with mycotoxins of the ZEN group or use of ZAL as veterinary drug, it may be necessary to determine the relative proportions of the different residues, e.g. as ZEN + alpha- and beta-ZAL against ZAL. A ratio of 5 or more probably indicates only contamination by mycotoxins.

Marine biotoxins

Saxitoxin group

Reference to JECFA: -
Toxicological guidance value: ARfD 0.7 µg/kg bw (2004; FAO/IOC/WHO ad hoc Expert Consultation)
Synonyms: Abbreviation, STX

Commodity / Product Name	Maximum Level (ML) (mg/kg mollusc flesh)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Live and raw bivalve mollusk	0.8	Adopted	CS 292-2008	FFP, CF	Edible parts of bivalve mollusk (the whole part or any part intended to be eaten separately)	Relevant Codex commodity standard is CODEX STAN 292-2008.	(2HCL) of saxitoxin equivalent Not listed in GSCTFF

The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxin in Bivalve Molluscs (2004) was asked to perform risk assessments for a number of biotoxins that are present in bivalve molluscs. Since exposure to biotoxins generally involves only occasional consumption, and because most of the available toxicological data involve only acute and short-term studies, priority was given to the establishment of an acute reference dose, and generally insufficient data were available to establish a tolerable daily intake. It must be pointed out that the Expert Consultation did not have enough time to fully evaluate epidemiological data or to assess the effects of cooking or processing for deriving the provisional guidance levels/maximum levels for several toxin groups (especially the AZA and STX groups). The Consultation agreed that there is a need for a further in-depth review of these data to better derive the guidance levels/maximum levels.

The 29th CCFFP (2008) agreed that at this stage it was not necessary to ask for additional scientific advice from FAO/WHO and that this issue would be kept under review and may be reconsidered when further scientific advice became available.

The 2nd CCCF (2008) the Committee agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with the view to revising these levels where necessary, when more data became available (ALINORM 08/31/41 para. 31).

The 31st CAC (2008) adopted the Draft Standard for Raw and Live Bivalve Molluscs at Step 8 with a correction to the scope of the Spanish version by replacing “desbullados” with “abiertos” (ALINORM 08/31/REP. para. 36).

Saxitoxin-group toxins are a group of closely related tetrahydropurines occurring in bivalbe molluscs, such as oysters, mussels, scallops and clams. STX-group toxins are neurotoxic and cause paralytic shellfish poisoning (PSP) in humans. PSP can be characterized by symptoms ranging from a slight tingling sensation or numbness around the lips, tongue and mouth to fatal respiratory paralysis. From the different STX analogues that have been identified seem STX, NeoSTX, GTX1 and dc-STX to be the most toxic ones.

A provisional ARfD was calculated by the FAO/IOC/WHO ad hoc Expert Consultation based on a dose of 2 µg STX eq/kg bw derived from epidemiological data as LOAEL. Because mild illness at lower doses is readily reversible and the data on PSP represent a range of individuals with varying susceptibilities, a safety factor of 3 was considered appropriate to derive a provisional ARfD. The provisional ARfD is therefore calculated to be 0.7 µg STX eq/kg bw. An additional note was however made that further effort is needed to evaluate epidemiological data fully or to assess the effects of cooking or processing for deriving the ARfD and provisional guidance levels/maximum levels for the STX group.

Marine biotoxins

Okadaic acid group

Reference to JECFA: -
Toxicological guidance value: ARfD 0.33 µg/kg bw (2004; FAO/IOC/WHO ad hoc Expert Consultation)
Synonyms: Abbreviation, OA

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Live and raw bivalve mollusk	0.16	Adopted	CS 292-2008	FFP, CF	Edible parts of bivalve mollusk (the whole part or any part intended to be eaten separately)	Relevant Codex commodity standard is CODEX STAN 292-2008.	okadaic equivalent Not listed in GSCTFF

The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxin in Bivalve Molluscs (2004) was asked to perform risk assessments for a number of biotoxins that are present in bivalve molluscs. Since exposure to biotoxins generally involves only occasional consumption, and because most of the available toxicological data involve only acute and short-term studies, priority was given to the establishment of an acute reference dose, and generally insufficient data were available to establish a tolerable daily intake. It must be pointed out that the Expert Consultation did not have enough time to fully evaluate epidemiological data or to assess the effects of cooking or processing for deriving the provisional guidance levels/maximum levels for several toxin groups (especially the AZA and STX groups). The Consultation agreed that there is a need for a further in-depth review of these data to better derive the guidance levels/maximum levels.

The 29th CCFFP (2008) agreed that at this stage it was not necessary to ask for additional scientific advice from FAO/WHO and that this issue would be kept under review and may be reconsidered when further scientific advice became available.

The 2nd CCCF (2008) the Committee agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with the view to revising these levels where necessary, when more data became available (ALINORM 08/31/41 para. 31).
The 31st CAC (2008) adopted the Draft Standard for Raw and Live Bivalve Molluscs at Step 8 with a correction to the scope of the Spanish version by replacing “desbullados” with “abiertos” (ALINORM 08/31/REP. para. 36).

Okadaic acid (OA) forms together with its analogues the dinophysis toxins (DTX), the group of OA toxins. OA toxins can be found in microalgae and various species of shellfish, mainly in filter-feeding bivalve molluscs such as oysters, mussels, scallops and clams and can cause diarrhoeic shellfish poisoning (DSP). DSP is characterized by symptoms such as diarrhea, nausea, vomiting and abdominal pain. The onset of DSP in humans is shortly after consumption. OA toxins possess tumour promoting activity, and okadaic acid itself also shows genotoxic and immunotoxic activity. It is unlikely that a substantial risk of cancer exists in consumers of shellfish because of these toxins, but still the question may be raised what the human health risks are of (sub)chronic exposure to low levels.
A provisional ARfD of 0.33 µg OA eq/kg bw could be established. This value is based on a LOAEL of 1.0 µg OA eq/kg bw and a safety factor of 3 because of documentation of human cases including more than 40 persons and because DSP symptoms are readily reversible.
More studies on pharmacokinetics, data on long-term/carcinogenicity and further studies on genotoxicity and reproductive toxicity are needed for establishing a TDI.

Marine biotoxins

Domoic acid group

Reference to JECFA: -
Toxicological guidance value: ARfD 100 µg/kg bw (2004; FAO/IOC/WHO ad hoc Expert Consultation)
Synonyms: Abbreviation, DA

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Live and raw bivalve mollusk	20	Adopted	CS 292-2008	FFP, CF	Edible parts of bivalve mollusk (the whole part or any part intended to be eaten separately)	Relevant Codex commodity standard is CODEX STAN 292-2008.	domoic acid Not listed in GSCTFF

The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxin in Bivalve Molluscs (2004) was asked to perform risk assessments for a number of biotoxins that are present in bivalve molluscs. Since exposure to biotoxins generally involves only occasional consumption, and because most of the available toxicological data involve only acute and short-term studies, priority was given to the establishment of an acute reference dose, and generally insufficient data were available to establish a tolerable daily intake. It must be pointed out that the Expert Consultation did not have enough time to fully evaluate epidemiological data or to assess the effects of cooking or processing for deriving the provisional guidance levels/maximum levels for several toxin groups (especially the AZA and STX groups). The Consultation agreed that there is a need for a further in-depth review of these data to better derive the guidance levels/maximum levels.

The 29th CCFFP (2008) agreed that at this stage it was not necessary to ask for additional scientific advice from FAO/WHO and that this issue would be kept under review and may be reconsidered when further scientific advice became available.

The 2nd CCCF (2008) the Committee agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with the view to revising these levels where necessary, when more data became available (ALINORM 08/31/41 para. 31).
The 31st CAC (2008) adopted the Draft Standard for Raw and Live Bivalve Molluscs at Step 8 with a correction to the scope of the Spanish version by replacing “desbullados” with “abiertos” (ALINORM 08/31/REP. para. 36).

Domoic acid (DA) and its isomers may cause amnesic shellfish poisoning (ASP) in humans. Symptoms include gastroinstestinal symptoms such as vomiting, diarrhoe or abdominal cramps, and/or neurological symptoms such as confusion, loss of memory or other serious signs such as seizure or coma. These symptoms generally occur within 24-48 hours after consuming contaminated shellfish or other types of seafood.

The toxicological database for DA is limited. Neurotoxicity is the critical toxicological effect identified in experimental animals as well as in humans. Based on the results of the first outbreak of ASP in Canada in 1987, an ARfD could be established. In this outbreak, a dose-related increase in severity of the signs and symptoms was observed in patients consuming between 1 mg/kg bw and 5 mg/kg bw. These findings are supported by studies in rodents and monkeys. The LOAEL of 1 mg/kg bw was divided by a safety factor of 10 to cover intrahuman susceptibility and account for the fact that the starting point was a LOAEL, to derive a provisional ARfD of 100 µg/kg bw.
The Joint FAO/IOC/WHO ad hoc Expert Consultation noted that although very few animal studies have been conducted on the subchronic and chronic toxicity of DA, these limited data suggest that cumulative effects of low doses of DA are unlikely. Hence, there conclusion was that the ARfD may also be considered as a provisional chronic TDI.

Marine biotoxins

Brevetoxin group

Reference to JECFA: -
Toxicological guidance value: -
Synonyms: Abbreviation, BTX

Commodity / Product Name	Maximum Level (ML) (mouse units/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Live and raw bivalve mollusk	200	Adopted	CS 292-2008	FFP, CF	Edible parts of bivalve mollusk (the whole part or any part intended to be eaten separately)	Relevant Codex commodity standard is CODEX STAN 292-2008.	mouse units or equivalent Not listed in GSCTFF

The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxin in Bivalve Molluscs (2004) was asked to perform risk assessments for a number of biotoxins that are present in bivalve molluscs. Since exposure to biotoxins generally involves only occasional consumption, and because most of the available toxicological data involve only acute and short-term studies, priority was given to the establishment of an acute reference dose, and generally insufficient data were available to establish a tolerable daily intake. It must be pointed out that the Expert Consultation did not have enough time to fully evaluate epidemiological data or to assess the effects of cooking or processing for deriving the provisional guidance levels/maximum levels for several toxin groups (especially the AZA and STX groups). The Consultation agreed that there is a need for a further in-depth review of these data to better derive the guidance levels/maximum levels.

The 29th CCFFP (2008) agreed that at this stage it was not necessary to ask for additional scientific advice from FAO/WHO and that this issue would be kept under review and may be reconsidered when further scientific advice became available.

The 2nd CCCF (2008) the Committee agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with the view to revising these levels where necessary, when more data became available (ALINORM 08/31/41 para. 31).

The 31st CAC (2008) adopted the Draft Standard for Raw and Live Bivalve Molluscs at Step 8 with a correction to the scope of the Spanish version by replacing “desbullados” with “abiertos” (ALINORM 08/31/REP. para. 36).

Brevetoxins (BTX) can accumulate in shellfish and fish. BTX-toxins can cause neurologic shellfish poisoning (NSP) which is characterized by symptoms and signs such as nausea, vomiting, diarrhea, parasthesia, cramps, bronchoconstriction, paralysis, seizures and coma.

The toxicological database for BTX-toxins is limited, comprising mostly acute toxicity studies. Quantitative data of human poisonings are also very limited. There is some evidence that BTX-2 forms DNA adducts raising concerns about possible carcinogenicity and consequential long term effects. In view of the lack of data, the Joint FAO/IOC/WHO ad hoc Expert Consultation concluded that there is a need for further investiagtions into the mechanisms of action of BTXs and its analogues, and an accurate assessment of long term effects because of low-dose and/or repeated ingestion of BTXs and its analogues in animal experiments. In particular, studies of the possible health effects of chronic low-level exposure are needed in humans and animals.

Marine biotoxins

Azaspiracid group

Reference to JECFA: -
Toxicological guidance value: ARfD 0.04 µg/kg bw (2004; FAO/IOC/WHO ad hoc Expert Consultation)
Synonyms: Abbreviation, AZP

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks	Notes for CCCF
Live and raw bivalve mollusk	0.16	Adopted	CS 292-2008	FFP, CF	Edible parts of bivalve mollusk (the whole part or any part intended to be eaten separately)	Relevant Codex commodity standard is CODEX STAN 292-2008.	Not listed in GSCTFF

The Joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxin in Bivalve Molluscs (2004) was asked to perform risk assessments for a number of biotoxins that are present in bivalve molluscs. Since exposure to biotoxins generally involves only occasional consumption, and because most of the available toxicological data involve only acute and short-term studies, priority was given to the establishment of an acute reference dose, and generally insufficient data were available to establish a tolerable daily intake. It must be pointed out that the Expert Consultation did not have enough time to fully evaluate epidemiological data or to assess the effects of cooking or processing for deriving the provisional guidance levels/maximum levels for several toxin groups (especially the AZA and STX groups). The Consultation agreed that there is a need for a further in-depth review of these data to better derive the guidance levels/maximum levels.

The 29th CCFFP (2008) agreed that at this stage it was not necessary to ask for additional scientific advice from FAO/WHO and that this issue would be kept under review and may be reconsidered when further scientific advice became available.

The 2nd CCCF (2008) the Committee agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with the view to revising these levels where necessary, when more data became available (ALINORM 08/31/41 para. 31).

The 31st CAC (2008) adopted the Draft Standard for Raw and Live Bivalve Molluscs at Step 8 with a correction to the scope of the Spanish version by replacing “desbullados” with “abiertos” (ALINORM 08/31/REP. para. 36).

Azaspiracids (AZAs) are a group of shellfish toxins causing AZA poisoning (AZP). AZP is characterized by symptoms such as nausea, vomiting, diarrhea and stomach cramps. AZAs can be found in various species of filter-feeding bivalve molluscs such as oysters, mussels, scallops and clams. Monitoring data shows that mussels are the most affected species for this group of toxins.

The toxicological database for AZAs is limited and comprises mostly studies on the acute toxicity of AZAs. Limited data in humans indicate an LOAEL between 23 and 86 µg/person for acute gastrointestinal effects. The Joint FAO/IOC/WHO ad hoc Expert Consultation established a provisional ARfD of 0.04 µg/kg bw, based on the LOAEL of 23 µg/person and a bodyweight of 60 kg, using a tenfold safety factor to take into consideration the small number of people involved. Because of insufficient data on the chronic effects of AZA, no TDI could be established. The Joint FAO/IOC/WHO ad hoc Expert Consultation further noted that some preliminary studies indicate the possibility of severe and prolonged toxic effects at low doses. Repeated studies involving administration of AZA by feeding are therefore required. In addition, information on absorption, excretion and metabolism, on long-term carcinogenicity and genotoxicity and reproductive toxicity are needed.

Plant toxins

Hydrocyanic acid

Reference to JECFA:	39 (1992), 74 (2011)
Toxicological guidance value:	ARfD 0.09 mg/kg bw as cyanide (2011, this cyanide-equivalent ARfD applies only to foods containing cyanogenic glycosides as the main source of cyanide PMTDI 0.02 mg/kg bw as cyanide (2011)
Contaminant definition:	See explanatory notes in the column "Notes/Remarks"
Synonyms:	HCN
Related code of practice:	Code of practice for the reduction of hydrocyanic acid (HCN) in cassava and cassava products (CAC/RCP 73-2013)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Cassava flour	10	Adopted	CS 176-1989 2013	CPL CF		The ML is expressed as total hydrocyanic acid. Relevant Codex commodity standards include CODEX STAN 176-1989.	
Gari	2	Adopted	CS 151-1989 2013	CPL CF	Whole commodity	The ML is expressed as free hydrocyanic acid. Relevant Codex commodity standards include CODEX STAN 151-1989.	

Excessive dietary exposure to cyanogenic glycosides has been assessed at the 39th JECFA (1992). Due to the lack of quantitative toxicological and epidemiological information no safe level of dietary exposure could be determined. However, it was concluded that a level up to 10 mg/kg HCN in the Standard for Edible Cassava Flour (CODEX STAN 176-1989) was not associated with acute toxicity.
The CAC agreed with the recommendation of the 59th Executive Committee (2007) to adopt the Draft Standard for Bitter Cassava (a cyanogenic glycoside food) as elaborated by CCFFV). In the Draft Standard the proposed levels for HCN (a breakdown product of cyanogenic glycosides) are indicated as follow: 'bitter varieties of cassava are those that contain more than 50 mg/kg but less than 200 mg/kg HCN (fresh weight basis). In any case, cassava must be peeled and fully cooked before being consumed'. However, the CAC (2008) recognized safety concerns if cassava is consumed without adequate processing; the CCCF should consider the safety levels of hydrogen cyanide (HCN) as proposed in the standard with a view to a re-evaluation of cyanogenic glycosides by JECFA (ALINORM 08/31/REP).

The 2nd CCCF (2008) considered the need for a re-evaluation of cyanogenic glycosides by JECFA and agreed to establish an electronic working group to prepare a discussion paper which should include an overview of available data on cyanogenic glycosides with a view to possible re-evaluation by JECFA. (ALINORM 08/31/41, para. 180)
The 3rd CCCF (2009) agreed to request JECFA to review data available on occurrence of cyanogenic glycosides in foods and feeds, the mechanisms of releasing hydrogen cyanide in the human body, the effects of processing on reducing levels of hydrogen cyanide in the final product, and report back to the Committee in future. (ALINORM 09/32/41, para 108).

Plant toxins

Hydrocyanic acid

The 74th JECFA re-evaluated cyanogenic glycosides in 2011. JECFA recognized that human exposure to HCN from cyanogenic glycosides in food commodities would be from a combination of intact glycoside and totally degraded glycoside. The Committee concluded that there were no appropriate studies on which a long-term health-based guidance value could be based. However, as the potential toxicity of ingested cyanogenic glycosides was considered to bedirectly related to the in situ generation of HCN, the Committee concluded that animal studies with cyanide compounds could serve as the basis for establishing a PMTDI. Also, an ARfD could be determined.

The JECFA established a cyanide-equivalent ARfD of 0.09 mg/kg bw. This ARfD is based on a $BMDL_{10}$ for linamarin of 85 mg/kg bw for increased skeletal defects in developing hamster fetuses following acute exposure of maternal animals. Following application of a 100-fold uncertainty factor, the Committee established an ARfD for linamarin of 0.9 mg/kg bw (equivalent to 0.09 mg/kg bw as cyanide). This cyanide-equivalent ARfD applies only to foods containing cyanogenic glycosides as the main source of cyanide.

The JECFA noted that the ARfD was exceeded 3-fold for cassava for adults, less than 2-fold for apple juice for children, between 2- and 5-fold for bitter apricot kernels and up to 10-fold for ready-to-eat cassava chips/crisps, depending on the population group. The available occurrence data for cyanogenic glycosides were deemed not to be appropriate to determine international estimates of dietary exposure to total HCN.

A PMTDI of 20 µg/kg bw was recommended by applying a 100-fold uncertainty factor for interspecies and intraspecies differences to a BMDL1SD of 1.9 mg/kg bw per day. This BMDL1SD was derived from a 13-week NTP study in which male rats displayed decreased cauda epididymis weights after exposure to sodium cyanide via drinking-water. The Committee decided that it was not necessary to apply an additional uncertainty factor to account for the absence of a long-term study, considering the acute nature of cyanide toxicity and the sensitivity of the effect (i.e. the reduction of absolute cauda epididymis weight).

It was noted that, based on national estimates of chronic dietary exposure to total HCN, there is potential to exceed the PMTDI for populations reliant on cassava as a staple food: between 1- and 3-fold in children and between 1- and 2-fold in adults. This would also be possible for populations not reliant on cassava: between 1- and 5-fold for children and between 1- and 3-fold for adults.

Application of the ML of 50 mg/kg as HCN for sweet cassava could result in dietary exposures that exceed the ARfD by less than 2-fold for the general population and up to 4-fold for children, and exceed the PMTDI by between 2- and 10-fold, depending on the population group assessed. These estimates did not take into consideration any reduction in concentration of total HCN as a result of food preparation or processing. For the ML of 10 mg/kg as HCN for cassava flour, there were no estimates of dietary exposure available that exceed the ARfD or PMTDI. This was supported by the maximum amount of food that could be consumed based on existing Codex MLs before the health-based guidance values would be exceeded, which is as low as 25 g/day for cassava for chronic exposure. More detailed estimates of cassava and cassava flour consumption and concentrations in food for cassava-eating communities would help in supporting the conclusion that dietary exposures to total HCN could exceed health-based guidance values.

The JECFA recommended that further research is needed to quantify how nutritional factors ultimately contribute to the human diseases observed in populations whose diets consist mainly of improperly processed cassava. There is also need for more extensive occurrence data for cyanogenic glycosides including data showing the ratio of cyanogenic glycosides to cyanohydrins to HCN in raw and processed foods containing cyanogenic glycosides. Distributions of occurrence data could then be used for probabilistic dietary exposure assessments. More consumption data for cassava and cassava products from a broader range of countries would enable more detailed estimates of dietary exposure to be conducted or refined.

The 6th CCCF (2012) agreed to establish an electronic Working Group led by Australia and co-chaired by Nigeria to start new work on a code of practice and MLs for hydrocyanic acid in cassava and cassava products for comment at Step 3 and consideration by the next session. The Committee agreed that the electronic Working Group would:

Plant toxins

Hydrocyanic acid

- undertake a review of the MLs for hydrocyanic acid in existing Codex commodity standards for bitter cassava and sweet cassava with a view of the possible revision of these MLs and the establishment of new MLs for additional commodities, such as ready-to-eat cassava chips;
- develop a code of practice to reduce the presence of hydrocyanic acid in cassava in which the agricultural aspects and the methods of processing are addressed; and
- identify methods of analysis suitable for analysis of hydrocyanic acid in foods (REP12/CF, paras. 165-167).

The 7th CCCF (2013) agreed to discontinue work on the revision or establishment of MLs for cassava and cassava products and to inform 36th CAC accordingly. The Committee agreed to transfer the MLs for HCN for cassava flour and gari to the GSCTFF with the current descriptors for the content of HCN in these products. In taking this decision, the Committee agreed to introduce consequential amendments to the standards for edible cassava flour and gari to remove these MLs from the standard and to include a general reference to the GSCTFF in the section on contaminants. Along these lines, the Committee also agreed to make a consequential amendment in the section on contaminants in the Standard for Sweet Cassava to refer the ML for HCN to the national legislation of the importing country (REP13/CF, paras. 87-88 and Appendix V).
The 36th CAC (2013) approved discontinuation of work on proposed draft maximum levels hydrocyanic acid in cassava and cassava products and adopted consequential amendments to the Standard for Edible Cassava Flour, Gari and Sweet Cassava.

The 7th CCCF agreed to forward the proposed draft Code of practice for the reduction of hydrocyanic acid (HCN) in cassava and cassava products to the 36th CAC for adoption at Step 5/8 (REP13/CF, para. 92).
The 36th CAC adopted the Code of Practice for the reduction of hydrocyanic acid in cassava and cassava products.

Cyanogenic glycosides (CG) may be defined chemically as glycosides of the α-hydroxynitriles and are secondary metabolites produced by plants. CG occur in at least 2000 plant species of which many are used as food, such as cassava, lima beans, sorghum, almonds, stone fruits, bamboo shoots, flax seed and elderberries. CG can be broken down to hydrogen cyanide (HCN) as a result of enzymatic hydrolysis by β-glucosidases following structure disrupture of plant cells or by the action of gut microflora. The cyanogenic glycoside content of foods is often reported as mg/kg of HCN in the food. Levels of HCN in a respective food may vary depending on variety, growing conditions (altitude, geographical location, seasonal condition) and production conditions. Acute toxicity results when the rate of HCN is such that the metabolic detoxification capacity of the body is exceeded.

The toxicity of a cyanogenic plant depends on the potential that its consumption will produce a toxic concentration of HCN, HCN causing the inhibition of mitochondrial oxidation. This will cause energy deprivation and result in non-specific symptoms that reflect oxygen deprivation of the brain and heart, such as headache, nausea, vomiting, dizziness, palpitations, hyperpnoea then dyspnoea, bradycardia, unconsciousness and convulsions, followed by death. Chronic uptake of HCN in sub-acutely toxic doses, may be involved in disturbance of thyroid function and neuropathies. However, suitable long-term toxicity studies are lacking. No ADI or ARfD has been established yet, however, as HCN clearance is rapid and its half life is short, cumulative toxicity is not expected and the appropriate toxicological reference value must reflect acute rather than cumulative toxicity.

Plant toxins

Pyrrolizidine alkaloids

Reference to JECFA:	80 (2015)
Toxicological guidance value:	$BMDL_{10}$ (for riddelliine) 182 µg/kg bw/day; MOE for high adult consumers of tea and honey and for average tea consumption by children indicated a concern
Contaminant definition:	Pyrrolizidine alkaloids
Synonyms:	PA
Related code of practice:	Code of Practice for Weed Control to prevent and reduce Pyrrolizidine Alkaloid Contamination in Food and Feed (CAC/RCP 74-2014)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

The 6th CCCF (2012) agreed to initiate new work on the development of a Code of Practice for weed control to prevent and reduce pyrrolizidine alkaloid contamination in food and feed. Subject to approval by the Commission, the Committee agreed that the proposed code of practice would be developed by an electronic Working Group led by the Netherlands for comments at Step 3 and consideration at the next session.
The Committee also agreed that this electronic Working Group would prepare a discussion paper for consideration by the next session on the topics 'Management practices to reduce exposure of animals to PAs', 'Management practices to reduce exposure of food-producing animals to PA-containing plants – livestock and bees' and 'Management practices to reduce presence of PAs in commodities – raw and processed' to explore their possible inclusion in the proposed Code of Practice (REP12/CF, paras. 114-115 and Appendix VII).The 35th CAC (2012) approved the new work (REP12/CAC, Appendix VI).

The 7th CCCF (2013) agreed to return the Code to Step 2/3 for redrafting, circulation for comments and consideration at the 8th session of the Committee. The Committee also agreed to resume the consideration on management practices to reduce exposure of food-producing animals (livestock and bees) to PAs; and to reduce presence of Pas in commodities (raw and processed) if more information would become available e.g. in 2 or 3 years time (REP13/CF, para. 96 and 112).

The 7th CCCF (2013) agreed with the recommendations of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA to maintain Pyrrolizidine alkaloids in the Priority List (REP 13/CF, para 142 and APPENDIX VII).

The 8th CCCF (2014) agreed to forward the proposed draft COP to Step 5/8 (with omission of Steps 6/7) for adoption by the 37th CAC. The Committee agreed that for the time-being it would keep the reference to the non-exhaustive list of PA-containing plants (Annex I of CX/CF 11/15/14) in the report for further consultation noting that reports of Codex committee meetings' are available to Codex members and the general public on the Codex website (REP 14/CF, paras. 78-82, Appendix VI). The 37th CAC adopted the COP at Step 5/8 (REP 14/CAC, para. 47, Appendix III).

The 80th JECFA (2015) evaluated PAs. A systematic review approach was used to gather data. As the approach proved to be very labour intensive and there was insufficient time left before the JECFA meeting, stages of the systematic review subsequent to the title/abstract selection were not performed according to the systematic review protocol, and full text selection was done using the critical appraisal method regularly used in the preparation of JECFA monographs. Because of the narrow time frame between the work on the selection of references and the JECFA meeting, the evaluation could not be completed at the meeting, but the Committee considered the information sufficient to determine an approach for the evaluation and to agree upon preliminary results, which will need confirmation later when all studies have been quality assessed and described in detail.

Plant toxins

Pyrrolizidine alkaloids

The Committee considered that the genotoxic mode of action does not allow derivation of a health-based guidance value for chronic toxicity and a lower limit on the benchmark dose for a 10% response ($BMDL_{10}$) of 182 µg/kg bw per day for liver haemangiosarcoma in female rats treated with riddelliine was used as the point of departure in an MOE approach. Dietary exposures were estimated based on limited data for exposure to PAs through honey and tea consumption, for adults and children. The calculated MOEs for high adult consumers of tea and honey and for average tea consumption by children indicated a concern.
Available data were not sufficient to identify relative potency factors for different 1,2-unsaturated PAs in order to evaluate the possible effects of combined exposure. The Committee considered that acute toxicity is of concern, and data, in particular human case reports, would be reviewed in detail for their potential use in the derivation of dose levels of concern.

Pyrrolizidine alkaloids (PAs) are toxins found naturally in a wide variety of plant species. PAs are heterocyclic compounds and most of them are derived from four necine bases: retronecine, heliotridine, otonecine and platynecine; the platynecine type PAs are considered non-toxic. Over 350 different tertiary amine PA structures are known, most of the naturally occurring PAs in plants are esterified necines or alkaloid N-oxides (except for the otonecine-type alkaloids), whereas non-esterified PAs occur less frequently in plants.

PAs are widely distributed natural toxins and affect wildlife, livestock and humans. Human cases of poisoning can result from the direct and deliberate use of toxic plant species as herbal teas or traditional medicines, or direct contamination of foods with PA-containing plants. Animal mediated contamination of food includes transfer of PAs from feed to animal products like milk, and contamination of honey by PA-containing pollen.

PAs have a common toxicity profile; liver is the main target organ of toxicity. Major signs of toxicity in all animal species include various degrees of progressive liver damage (centrolobular hepatocellular necrosis), and veno-occlusive disease. Furthermore bile duct proliferation, hepatic megalocytosis, and liver fibrosis are reported. Also effects on other organs such as lungs (pulmonary hypertension), the cardiovascular system (cardiac right ventricular hypertrophy) and degenerative injury in the kidneys are seen. IPCS evaluated PAs in 1988. IPCS concluded that a daily intake of PAs as low as the equivalent of 0.01 mg/kg heliotrine may cause disease in humans and that humans might be more sensitive to PA toxicity than rats; however, they stated also that these estimates were of uncertain reliability. Still, it was recommended to minimize exposure if possible. IARC has classified three PAs, lasiocarpine, monocrotaline and riddelliine, as ‘possibly carcinogenic to humans’ (Group 2B).

Plant toxins

Scopoletin

Reference to JECFA: -
Toxicological guidance value: -
Contaminant definition: -
Synonyms: -
Related code of practice: -

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

The 13th Session of the FAO/WHO Coordinating Committee for North America and South-West Pacific (2014) considered the request for determination of safe intake levels for scopoletin in fermented noni juice. The Coordinating Committee agreed to request advice from the CCCF on a safe maximum level for scopoletin as well as a method of analysis.
The 9th CCCF (2015) considered the above request and agreed with a inclusion of of scopoletin for a full risk assessment in the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA. (REP 15/CF, paras. 145-152)

Scopoletin is a coumarin found in the root of plants in the genus Scopolia such as *Scopolia carniolica* and *Scopolia japonica*, in chicory, in *Artemisia scoparia*, in the roots and leaves of Stinging Nettle (*Urtica dioica*), in the passion flower, in Brunfelsia, in *Viburnum prunifolium*, in *Solanum nigrum*, in *Mallotus resinosus*, or and in *Kleinhovia hospita*.

Other Chemical Contaminants (except radionuclides)

Acrylamide

Reference to JECFA:	64 (2005), 72 (2010)
Toxicological guidance value:	(Intake estimates: mean 0.001 mg/kg bw/day; high 0.004 mg/kg bw/day Margin of exposure (MOE): morphological changes in nerves (NOEL 0.2 mg/kg bw/day), mean intake 200, high intake 50; MOE mammary tumours in rats ($BMDL_{10}$ 0.31 mg/kg bw/day), mean intake 310, high intake 78 MOE Harderian gland tumours in mice ($BMDL_{10}$ 0.18 mg/kg bw/day), mean intake 180, high intake 45.)
Related code of practice:	Code of Practice for the Reduction of Acrylamide in Foods (CAC/RCP 67-2009)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

JECFA was asked by the 36th Session of CCFAC (2004) to evaluate acrylamide.

The 64th JECFA (2005) concluded that a dietary intake of 1 µg/kg/day of acrylamide represents the average for the general population and an intake of 4 µg/kg bw/day represents the high consumers; this includes children. Comparison of these intakes with the NOEL of 0.2 mg/kg bw/day for morphological changes in nerves would provide MOEs of 200 and 50, respectively. Comparison with the NOEL of 2 mg/kg bw/day for reproductive, developmental and other non-neoplastic effects would provide MOEs of 2000 and 500, respectively. For the induction of tumors, the MOE is calculated by comparing those intakes with the BMDL of 0.3 mg/kg bw/day for mammary tumours in rats to be 300 and 75, respectively.

The 64th JECFA (2005) concluded that adverse effects on morphological changes in nerves and on reproductive, developmental and other non-neoplastic effects are unlikely at the estimated average intakes, but that morphological changes in nerves cannot be excluded for some individuals with very high intakes. It considered the MOEs (induction of tumors - mean and high intakes) to be low for a compound that is genotoxic and carcinogenic and that they may indicate a human health concern. Therefore, appropriate efforts to reduce acrylamide concentrations in food stuffs should continue.

Recommendations by the 64th JECFA:
- Acrylamide be re-evaluated when results of ongoing carcinogenicity and long-term neurotoxicity studies become available.
- Work should be continued on using PBPK modeling to better link human biomarker data with exposure assessments and toxicological effects in experimental animals.
- Appropriate efforts to reduce acrylamide concentrations in food should continue.
- In addition, the Committee noted that it would be useful to have occurrence data on acrylamide in foods as consumed in developing countries. This information will be useful in conducting intake assessments as well as considering mitigation approaches to reduce human exposure (Sixty-fourth Report of the Joint FAO/WHO Expert Committee on Food Additives, pages 8-26).

The 37th CCFAC (2005) agreed to revise the discussion paper which would include an outline of a code of practice and a project document for starting new work on the elaboration of the code of practice, taking into account the 64th JECFA evaluation of acrylamide; national mitigation strategies; and the role of food processors, catering services, and consumers (ALINORM 05/28/12, paras 193-196).

The 38th CCFAC (2006) agreed to forward to the CAC for approval as new work the project document on the elaboration of a Code of Practice for Reduction of Acrylamide in Food, and agreed that, subject to the approval of the CAC, an electronic working group would elaborate an initial draft Code of Practice for comment at Step 3 (ALINORM 06/29/12, paras 184 & 185).

Acrylamide

The First CCCF (2007) decided to maintain paras 52 and 53 describing recommendations to national authorities on consumer practices since consumer practices were considered to add significantly to acrylamide exposure and similar recommendations had already been incorporated in other codes of practice. The Committee, noting the opinion of the ad hoc physical working group that the document was not yet ready for advancement in the Codex Procedure, agreed that a revised proposed draft should be prepared, taking account of additional data and information which would become available in the coming year from ongoing studies. The Committee agreed to return the proposed draft Code of Practice to Step 2 for redrafting by an electronic working group chaired by the USA and the UK on the basis of the written comments received and the discussion in the ad hoc Working Group and the in the First Session of the Committee, with a view to circulation for comments at Step 3 and consideration at Step 4 at the next session of the Committee (ALINORM 07/30/41, paras 95, 96, 97).

The Second CCCF (2008) agreed to forward the proposed draft Code of Practice, which focus mainly on foods produced from potatoes and cereals reflecting their importance in terms of dietary exposure to acrylamide, to the 31st Session of the Codex Alimentarius Commission for adoption at Step 5 (ALINORM 08/31/41, paras 75 and 95).

The 31st Commission adopted the proposed draft Code of Practice and advanced it to Step 6 (ALINORM 08/31/REP, para. 65).

The 72nd JECFA in February 2010 noted that neither the estimated average acrylamide exposure for the general population (0.001 mg/kg bw per day) nor the exposure for consumers with high dietary exposure (0.004 mg/kg bw per day) had changed since the sixty-fourth meeting. The MOE calculated relative to the no-observed-adverse-effect level (NOAEL) of 0.2 mg/kg bw per day for morphological changes in nerves in rats therefore remains unchanged. For the general population and consumers with high dietary exposure, the MOE values are 200 and 50, respectively. Consistent with the conclusion made at the sixty-fourth meeting, the Committee noted that while adverse neurological effects are unlikely at the estimated average exposure, morphological changes in nerves cannot be excluded for individuals with a high dietary exposure to acrylamide.

When average and high dietary exposures are compared with the $BMDL_{10}$ (the BMDL for a 10% response) of 0.31 mg/kg bw per day for the induction of mammary tumours in rats, the MOE values are 310 and 78, respectively. For Harderian gland tumours in mice, the $BMDL_{10}$ is 0.18 mg/kg bw per day, and the MOE values are 180 and 45 for average and high exposures, respectively. The Committee considered that for a compound that is both genotoxic and carcinogenic, these MOEs indicate a human health concern. The Committee recognized that these MOE values were similar to those determined at the sixty-fourth meeting and that the extensive new data from cancer bioassays in rats and mice, physiologically based pharmacokinetic modelling of internal dosimetry, a large number of epidemiological studies and updated dietary exposure assessments support the previous evaluation.

To better estimate the cancer risk from acrylamide in food for humans, the 72nd JECFA recommended that longitudinal studies on intra-individual levels of acrylamide and glycidamide hemoglobin adducts be measured over time in relation to concurrent dietary. Such data would provide a better estimate of acrylamide exposure for epidemiological studies designed to assess the risk associated with consumption of certain foods.

The 3rd CCCF (2009) agreed to forward the Draft Code of Practice for the Reduction of Acrylamide in Foods to CAC32 for adoption at Step 8 (ALINORM 09/32/41, para. 64 and Appendix IV). The 32nd CAC (2009) adopted the code of practice for the reduction of acrylamide in foods (ALINORM 09/32/REP, Appendix III).

The 4th CCCF(2010) discussed Part 2 of the report of the in-session Working Group on Priorities: Follow-up on results of JECFA evaluations for CCCF, and agreed with the recommendations:

- To encourage the use of the Code of Practice to reduce acrylamide formation;
- To stimulate research on the mitigation measures and their impact on acrylamide production;
- To reconsider work on acrylamide in future to allow sufficient time for the implementation of the Code of Practice.

Acrylamide

Acrylamide is an important industrial chemical used since the mid 1950s as a chemical intermediate in the production of polyacrylamides, which are used as flocculants for clarifying drinking water and other industrial applications. Recently, attention was drawn to the formation of acrylamide at high temperatures during frying, baking or other thermal processing of a variety of foods, typically plant commodities high in carbohydrates and low in protein. In this Maillard reaction, the most important precursor amino acid asparagine reacts with reducing sugars. After its formation acrylamide seems to be stable in a large majority of the affected foods. Acrylamide levels in commodities are highly variable because its formation is dependent on the exact conditions of time and temperature used to heat process the food and the composition of the food. Research on acrylamide formation is ongoing; mitigation could be accomplished by adjustments in existing production procedures.

In experimental animals, acrylamide is rapidly and extensively absorbed following oral administration and widely distributed to the tissues, as well as the fetus. It has also been found in breast milk. The major metabolite is glycidamide, formed by a CYP2E1-mediated oxidation, which is much more reactive with DNA than acrylamide itself. Acrylamide and metabolites are rapidly eliminated via urine.

The neurotoxicity of acrylamide in humans is well-known from occupational and accidental exposures. In addition, experimental studies in animals have shown reproductive, genotoxic and carcinogenic properties. The nervous system is the principal site of toxic actions of acrylamide, which is expressed by morphological changes. Degenerative changes in nerves (NOEL 0.2 mg/kg/day, based on a study in rats). Reproduction studies showed reduced fertility, adverse effects on sperm-count and -morphology in male rodents, however, no adverse effects have been observed in female rodents (NOEL 2 mg/kg/day). Furthermore, acrylamide was not teratogenic in mice or rats. Acrylamide is genotoxic, however, metabolism to glycidamide appears to be a prerequisite.

Acrylamide was evaluated by IARC in 1994 and classified as probably carcinogenic to humans on the basis of a positive cancer bioassay and evidence that acrylamide is efficiently biotransformed to the genotoxic metabolite glycidamide. BMDL for 10% extra risk of tumors was established by the JECFA to be 0.3 mg/kg/day.

A wide range of commodities may be contaminated with acrylamide, such as cereals and cereals-based products, fish and seafood, meat and offals, milk and milk products, nuts and oilseeds, pulses, potato and potato products, coffee, sugars and honey, vegetables.

Studies conducted in Sweden in 2002 showed the formation of high levels of acrylamide during frying or baking of a variety of food.

Acrylonitrile

Reference to JECFA:	28 (1984)
Toxicological guidance value:	Provisional Acceptance (1984, the use of food-contact materials from which acrylonitrile may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable.)
Contaminant definition:	acrylonitrile (monomer)
Synonyms:	2-Propenenitrile; vinyl cyanide (VCN); cyanoethylene; abbreviations, AN, CAN.
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Food	0.02	Adopted	2006	FAC			

Guideline Levels for Acrylonitrile in Food and Vinyl Chloride Monomer in Food and Food Packaging Materials were adopted by the CAC at its 19th session (1991) with the understanding that the AOAC and the ISO would be requested to elaborate appropriate sampling plans and methods of analysis. (ALINORM 91/40, paras 203-204)

The 29th CAC (2006) adopted GSCTF, including Schedule 1 and revoked Guideline Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material (CAC/GL 6-1991) (ALINORM 06/29/41).

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as packaging material for foods. Acrylonitrile is not known to occur as a natural product. Acrylonitrile is classified by IARC as possibly carcinogenic to humans (Group 2B). Polymers derived from acrylonitrile may still contain small amounts of free monomer. Migration of possibly harmful substances from food contact materials has been discussed in the CCFA/CCFAC in the period 1986-1991. (IARC Vol. 71, 43-108)

Benzene

Reference to JECFA:	This compound has not been evaluated by JECFA
Toxicological guidance value:	-
Contaminant definition:	-
Synonyms:	-
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

In the first edition of the WHO Guidelines for Drinking-water Quality, published in 1984, a health-based guideline value of 0.01 mg/liter was recommended for benzene based on human leukaemia data from inhalation exposure applied to a linear multistage extrapolation model. The 1993 Guidelines estimated the range of benzene concentrations in drinking-water corresponding to an upper-bound excess lifetime cancer risk of 10-5 to be 0.01–0.08 mg/liter based on carcinogenicity in female mice and male rats. As the lower end of this estimate corresponds to the estimate derived from epidemiological data, which formed the basis for the previous guideline value of 0.01 mg/liter associated with a 10-5 upper-bound excess lifetime cancer risk, the guideline value of 0.01 mg/liter was retained.

The Third CCCF noted that benzene in soft drinks was not a major contributor to overall benzene exposure and in view of the considerable guidance available to industry to limit formation of benzene in soft drinks, in particular, the guidance by the International Council of Beverages Associations (ICBA) which is available in various languages, a code of practice was not necessary at this time. The Committee, however, agreed to encourage member countries, especially those in the tropics to continue data collection on the occurrence of benzene in soft drinks (ALINORM 09/32/41, para 104).

Benzene is colourless liquid at room temperature, which evaporates rapidly. It is slightly soluble in water and miscible with most organic solvents. Benzene is a naturally occurring chemical found in crude petroleum, but it is also produced in large quantities. Emissions arise during the processing of petroleum products, in the coking of coal, during the production of industrial solvents (toluene, xylene and other aromatic compounds) and from its use in consumer products as a chemical intermediate and as a component of gasoline (petrol). Human exposure occurs mainly by outdoor environmental levels of benzene (gasoline, industrial solvents), cigarette smoke, and occupationally when not protected.

In EHC 150 (1993) it is reported that benzene appears to be of low acute toxicity after oral exposure in various animal species. There are only a limited number of oral studies available on benzene. Exposure to benzene at high levels (by inhalation at the working place) is dose-dependently associated with bone marrow depression resulting in anemia. Benzene can easily cross the placental barrier, however, numerous animal experiments show no evidence of benzene being teratogenic even at maternally toxic doses, though in inhalation studies fetal toxicity has been demonstrated in mice and rats. Neurotoxicity and immunotoxicity of benzene has not been well studied in experimental animals or humans. IARC (1987) classified benzene in Group 1 (human carcinogenic).

Chloropropanols

Reference to JECFA: 41 (1993; for 1,3-dichloro-2-propanol only), 57 (2001), 67 (2006)
Toxicological guidance value: PMTDI 0.002 mg/kg bw (2001, for 3-chloro-1,2-propanediol; maintained in 2006. Establishment of tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorogenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA.)
$BMDL_{10}$ cancer, 3.3 mg/kg bw/day (for 1,3-dichloro-2-propanol); MOE, 65 000 (general population), 24 000 (high level intake, including young children))
Contaminant definition: 3-MCPD
Synonyms: Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD, also referred to as 3-monochloro-1,2-propanediol) and 1,3-dichloro-2-propanol (1,3-DCP)
Related code of practice: Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64-2008)

Commodity / Product Name	Maximum Level (mg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Liquid condiments containing acid-hydrolyzed vegetable protein	0.4	Adopted	2008	CF	The ML does not apply to naturally fermented soy sauces.	

The 57th JECFA (2001) noted that the dose that caused tumours in rats (19 mg/kg bw/day) was about 20000 times the highest estimated intake of 1,3-DCP by consumers of soya sauce (1mg/kg bw/day). The available evidence suggests that 1,3-DCP is associated with high concentrations of 3-MCPD in food. Regulatory control of the latter would therefore obviate the need for specific controls on 1,3-DCP. (57th Report of the Joint FAO/WHO Expert Committee on Food Additives, pages 118-121）

High levels of chloropropanols (up to 100 mg/kg and more) have especially been found in products like non-traditionally fermented soy sauces and hydrolyzed vegetable proteins (HVP). There is an obvious connection with the conditions of the production method; levels of chloropropanols in these products are shown to be declining in the last decade since the problem was noticed and measures have been taken to reduce the formation of chloropropanols. These compounds have also been found, however, in many other foods, including baked goods, bread, cooked/cured meat/fish and malt ingredients. There are (inconclusive) indications that cooking/grilling (high temperature treatment) could result in some formation of 3-MCPD. Also the resins in packaging materials and paper used for processing of food may contain 3-MCPD and could contribute to exposure via food, this has led to the development of resins with significantly lower levels of 3-MCPD. The available evidence suggests that 1,3-DCP occurs at lower levels than 3-MCPD in soy sauce (and related products) and in acid-HVP food ingredients. However, in meat products the concentrations of 1,3-DCP are generally higher than the levels of 3-MCPD as concluded at the 65th JECFA. Further information is required on the levels of chloropropanols in foods and food ingredients, on the dietary exposure to these compounds, on the origin and formation and on production methods which can be utilized to avoid chloropropanol contamination of foodstuffs.

The 37th CCFAC (2005) agreed to request JECFA to conduct an exposure assessment for chloropropanols from all sources (ALINORM 05/28/12, para. 189).

Chloropropanols

The 67th JECFA (2006) estimated the average exposure to 3-MCPD (at the national level in a wide range of foods including soya-sauce and soya-sauce related products) to be 1% to 35% of the PMTDI in the general population. For consumers at the 95th percentile the estimated intakes ranged from 3% to 85%, and for young children up to 115% of the PMTDI. The Committee noted that a reduction in the concentration of 3-MCPD in soya sauce and related products made with acid-HVP could substantially reduce the intake of this contaminant by certain consumers. The Committee concluded that the critical effect of 1,3-DCP is carcinogenicity. Negative results were found in two new studies on genotoxicity in vivo. However, limitations in these studies, positive findings in in vitro test for genotoxicity as well as lack of knowledge on the modes of action operative at the various tumor locations led the Committee to the conclusion that a genotoxic mode of action could not be excluded.

The estimated intake of 1,3-DCP was calculated at 0.051µg/kg bw/day and 0.136 µg/kg bw/day, respectively for the general population and the high-level intake (including young children). Comparison of these intakes with the lowest $BMDL_{10}$ of 3.3 mg/kg bw/day (incidence data on tumour-bearing animals for all treatment-affected locations) resulted in a margin of exposure (MOE) of approximately 65,000 and 24,000, respectively. Based on these MOEs the Committee concluded that the estimated intakes of 1,3-DCP were of low concern for human health.

The 67th JECFA recommended that studies should be undertaken to evaluate the intake or toxicological significance of fatty acid esters of 3-MCPD, which have been reported to be present in foods.

The 8th CCCF (2014) agreed with the recommendations of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA to maintain 3-MCPD esters in the Priority List (REP 14/CF, paras. 126 and 130 and APPENDIX XIII).

Discussions on MLs

A position paper was written; the 35th CCFAC (2003) agreed that the paper should be revised on the basis of the discussions and of submitted comments and data (ALINORM 03/12A, para. 179).

The setting of MLs for 3-MCPD in foodstuffs was asked to be considered at the 35th session of the CCFAC. The CCFAC could not reach a consensus on a ML of 1 mg/kg for acid-HVP soy sauce as proposed, and deferred the elaboration of MLs in different foodstuffs until its next session; the revised position paper should include proposals for the elaboration of MLs for chloropropanols in relevant foods (ALINORM 03/12A, paras 173-179).

The 36th CCFAC (2004) agreed to commence work on the establishment of a maximum level for 3-MCPD in acid-HVPs and acid-HVP containing products subject to approval as new work. In addition, the CCFAC agreed that a working group would prepare an updated discussion paper (ALINORM 04/27/12, paras 193-194).

The 37th CCFAC (2005) agreed to use as a starting point a maximum level of 0.4 mg/kg for 3-MCPD in liquid condiments containing acid-HVP (excluding naturally fermented soya sauce). Due to the need to better define the products for which maximum levels should be set, the Committee agreed to prepare a discussion paper that will define the different acid HVP containing products and collect information on other products that contain 3-MCPD (ALINORM 05/28/12, paras 188 and 189).

The 38th CCFAC (2006) agreed to update the discussion paper in view of the results of the JECFA evaluation and other information relevant for discussions on the Maximum Levels and to maintain the proposed draft Maximum Level at Step 4 (ALINORM 06/29/12, paras 176 and 177).

Chloropropanols

The First CCCF agreed to forward the proposed draft ML of 0.4 mg/kg to the 30th Commission for adoption at Step 5. It was agreed that the draft ML should be further considered in light of finalization and implementation of the Codex of Practice for the Reduction of 3-MCPD during the Production of Acid-Hydrolyzed Vegetable Proteins (acid-HVPs) and Products that Contain Acid-HVPs (ALINORM 07/30/41).

Discussions on COP
The 37th CCFAC (2005) agreed to forward to the Commission for approval as new work the project document on the elaboration of a Code of Practice for Reduction of the reduction of chloropropanols during the production o acid HVPs and products that contain acid HVPs and pending the approval of the Commission, to elaborate the proposed draft Code of Practice (ALINORM 05/28/12, para. 183).

The 38th CCFAC (2006) agreed to urge professional organisations and governments to provide additional data on measures to reduce the presence of chloropropanols in acid HVP produced under industrial conditions, thereby considering, in particular, that which was feasible from an organoleptic point-of-view and the Committee also agreed to revise the proposed draft. In revising the Code of Practice, the electronic Working Group should consider revision of the title to specifically refer to 3-MCPD, on account of the co-occurrence of 3-MCPD and other chloropropanols (ALINORM 06/29/12, paras 172 and 173).

The First CCCF (2007) agreed to most of the amendments proposed by the ad hoc physical working group and two additional changes and forwarded the proposed draft Code of Practice, as amended at the session, to the 30th Session of the Commission for adoption at Step 5 (ALINORM 07/30/41, paras 92-93).
The 30th CAC (2007) adopted the proposed draft Code and ML at Step 5 (ALINORM 07/30/REP, paras 80 and 94).

The 31st CAC (2008) adopted the code of practice for the reduction of 3-monochloropropane-1,2-diol (3-MCPD) during the production of acid-hydrolyzed vegetable protein (acid-HVPs) and products that contain acid- HVPs The Committee also adopted the draft Maximum Level of 0.4 mg/kg for 3-MCPD in Liquid Condiments containing Acid-Hydrolyzed Vegetable Proteins (Excluding Naturally Fermented Soy Sauce) at Step 8 (ALINORM 08/31/REP, para. 24 and APPENDIX XII).

Chloropropanols can be formed in foods as a result of specific processing and storage conditions. The main source is acid hydrolyzation of vegetable proteins for the production of savoury food ingredients (e.g. soy sauce). In this process the use of hydrochloric acid at high temperatures can result in chlorination of lipids present in the protein starting materials. 3-MCPD has been shown to be a precursor for 1,3-DCP-formation and control of the levels of 3-MCPD is expected to obviate the need for specific control on 1,3-DCP.

Toxicity of 3-MCPD:
3-MCPD crosses the blood-testis barrier and the blood-brain barrier and is widely distributed in the body fluids. The parent compound is partly detoxified by conjugation with glutathione, resulting in excretion of the corresponding mercapturic acid, and is partly oxidized further to oxalic acid. Intermediate formation of an epoxide has been postulated but not proven. The incidence of tubule hyperplasia in the kidneys of treated rats was the most sensitive end-point for deriving a tolerable intake. This effect was seen in the long-term study of toxicity and carcinogenicity in rats in a dose-related manner. 3-MCPD is neither genotoxic in vitro at concentrations at which other toxic effects are observed, nor genotoxic in vivo. (Fifty-seventh Report of the Joint FAO/WHO Expert Committee on Food Additives, pages 114-118)

Chloropropanols

Toxicity of 1,3-DCP:

Although only a few studies of kinetics, metabolism, short- and long-term toxicity and reproductive toxicity were available for evaluation, the results clearly indicated that 1,3-dichloro-2-propanol was genotoxic in vitro, was hepatotoxic and induced a variety of tumours in various organs in rats. The JECFA concluded that it would be inappropriate to estimate a tolerable intake because of the nature of the toxicity observed:

- The results of the long-term study of toxicity and carcinogenicity showed significant increases in the incidences of both benign and malignant neoplasms in at least three different tissues.
- It has been shown unequivocally that this contaminant can interact with chromosomes and/or DNA; however, the tests were confined to bacterial and mammalian test systems in vitro, and there were no data on intact mammalian organisms or humans (57th Report of the Joint FAO/WHO Expert Committee on Food Additives, pages 118-121).

3-MCPD ester

Reference to JECFA: (see also Chloropropanols)
Toxicological guidance value: -
Contaminant definition: -
Synonyms: abbreviation: MCPDE
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)
Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the Production of Acid-Hydrolyzed Vegetable Protein (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64-2008)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML					

In 2007, the presence 3-MCPD esters was reported for the first time in a number of foodstuffs including refined edible fats, such as margarine and oils, as well as infant formula and breast milk. Since 3-MCPD can be released from the esters, the presence of 3-MCPD esters considered as health concern.

At the 2nd CCCF (2008), Germany reported that recent data show levels of MCPD esters in refined vegetable oils that may lead to exceeding of the PMTDI for 3-MCPD, if assuming full hydrolysis and uptake. The Committee agreed to include 3-MCPD ester in the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA, but not to assign a high priority, due to the fact that there were currently only limited data available and kinetic studies and collection of exposure data were still ongoing.

3-Chloro-1,2-propanediol is formed when chloride ions react with lipid components in foods under a variety of conditions, including food processing, cooking, and storage. The compound has been found as a contaminant in various foods and food ingredients, most notably in acid-hydrolysed vegetable protein and soy sauces.
The 67th JECFA (2006) noted that it has been reported that fatty acid esters of 3-MCPD are present in foods, but there were insufficient data to enable either their intake or toxicological significance to be evaluated. The Expert Committee recommended that studies be undertaken to address this question.

Other Chemical Contaminants (except radionuclides)

Dioxins

Reference to JECFA: 57 (2001)
Toxicological guidance value: PTMI 70 pg TEQ/kg bw (2001, Including coplanar PCBs)
Synonyms: Polychlorinated dibenzo-dioxins and -furans
Related code of practice: Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML					

The situation regarding dioxins has been reviewed in a discussion paper (last version CX/FAC 00/26). The 32nd CCFAC (2000) requested an additional position paper in which recent intake assessments and national regulations regarding dioxins are assembled. This was presented to the 33rd CCFAC (2001). A revision of this document was requested, with also data on dioxin levels in food and feedingstuffs and breast-milk; the latest version is CX/FAC 03/32. The 34th CCFAC (2002) agreed that it should not draft MLs for dioxins at the time. The 35th CCFAC (2003) requested a revision of the position paper, including the insertion of a new section to cover ranges of data on background levels of dioxins and dioxin-like PCBs in food and feed. The 36th CCFAC (2004) encouraged Codex members to submit data on dioxins and dioxin-like PCBs in foods, and it agreed to request WHO to report in a detailed way to the Committee on the data submitted within three years time. In view of this, the CCFAC agreed to discontinue the consideration of the position paper (ALINORM 04/27/12, paras 188-189).

The 29th CAC (2006) agreed to invite the CCMAS to review the sections on sampling and analytical methods and assess the need for future revisions of the Code, taking into account the comments made at the 29th CAC (ALINORM 06/29/41, paras 60-62).

The 29th CCMAS (2008) agreed that the Delegation of Germany would lead an EWG in order to update document CX/MAS 06/27/8 in the light of the remarks made by CCCF; answer the questions on the applicability of the methods for the indicated ranges and commodities concerned; review the validation data for the methods; and set criteria for dioxin analysis. (ALINORM 08/31/23 para. 128) The 30th CCMAS agreed to forward this discussion paper for consideration by the CCCF (ALINORM 09/32/23 para.140).

The 3rd CCCF (2009) considered the discussion paper prepared by the CCMAS on methods of analysis for dioxins and dioxin-like PCBs, following the earlier request of the Committee in relation to the development of the Code of Practice for the Prevention and Reduction of Dioxins and Dioxin-like PCBs and further clarification provided on the ranges for the determination of dioxins and dioxin-like PCBs. The document considered the methods currently used and the criteria for the methods, as well as information provided by governments and organizations which participated in the preparation of the discussion paper. The Committee noted that the document provided useful information that could be used by governments at the national level as a reference for the purpose of monitoring contamination by dioxins and dioxin-like PCBs. The Committee recalled its earlier decision not to establish MLs for dioxins in foods and discussed how to proceed further, in view of the lack of new data since 2004 on dioxin and dioxin-like PCB contamination in the GEMS/Foods database at this moment. Several delegations informed the Committee that they had collected data on the occurrence of dioxins in foods and feeds or had initiated surveys for that purpose and indicated that they could send their data to GEMS/Foods. The JECFA Secretary pointed out that very limited data submitted since 2004 in GEMS/Foods and that there was a need for more data originating from different regions in order to consider exposure to dioxins. The Committee invited all countries to submit relevant data to GEMS/Foods and agreed that the question of dioxins and PCBs would not be discussed further in the Committee, with the understanding that it could be reconsidered when relevant data became available (ALINORM 09/32/41 para. 9-13).

Dioxins

The 6th CCCF (2012) discussed the report of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for evaluation by JECFA. With regard to the request for re-evaluation of dioxins and dioxin-like PCBs, the JECFA Secretariat stated that dioxins were a known public health problem and that it might not be the best use of JECFA resources to perform a re-evaluation, but that it would be important for countries to implement source directed measures to reduce formation and release of dioxins into the environment, thereby reducing human exposure. The Committee agreed to not request a re-evaluation of dioxins and dioxin-like PCBs at this point (REP12/CF, para. 160 and 162).

The 9th CCCF (2015) discussed the report of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for evaluation by JECFA and agreed to include dioxins for update of the risk assessment. The Committee noted that this would not be a high priority, considering that extensive re-assessment was being undertaken by national and regional agencies, and as such the JECFA assessment could build on this work once completed (REP 15/CF, para. 147-148).

The term dioxins refers to a group of polychlorinated planar aromatic compounds. The group consists of 75 dibenzo-p-dioxins (PCDD) and 135 dibenzofurans (PCDF). The most studied and toxic dioxins are 17 congeners with a 2,3,7,8-chlorosubstitution pattern, of which 2,3,7,8-tetra-CDD (TCDD) is the most toxic and most studied congener. Dioxins are ubiquitously present as contaminants in the environment and in food, be it in minute amounts. Dioxins are lipophilic compounds which bind to sediment and organic matter in the environment and tend to be absorbed in animal and human fatty tissue. They are extremely resistant towards chemical and biological transformation processes and are consequently persistent in the environment and accumulate in the food chain. Dioxins are formed as unwanted by-products in combustion processes or industrial processes. Most of the dioxins enter the environment by emission to air. The Ah receptor is an important factor in the toxicological effects of dioxins. Activation of this receptor can result in endocrine and paracrine disturbances and alterations in cell functions including growth and differentiation.

Developmental neurobehavioral (cognitive) and reproductive effects and immunotoxic effects belong to the most sensitive endpoints of dioxin toxicology. TCDD is classified by IARC as Group 1 human carcinogen. It has been shown to be carcinogenic in several animal species at multiple sites, but TCDD is not an initiator of carcinogenesis and the tumour promotion in animal studies indicated a non-genotoxic mechanism.

The toxic equivalency concept has been developed for application to dioxins in order to assess the toxicity of a mixture of congeners as it exists in practice. Toxic Equivalency Factors (TEFs) have been established in relation to TCDD and the total toxicity of a mixture can thus be calculated as total toxic equivalents (TEQs). It has been shown that also some PCB-congeners (those with a planar dioxin-like structure) have effects on the Ah receptor and thus they are given TEFs and can be combined with the dioxins for the calculation of total TEQ of a sample.

Ethyl carbamate

Reference to JECFA:	64 (2005)
Toxicological guidance value:	(Intake estimates: from food (=mean) 15 ng/kg bw/day; from food and alcoholic beverages (=high) 80 ng/kg bw/day
	Margin of Exposure (MOE): cancer (BMDL 0.3 mg/kg bw/day), mean intake 20 000, high intake 3 800.)
Synonyms:	Urethane; abbreviation, EC
Related code of practice:	Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates (CAC/RCP 70-2011)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

When ethyl carbamate was discussed in the CCFAC in 1991, a Danish national TDI of 0.2 ug/kg bw was reported. The intake of a person consuming some of the higher contaminated food products was estimated to be more than 50% of this TDI. Therefore measures aimed at reducing the EC formation were seen as necessary. No specific health effects by ethyl carbamate in humans related to dietary exposure are reported however.

Some countries mentioned national GLs for EC. No trade problems are reported however. The 27th CCFAC (1995) decided that no further action was needed at present.

The 64th JECFA (2005) evaluated the national estimates of intake submitted to the committee by Denmark, Switzerland, USA (assessments conducted in the early 1990s) and South Korea, Australia, New Zealand (assessments conducted more recently). The committee noted that mitigation measures have been effective in reducing residual concentrations of ethyl carbamate, and that, consequently the older data published in the early 1990s and used to make the initial estimates of intake of ethyl carbamate no longer accurately reflect current intake from alcoholic beverages. The committee estimated the mean intake of ethyl carbamate from food to be approximately 15 ng/kg bw/day, this was based on the relevant foods, including bread, fermented milk products and soy sauce; alcoholic beverages were not included. With the inclusion of alcohol beverages the estimated intake is 80 ng/kg bw/day. High consumption of stone-fruit brandies could lead to higher intakes of ethyl carbamate.

The 64th JECFA concluded that intake of ethyl carbamate from foods excluding alcoholic beverages would be of low concern (MOE: 20 000). However, the MOE from all intakes, food and alcoholic beverages combined (MOE: 3800), is of concern and therefore mitigation measures to reduce concentrations of ethyl carbamate in some alcoholic beverages should be continued.

The 64th JECFA had concluded that health risks for the general population were low and that only sub-populations consuming a high quantity of specific alcoholic beverages might be exposed to certain health risks (ALINORM 07/30/41, para. 137).

The 37th CCFAC (2005) observed the matter of ethyl carbamate was relevant but not of a high priority and that, due to the limited resources, it should be taken up at a later stage (ALINORM 05/28/12, para. 41).

The Second CCCF (2008) agreed that the Delegation of Germany would prepare a discussion paper on ethyl carbamate in alcoholic beverages for consideration by the next session of the CCCF with a view to determining how and to what extent this matter could be approached within the CCCF (ALINORM 08/31/41, para. 191).

Ethyl carbamate

The 3rd CCCF (2009) agreed to start new work on a proposed draft Code of Practice for the Reduction of Ethyl Carbamate in Stone Fruit Distillates which will not include a signal value subject to approval by the Commission. It further agreed that the Delegation of Germany would prepare a proposed the draft Code of Practice for comments at Step 3 and consideration by the next session of the Committee. (ALINORM 09/32/41, paras 115 and 116). The proposal for new work was subsequently approved by the Commission at its 32nd Session (ALINORM 09/32/REP, Appendix VI).

The 5th CCCF (2011) agreed to forward the proposed draft Code of Practice to the 34th CAC for adoption at Step 5/8 with omission of Steps 6 and 7 (REP11/CF, para. 26 and Appendix II).
The 34th CAC (2011) adopted the Code of Practice for the Prevention and Reduction of Ethyl Carbamate Contamination in Stone Fruit Distillates at step 5/8 (REP11/CAC, Appendix III).

Ethyl carbamate can be formed from various substances derived from food and beverages, including hydrogen cyanide, urea, citrulline and other N-carbamyl compounds. Cyanate is probably the ultimate precursor, reacting with ethanol to form the carbamate ester. Over the past years, major reductions in concentrations of EC have been achieved using two approaches: first, by reducing the concentration of the main precursor substances in the food and beverages; second, by reducing the tendency for these precursor substances to react to form cyanate, e.g. by the exclusion of light from bottled spirits. Also, diethylpyrocarbonate, an inhibitor of fermentation, and azodicarbonamide, a blowing agent for sealing gaskets, can form ethyl carbamate. Diethylpyrocarbonate is revoked by the JECFA at its 17th meeting, azodicarbonamide is not recommended for bottling alcoholic beverages.

Ethyl carbamate is well absorbed from the gastrointestinal tract and is rapidly distributed throughout the body. Elimination is also rapid, with most being excreted as carbon dioxide as studied in mice. CYP2E1 activity is responsible for most of the metabolism of EC to carbon dioxide. EC may also undergo metabolic activation to vinyl carbamate epoxide, which binds covalently to nucleic acids and proteins. Moreover, hydrolysis to ethanol and ammonia may occur.

The acute oral toxicity of EC is low; however, high doses caused anesthesia in rodents. Effects on lung, liver, kidney, heart, spleen, lymph nodes, thymus, bone marrow and ovaries were seen during chronic exposure to EC, as studied in mice and rats. Reproduction studies showed high rates of embryonic/fetal mortality and malformations. Ethyl carbamate is genotoxic and carcinogenic. Single doses, short-term and long-term oral dosing of ethyl carbamate have been shown to induce tumors in all species tested (BMDL 0.3 mg/kg bw/day). IARC classified ethyl carbamate in Group 2B, possibly carcinogenic to humans (1974). No quality data for humans are available.

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Other Chemical Contaminants (except radionuclides)

Furan

Reference to JECFA: 72 (2010)
Toxicological guidance value: (Intake estimates: mean 0.001 mg/kg bw/day; high 0.002 mg/kg bw/day, Margin of exposure (MOE): hepatocellular adenomas and carcinomas in female mice ($BMDL_{10}$ 0.96 mg/kg bw/day), mean intake 960, high intake 480.)
Contaminant definition: -
Synonyms: furfuran
Related code of practice: -

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

Information available to 72nd JECFA in 2010 suggested that the major route of exposure to furan in the human population is through consumption of heat-treated foods and beverages.

MOEs were calculated at dietary exposures of 0.001 mg/kg bw per day, to represent the average dietary exposure to furan for the general population, and 0.002 mg/kg bw per day, to represent the dietary exposure to furan for consumers with high dietary exposure. This estimate will also cover dietary exposure of children. Comparison of these dietary exposures with the $BMDL_{10}$ of 1.3 mg/kg bw, corresponding to 0.96 mg/kg bw per day when adjusted from a 5 day/week dosing schedule to an average daily dose, for induction of hepatocellular adenomas and carcinomas in female mice gives MOEs of 960 and 480 for average and high dietary exposures, respectively. The Committee considered that these MOEs indicate a human health concern for a carcinogenic compound that might act via a DNA-reactive genotoxic metabolite.

The furan levels can be reduced in some foods through volatilization (e.g. by heating and stirring canned or jarred foods in an open saucepan). However, there is currently a lack of quantitative data for all foods, and no information is available on other mitigation methods.

The 4th CCCF (2010) agreed that a discussion paper prepared by an electronic Working Group, working in English, led by the Delegation of the United States of America would be presented to the next session of the Committee for consideration (ALINORM 10/33/41, para. 116).

The 5th CCCF (2011) agreed that this work could be taken up in the future when more adequate data became available and that at that time the re-establishment of the electronic Working Group to further develop the discussion paper could be considered (REP11/CF, para. 79).

Furan (C_4H_4O) (CAS No. 110-00-9) is a highly volatile cyclic ether that can be formed unintentionally in foods during processing from precursors that are natural food components. Furan is hepatotoxic and hepatocarcinogenic in rats & mice; JECFA considered carcinogenicity the critical endpoint for use in human health risk assessment.

Glycidyl ester

Reference to JECFA: -
Toxicological guidance value: -
Contaminant definition: -
Synonyms: glycidol ester, abbreviation: GE
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

At the 5th CCCF (2011), Germany requested to include glycidyl esters in the 3-MCPD ester evaluation by JECFA. The Committee agreed to include glycydoll esters in the priority list of contaminants and naturally occurring toxicants proposed for evaluation by JECFA, but separate from the 3-MCPD esters.(REP 11/CF, paras. 91-93)

Glycidol is an epoxide used as a chemical intermediate in the production of functional epoxides, glycidyl urethanes, pharmaceuticals and other products. The IARC (2000) has assessed the carcinogenic potential of glycidol and concluded that glycidol is probably carcinogenic to humans (Group 2A).
Glycidyl esters are compounds formed independently from 3-MCPD esters during the processing of all oils and fats. They are likely formed from the diglycerides naturally present in all oils when heated to high temperatures. They are consequently found in foods that contain refined oils and fats.

Halogenated solvents

Reference to JECFA:	39 (1992), 51 (1998) (dichloromethane)
Toxicological guidance value:	ADI "should be limited to current uses" (dichloromethane)
Contaminant definition:	
Synonyms:	Methylene chloride, methylene dichloride
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Olive oils and pomace oils	0.1 (individual) 0.2 (sum)	Adopted	CS 33-1981	FO			Not listed in GSCTFF

The 7th CCCF (2013) considered a request from the Committee on Fats and Oils (CCFO) on the transfer of MLs for halogenated solvents from the Standard for Olive Oils and Pomace Oils (CODEX STAN 33-1981) to the GSCTFF and agreed that the Delegation of the European Union would prepare a discussion paper on what substances were included under the term "halogenated solvents" and whether the MLs in section 5.8 of CODEX STAN 33-1981 related to food safety or food quality (REP13/CF, para. 11).

The 8th CCCF (2014) noted the work done by the Delegation of the European Union and was informed that these MLs referred to the use of these substances as processing aids/extraction solvents when such substances were allowed in the production of these oils. It was further noted that JECFA had evaluated halogenated solvents and had limited their use to extraction solvent for spice oleoresins and decaffeination of coffee and tea and that there was no information on presence of halogenated solvents in olive oils or pomace oils from other uses than as extraction solvents, however their use as such was no longer allowed in the production of these oils. In addition, there was no information on potential public health implications resulting from exposure to halogenated solvents in olive oil and olive pomace oils nor information on environmental contamination resulting from the use of these substances in food products.
Following this presentation, the Committee noted that there was no support for the transfer of the levels for halogenated solvents from the Standard for Olive Oils and Pomace Oils (CODEX STAN 33-1981) to the GSCTFF, however it agreed to recommend CCFO to maintain these levels in CODEX STAN 33-1981 until such time more information on environmental contamination became available that would allow CCCF to make a decision on this matter. The Delegation of European Union agreed to follow-up on this issue and report back to the Committee in the future (REP 14/CF paras. 122-124).

A halogenated solvent refers to an organic solvent which contains halogenic atoms (chlorine, fluorine, bromine or iodine). Examples include compounds such as bromoform, chloroform and trichloroethylene. Halogenated solvents have been widely used in many industrial and commercial applications due to their excellent ability to dissolve oils, their fast evaporation rates and their chemical stability. Major uses were as dry cleaning fluids, degreasing solvents, electrical cleaning solvents, paint strippers, propellants and refrigerants. However, because halogenated organic solvents are often environmental and health hazards, their use in open applications has now been banned worldwide. They are still widely used by chemical and pharmaceutical industries in closed applications. Some halogenated solvents are naturally occurring, especially in marine environments.
Health effects from direct exposure to halogenated solvents are well known and include toxicity to the nervous system, reproductive damage, liver and kidney damage, respiratory impairment, cancer and dermatitis. Human health effects from low environmental exposures are unknown. Halogenated solvents generally do not persist in soil or water but some of the widely used substances, such as trichloroethene, can contaminate surface and ground water. Also chlorination can result in contamination of water with halogenated solvents, mainly trihalomethanes. For these reasons, maximum levels (ML) for certain halogenated solvents in drinking water have been set by many jurisdictions, including the WHO. (WHO Guidelines for drinking water quality 4th edition–Chapter 8 http://whqlibdoc.who.int/publications/2011/9789241548151_eng.pdf).

Halogenated solvents

JECFA evaluated dichloromethane in 1992 and specifications have been set and revised by JECFA in 1998. JECFA concluded in its evaluation in 1992 that "the use should be limited to current uses as an extraction solvent for spice oleoresins and the decaffeination of coffee and tea, and for food additives in which previous specifications drawn up by the Committee included residues of dichloromethane"

Melamine

Reference to JECFA: FAO/WHO Expert Meeting (2008)
Toxicological guidance value: TDI 0.2 mg/kg bw (2008)
Contaminant definition: melamine

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Foods (other than infant formula) and feed	2.5	Adopted	2010	CF	The ML applies to food other than infant formula. The ML applies to levels of melamine resulting from its non-intentional and unavoidable presence in feed and food. The ML does not apply to feed and food for which it can be proven that the level of melamine higher than 2.5 mg/kg is the consequence of - authorised use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine - migration from food contact materials taking account of any nationally authorised migration limit. The ML does not apply to melamine that could be present in the following feed ingredients/additives: guanidino acetic acid (GAA), urea and biuret, as a result of normal production process.	
Liquid Infant formula	0.15	Adopted	2012	CF	The ML applies to liquid infant formula as consumed.	
Powdered Infant formula	1	Adopted	2010	CF		

An FAO/WHO Expert Meeting in December 2008 established a tolerable daily intake (TDI) of 0.2 mg/kg body weight for melamine, based on dose–response assessment of subchronic rat studies, modelling of the incidence of bladder stones and application of a safety factor of 200 to account for extrapolation from rats to humans, variation within humans and uncertainties associated with the data. The TDI is applicable to the whole population, including infants, and applicable to exposure to melamine alone.

Available data indicated that simultaneous exposure to melamine and cyanuric acid is more toxic than exposures to each compound individually. Data were not adequate to allow the calculation of a health-based guidance value for this co-exposure. A TDI of 1.5 mg/kg body weight for cyanuric acid had previously been derived by WHO.

Melamine

Maximum Levels for Melamine in Food and Feed

The 3rd CCCF (2009) agreed to start new work on MLs for Melamine in Food and Feed (ALINORM 09/32/41, para. 126 and Appendix X). The 32nd CAC approved this new work.

The 4th CCCF (2010) agreed to forward the proposed draft maximum levels for liquid infant formula to Step 3 for comments and consideration by the next session (ALINORM 10/33/41, para. 68).

The 5th CCCF (2011) agreed to forward the proposed draft maximum level for liquid infant formula to the 34th Session of the Codex Alimentarius Commission for adoption at Step 5/8 with omission of Steps 6 and 7 (ALINORM 11/34/41, Appendix III). The 34th CAC (2011) agreed to adopt the ML at Step 5, to advance to Step 6 for comments and discussion in the Committee on Contaminants in Foods.

The 6th CCCF (2012) agreed to forward the proposed draft maximum level for liquid infant formula to the 35th Session of the Codex Alimentarius Commission for adoption at Step 8 (REP12/CF, para58 and Appendix V). The 35th CAC (2012) adopted the ML at Step 8 (REP12/CAC, Appendix III).

Melamine is an industrially synthesized chemical used for a wide variety of applications, such as laminates, coatings and plastics. Commercially produced melamine may contain structural analogues, such as cyanuric acid, ammelide and ammeline.

Humans are exposed to melamine and its analogues from a number of different sources, including food and environmental sources. Sources range from breakdown of the pesticide cyromazine which is approved for use in many countries, to migration from approved food packaging material to the adulteration of specific foods from the (mostly non-approved) presence of melamine in animal feed or feed ingredients. Data have shown carry-over from feed to products of animal origin (e.g. milk, eggs, meat), including fish.

Melamine produces crystals in urine when its concentration exceeds a threshold. This results in renal failure from both intrarenal crystal-associated obstruction and an elevation in renal pressure that reduces renal blood flow and glomerular filtration.

Perchlorate

Reference to JECFA: 72 (2010)
Toxicological guidance value: PMTDI 0.01 mg/kg bw
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML					

The 72nd JECFA (2010) considered appropriate to derive a PMTDI as perchlorate has a very short half-life and is rapidly cleared from the body. The $BMDL_{50}$ of 0.11 mg/kg bw per day for inhibition of uptake of radiolabelled iodide by the thyroid in a clinical study in healthy adult volunteers was chosen as the POD for derivation of a PMTDI. As it was based on human data, there was no need to apply any interspecies uncertainty factor. The Committee concluded that it was not necessary to apply an uncertainty factor to account for the short duration of the pivotal study. The Committee concluded that an uncertainty factor of 10 would be appropriate to cover any differences in the general population, including those in potentially vulnerable subgroups. Applying this 10-fold factor to the $BMDL_{50}$ and rounding to one significant figure, a PMTDI of 0.01 mg/kg bw was established for perchlorate.The estimated dietary exposures of 0.7 µg/kg bw per day (highest) and 0.1 µg/kg bw per day (mean), including both food and drinking-water, are well below the PMTDI. The Committee considered that these estimated dietary exposures were not of health concern.

The 5th CCCF (2011) agreed that no follow-up was necessary since no health concern was identified at current estimated levels of exposure from food and drinking water (REP11/CF, para. 99).

The perchlorate ion ($ClO4^-$) is very stable in water, and its salts are highly soluble in water. Perchlorate occurs naturally in the environment, in deposits of nitrate and potash, and can be formed in the atmosphere and precipitate into soil and groundwater. It also occurs as an environmental contaminant arising from the use of nitrate fertilizers and from the manufacture, use and disposal of ammonium perchlorate (CAS No. 7790-98-9) used in rocket propellants, explosives, fireworks, flares and air-bag inflators and in other industrial processes. Perchlorate can also be formed during the degradation of sodium hypochlorite used to disinfect water and can contaminate the water supply. Water, soil and fertilizers are considered to be potential sources of perchlorate contamination in food. Potassium perchlorate (CAS No. 7778-74-7) has been used as a human therapeutic medicine to treat thyroid disease. The primary effect of perchlorate is its ability to competitively inhibit uptake of iodide by the thyroid gland.

Polybrominated diphenyl ethers

Reference to JECFA: 64 (2005)
Toxicological guidance value: (Intake estimates: mean approximately 4 ng/kg bw/day
Based on limited toxicity data, the 64th JECFA concluded that there appeared to be a large MOE for a non-genotoxic compound which, despite the inadequacy of the data on toxicity and intake, gave reassurance that intakes of PBDEs are not likely to be a significant health concern.)
Synonyms: PBDEs
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

In 1994, WHO published an Environmental Health Criteria document on PBDEs. Recent analysis of samples from environment and from human collected over the last 3-4 decades demonstrated significant increases in concentrations of PBDEs. At its 35th session the CCFAC requested to evaluate the potential risks associated with the presence of PBDEs in food.

The 64th JECFA (2005) noted that the available data on PBDEs were not adequate to allocate a PTWI or PMTDI, because:
- PBDEs represent a complex group of related chemicals and the pattern of PDBE congeners in food is not clearly defined by a single commercial mixture;
- Data are inadequate to establish a common mechanism of action that would allow a single congener to be used as a surrogate for total exposure or, alternatively, as the basis for establishing toxic equivalence factors;
- There is no systematic database on toxicity including long-term studies on the main congeners present in diet, using standardized testing protocols that could be used to define a NOEL for individual PBDEs of importance;
- Several of the reported effects are biological outcomes for which the toxicological significance remains unclear;
- Studies with purified PBDE congeners in vitro have shown a lack of Ah receptor activation, however, many of the adverse effects reported are similar to those found with dioxin-like contaminants, suggesting that some toxicity data may be confounded by the presence of traces of impurities that are potent Ah receptor agonists.

The 64th JECFA recognized the preliminary nature of the data on concentrations of PBDEs in food and human milk and estimated the dietary intake for the sum of all measured PBDE congeners to be approximately 4 ng/kg bw/day, while intake by breastfeeding infants could be up to 100 ng/kg bw/day. Adverse effects for PBDE congeners would be unlikely to occur at doses of less than approximately 100 µg/kg bw/day.

Based on limited toxicity data, The 64th JECFA concluded that there appeared to be a large MOE for a non-genotoxic compound which, despite the inadequacy of the data on toxicity and intake, gave reassurance that intakes of PBDEs are not likely to be a significant health concern. The committee considered that continuing studies of PBDEs in samples from humans, including human milk, would be useful in assessing the overall exposures to PBDEs in foods and other possible sources.

The 37th CCFAC (2005) endorsed the recommendations of the ad hoc Working Group on the Contaminants and Toxins that no action was required for PBDEs (ALINORM 05/28/12, para. 41 and Appendix IV).

Polybrominated diphenyl ethers

Polybrominated diphenyl ethers (PBDEs) are anthropogenic chemicals that are added to a wide variety of consumer/commercial products (e.g. plastics, polyurethane foam, textiles) in order to improve their fire resistance. Theoretically, 209 distinct PBDE isomers are possible, however, each commercial mixture usually only contains a limited number of congeners from each homologue group. PDBEs have been produced primarily as three main commercial products (mixtures): pentabromodiphenyl oxide or ether (PentaBDE), octabromodiphenyl oxide or ether (OctaBDE) and decabromodiphenyl oxide or ether (DecaBDE). Some variability in composition is known to exist between products from different manufacturers. The worldwide demand for PBDEs in 2001 was estimated to be almost 70 000 tonnes, with DecaBDE accounting for almost 80% of the total market.

Absorption of PBDEs is directly related to the extent of bromination of the parent diphenyl ether; as a general rule, greater substitution of bromine leads to a decrease in bioavailability. The metabolism of PBDEs consists of hydroxylation and methoxylation reactions and, in the case of congeners with a higher degree of bromination, oxidative debromination. Faecal excretion appears to be the dominant route of elimination, however, species differences exist. Limited data are available regarding the half-lives, however, preliminary values ranged from 30 to 90 days for the tetra- to hexa-substituted congeners. Moreover, limited pharmacokinetic data are available for humans, however, based on the observed increase in concentrations of PBDEs in tissue in time, PDBEs are absorbed and bioaccumulate.

The acute toxicity of mixtures of PBDEs is low in rodents, however, increased mortality, neurobehavioral effects, changes in gross pathology, induction of enzymes, changes in levels of hormones have been observed. In short-term studies the main effects of mixtures of PBDEs were seen in the liver (enlargement, ‘round bodies’, vacuolization, necrosis), kidney (hyaline degenerative cytoplasmic changes) and thyroid (hyperplasia). Embryo and fetus may be more sensitive to PBDEs than maternal animals; exposure to OctaBDE mixtures caused an increase in the incidence of developmental abnormalities. The results of the majority of tests for genotoxicity indicated that PBDE mixtures and single congeners are not genotoxic. The only long-term study was conducted with the DecaBDE mixture in mice and rat, however, evidence for the carcinogenicity of DecaBDE is limited. No information is available on the carcinogenic potential of other PBDE mixtures. Available studies in humans are not adequate to evaluate whether exposure to PBDEs is associated with adverse health effects. Some toxicity data may be confounded by the presence of traces of impurities that are Ah-receptor agonists (e.g. dioxin).

Polychlorinated biphenyls

Reference to JECFA: 35(PCBs) (1989), 80(NDL-PCBs) (2015)
Toxicological guidance value: MOEs for adults ranging from 4.5 to 5000, MOEs for breastfed infants, which may have a body burden up to 2-fold higher than that of adults, would be approximately half of the adult values. The MOEs for children would be expected to be intermediate between those for adults and those for breastfed infants, owing to the initial contribution from breastfeeding and the subsequent lower dietary contribution compared with human milk.
(For coplanar PCBs (dioxin-like PCBs), see the toxicological guidance value of Dioxins)
Synonyms: Abbreviations, PCBs, NDL-PCBs
Related code of practice: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

PCBs were discussed by the 35th JECFA (1989); it was difficult to come to clear conclusions about the toxicity of PCBs as such because impurities such as dioxins and related compounds (e.g., PCDFs) probably were present in the PCB-mixtures used for the animal studies. The Committee concluded that 0.04 mg/kg bw was the NOEL in monkey studies. However, because of the limitations of the data and the ill-defined nature of the materials used in the study, no tolerable intake for humans could be established. One of the complications is that humans are exposed to biologically filtered mixtures of congeners, which are rather different from the industrial PCB-mixtures that were used for the studies. No toxicological monograph was prepared (see however EHC 140).

The major foods in which contamination with PCBs can be significant are fish, milk and dairy products, meat and eggs. Because PCBs bioaccumulate, the levels will usually be higher in animals which are higher in the food chain, but local pollution and feed composition may have major influence on the levels in animal products. Humans with a considerable intake of animal fats also may accumulate high levels of PCBs and as a consequence also PCB-levels in breast milk and in human adipose fat may be high. The JECFA, however, considered that the advantages to the infant of breast-feeding outweigh any potential hazards due to the PCB-content of breast milk. The JECFA recommended that PCB-levels in foods are monitored, preferably by quantifying the most important individual congeners. Safety studies should be carried out on the toxicological potential of the PCB-congeners which are predominantly present in foods. It is evident that in relation to the persistent nature of PCBs and ongoing environmental contamination, it is still valid to pay due attention to PCBs. JECFA pointed out that a long-term goal should be the reduction of PCBs in the diet to a minimum.

PCBs are related to other chlorinated hydrocarbons, such as polybrominated biphenyls (PBBs), polychlorinated terphenyls (PCTs), tetrachlorobenzyltoluenes, and polychlorinated dibenzodioxins and dibenzofurans. Coplanar PCBs were integrated included in the toxicological evaluation of dioxins (see the PTMI of 3.08 Dioxins), but it has to be borne in mind that the toxicological effects of PCBs are broader than the dioxin-related effects. The CCFAC discussed PCBs from 1990 to 1994 on the basis of CX/FAC 90/20-Add.1 and further related documents. It was noted that several countries have established MLs for PCBs in food, so that trade issues might arise. Some of these countries have introduced MLs for the sum of some specific PCB-congeners, which is probably the best defined way of analyzing and reporting PCBs. The most important congeners for analysis of the general content of PCBs in foods are usually considered to be IUPAC numbers 28, 52, 101, 118, 138, 153 and 180. The CCFAC also acknowledged that source-directed measures were most important to reduce contamination with PCBs. The Committee agreed in 1992 that it was premature to set (maximum) levels for these contaminants at this stage. The discussions later were focused on dioxins and the dioxin-related PCBs.

FAO and WHO organized an expert consultation on the risks and benefits of fish consumption, taking into consideration the health risks associated with methylmercury (MeHg), dioxin and dioxin-like PCBs (DLC) and the nutritive and health benefits of eating fish, in response to the request of the 29th session of the Commission (ALINORM 09/32/41, para. 24). The Expert Consultation was held in January 2010.

Polychlorinated biphenyls

It was concluded that consumption of fish provides energy, protein, and a range of other important nutrients, including the long-chain n-3 poly unsaturated fatty acids (LC n-3 PUFA), that eating fish was part of the cultural traditions of many peoples and that in some populations fish was a major source of food and essential nutrients. The Consultation concluded that among the general adult population, consumption of fish, particularly oily fish, lowers the risk of coronary heart disease (CHD) mortality and that potential cancer risks of DLCs were well below established CHD benefits. At levels of maternal DLC intake (from fish and other dietary sources) that exceed the the provisional tolerable monthly intake (PTMI) of 70 picograms/kg bodyweight/month established by JECFA, neurodevelopmental risk may not be negligible. Among infants, young children, and adolescents, the available data were insufficient to derive a quantitative framework of health risks and benefits of eating fish. However, the Consultation stated that healthy dietary patterns that include fish and are established early in life influence dietary habits and health during adult life. To minimize risks in target populations, the Consultation recommended a series of steps that member states should take to better assess and manage the risks and benefits of fish consumption and more effectively communicate with their citizens.

NDL-PCBs

The 8th CCCF (2014) agreed with the recommendations of the in-session Working Group on the Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by JECFA to maintain Non-dioxin like PCBs in the Priority List (REP 14/CF, paraa. 126 and 130 and APPENDIX XIII).

The 80th JECFA (2015) evaluated NDL-PCBs. For this evaluation, the Committee decided to focus on the six indicator PCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180), as there were sufficient data (toxicological, biomonitoring,occurrence and dietary exposure) available for review. Other NDL-PCBs were also considered where adequate data were available to make a risk characterization, as was found in the case of PCB 128.

National estimates of dietary exposure to the sum of the six indicator PCBs ranged, for mean exposure, from <1 to 82 ng/kg bw per day and, for high percentile exposure, from <1 to 163 ng/kg bw per day. International estimates based on Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) consumption cluster diets are in the same range. For the sum of the six indicator PCBs, the contribution of each of the individual congeners differs between countries and population groups. However, for both dietary exposure and body burden estimates (which also take into consideration kinetics and half-lives), the main contributor is PCB 153, followed by PCB 180, then PCB 101 and PCB 28, with the lowest contribution from PCB 52.

The Committee concluded that none of the available studies on the six indicator PCBs and PCB 128 was suitable for derivation of health-based guidance values or for assessment of the relative potency of the NDL-PCBs compared with a reference compound. Therefore, a comparative approach using the minimal effect doses was developed in order to estimate MOEs to provide guidance on human health risk. Based on the available toxicological data on individual congeners, subtle changes in liver and thyroid histopathology were evident from the lowest doses tested of 2.8–7 µg/kg bw per day and were similar across the short-term and long-term studies of toxicity. The Committee decided to take the lower end of the range of test doses used for each congener at which these subtle changes occurred as a conservative point of departure for estimating MOEs, after conversion of external doses to internal doses (body burdens), based on reported NDL-PCB congener concentrations in adipose tissue.

Owing to the long half-lives and to eliminate interspecies differences in toxicokinetics, the Committee considered it appropriate to estimate body burdens rather than using external dose (dietary exposure) for the risk characterization. From human biomonitoring studies, the Committee derived equivalent body burdens based on the reported range of NDL-PCB concentrations in human milk for each congener. In addition, using a one-compartment kinetic dietary exposure model, body burdens were simulated for each congener using dietary exposure data from countries.

Comparison of the human body burden estimates (derived from human milk concentrations) with the body burden estimates from animal studies derived as points of departure for each congener resulted in MOEs for adults ranging from 4.5 to 5000. MOEs for breastfed infants, which may have a body burden up to 2-fold higher than that of adults, would be approximately half of the adult values.

Polychlorinated biphenyls

The MOEs for children would be expected to be intermediate between those for adults and those for breastfed infants, owing to the initial contribution from breastfeeding and the subsequent lower dietary contribution compared with human milk. Because the MOEs are based on minimal effect doses, they were considered to give some assurance that dietary exposures to NDL-PCBs are unlikely to be of health concern for adults and children, based on the available data. For breastfed infants, the MOEs would be expected to be lower. However, based on present knowledge, the benefits of breastfeeding are considered to outweigh the possible disadvantages that may be associated with the presence of NDL-PCBs in breast milk.
The Committee recognized that there are similarities in some of the reported effects for NDL-PCBs and therefore that risk estimates for combined exposure are desirable. The Committee concluded that this cannot be done on the basis of currently available data. The Committee also noted that the end-point selected for derivation of the MOEs was particularly conservative, as it was not of clear toxicological significance, it was a minimal change, and the lowest doses at which it was seen were used for the point of departure, combined with upper-bound estimates of body burden.

PCBs in Natural Mineral Waters
The 2nd CCCF (2008) considered the proposed draft amendments to Section 3.2 "Health-Related Limits for Certain Substances" of the Codex Standard for Natural Mineral Waters, referred by the 8th CCNMW. The Committee also considered whether the health-related provision in Section 3.2 should be included in Schedule I of the GSCTF. It was pointed out that iron, zinc and copper had been considered as quality factors rather than safety factors and therefore the levels for those substances had been currently not included in Schedule I of the GSCTF. It was noted that some delegations believed that the level for copper was based on both safety and quality parameters of mineral water.
The Committee temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41, para. 23-27). After establishment of an EWG by CCCF4, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, para 89-90).

The Standard contains the following wording for Section 3.2 "Health-related limits for certain substances":
"The following substances shall be below the limit of quantification when tested, in accordance with the methods prescribed in Section 7: 3.2.18 Pesticides and PCBs"

PCBs are a class of stable chlorinated aromatic hydrocarbons which (mostly prior to the 1970s) have been produced since 1930 and used extensively in a wide range of industrial applications. One of the main uses which still persists is as dielectric and heat exchange fluids. Despite increasing withdrawal of the use and restrictions on the production, large amounts of PCBs continue to be present in the environment, either in use in existing industrial systems, or in waste materials, or dispersed as persistent pollutants. PCBs are mixtures of related chemicals which are formed by the chlorination of biphenyl. Theoretically, 209 congeners are possible; in practice about 130 are likely to occur in commercial products. Also related by-products are formed, such as polychlorinated dibenzofurans (PCDFs), and may be found in technical PCB-mixtures. Some of the trade names for technical PCB-mixtures as they were produced are Aroclor, Clophen, Kanechlor. The different congeners in PCB-mixtures can be designated by their IUPAC number, and different industrial PCB-mixtures can be characterized by their composition in terms of the relative percentages of the congeners. Degradation of PCBs in the environment depends on the degree of chlorination (higher chlorinated compounds are generally more persistent against photolytic, microbial and animal metabolic degradation) and on the position of the chlorine atoms in the molecule. All congeners are lipophilic and accumulate in the food chain.

PCBs were evaluated by IARC in 1978 and 1987. The conclusion was that PCBs are carcinogenic for laboratory animals and are probably carcinogenic for humans (IARC, 1987). Extensive documentation about PCBs is gathered in EHC 140 (WHO, 1993).

Polychlorinated biphenyls

The PCB-congeners that most easily adopt a co-planar configuration (the non-ortho substituted PCBs, numbers 77, 126 and 169) are potent Ah receptor agonists. Mono-ortho substituted PCBs are less potent but are included with a TEQ-factor for dioxin-like activity (nos 105, 114, 118, 123, 156, 157, 167, 189). Sometimes also PCB 81 and two di-ortho substituted PCBs (170 and 180) were included in the discussion about the TEF-approach for dioxins because of their ability to induce P4501A1 enzymes and their occurrence and persistence in the environment; they however were not incorporated in the WHO-recommendation about the TEF-approach for dioxin-related compounds (1998). The PCBs with a TEF form usually only a few percent of the total PCBs, but are relevant because of this specific toxicity, which can form an important contribution to the total TEQ for dioxins in a sample of food and in the human diet.

(NDL-PCBs)
Two linked benzene rings in which 1–10 chlorine atoms substitute the hydrogen atoms on the benzene rings comprise the class of chemicals known as PCBs. There are a total of 209 possible PCB congeners, based on the substitution positions along the phenyl rings. PCBs were intentionally produced in considerable amounts between the 1930s and 1970s and were used for a wide range of applications. Although there are 209 possible PCB congeners, of which 197 are NDL-PCBs, only about 130 have been reported in commercial mixtures. The congener profiles observed in commercial mixtures are not reflective of the congener profiles present in environmental compartments, food or human tissues. PCBs are thermally stable, persist in the environment and are found at large distances from their area of release. PCBs are lipophilic compounds and accumulate in the tissues of living organisms; they are taken up by humans primarily through the consumption of food, with foods of animal origin being the primary source of human exposure.

PCBs exhibit different toxicological effects depending on the site of chlorine substitution on the phenyl rings. The position of chlorine substitution on the ring structure is important, because the receptor interaction profile is highly dependent on it. Congeners having chlorine substitution in both para and at least two meta positions and also having zero or one chlorine atom present in an ortho position have the highest binding affinity for the aryl hydrocarbon receptor (AhR) and induce typical dioxin-like toxicity. These congeners, of which there are 12, are known as the DL-PCBs and have been assigned WHO toxic equivalency factors (TEFs). Congeners with two or more chlorine atoms in the ortho position are generally considered to be NDL-PCBs. The NDL-PCBs have a different spectrum of toxicological activity relative to DL-PCBs and PCDDs/ PCDFs. International bodies have identified seven PCBs that can be used to characterize the presence of PCB contamination. Six of these seven are NDLPCBs (PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180), and one is a DL-PCB (PCB 118). The six NDL-PCBs are often called “indicator PCBs”

Polycyclic aromatic hydrocarbons

Reference to JECFA:	37 (1990), 64 (2005)
Toxicological guidance value:	(Intake estimates for benzo[a]pyrene as marker for PAHs: mean 4 ng/kg bw/day; high 10 ng/kg b/day Margin of exposure (MOE): Cancer (BMDL for benzo[a]pyrene as marker for mixtures of PAHs 100 000 ng/kg bw/day), mean intake 25 000; high intake 10 000.)
Synonyms:	PAHs, Polynuclear aromatic hydrocarbons
Related code of practice:	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) Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

The 37th JECFA (1990) evaluated benzo[a]pyrene and recognized that it was one member of a family of PAHs that should be considered as a class. The most significant toxicological effect was carcinogenicity and it was noted that the estimated average daily intake of benzo[a]pyrene by humans was about four orders of magnitude lower than that reported to be without effect on the incidence of tumors in rats. However, the committee was unable to establish a tolerable intake for benzo[a]pyrene, based on the available data.

The 64th JECFA (2005) evaluated 33 compounds. Some were found to be clearly genotoxic and carcinogenic (benz[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, chrysene, dibenz[a,h]anthracene, dibenzo[a,e]pyrene, dibenzo[a,h]pyrene, dibenzo[a,l]pyrene, dibenzo[a,l]pyrene, indeno[1,2,3-cd]pyrene, 5-methylchrysene), whereas others were not. There is limited or no evidence on the reproductive toxicity of individual PAHs, other than benzo[a]pyrene, which showed impaired fertility in the offspring of female mice. Developmental toxicity after oral administration has been reported for benz[a]anthracene, benzo[a]pyrene, dibenz[a,h]anthracene and naphthalene. A NOEL for reproductive toxicity has not been established. Using parenteral administration, it was shown that PAHs exert immunosuppressive effects, probably via the Ah receptor. The NOEL for immunosuppressive effects of benzo[a]pyrene was 3 mg/kg bw/day. No quality data for humans are available.

To evaluate the combined toxicity of PAHs, the 64th JECFA decided to use a surrogate approach, with benzo[a]pyrene being used as a marker of exposure to, and effect of the 13 genotoxic and carcinogenic PAHs. A BMDL equivalent to 0.1 mg benzo[a]pyrene kg bw/day was derived for mixtures of PAHs in food. The committee concluded that a representative mean intake of benzo[a]pyrene of 0.004 µg/kg bw/day and high-level intake of 0.01 µg/kg bw/day could be used in the evaluation. Comparison of these mean and high-level intakes with the BMDL indicates MOEs of 25 000 and 10 000, respectively. Based on these MOEs, the committee concluded that the estimated intakes of PAHs were of low concern for human health. Measures to reduce intake of PAHs could include avoiding contact of foods with flames, and cooking with the heat source above rather than below the food. Efforts should be made to reduce contamination with PAHs during drying and smoking processes by replacing direct smoking (with smoke developed in the smoking chamber, traditionally in smokehouses) with indirect smoking. Washing or peeling fruit and vegetable before consumption would help to remove surface contaminants.

Recommendations by 64th JECFA:
- Future monitoring should include, but not be restricted to, analysis of the 13 PAHs identified as being genotoxic and carcinogenic.

Polycyclic aromatic hydrocarbons

The 37th CCFAC (2005) agreed to revise the discussion paper with particular attention to the 64th JECFA evaluation (ALINORM 05/28/12, para.199). The 38th CCFAC (2006) agreed to the elaboration of a Code of Practice for the reduction of PAH contamination in food and to limit its scope to smoking and direct drying process (ALINORM 06/29/12, para.187). An initial draft Code of Practice is to be considered at the 1st session of CCCF.

The 1st CCCF (2007) agreed to address smoke flavours in the introductory part only in the Code. The CCCF agreed to return the proposed draft Code of Practice to Step 2 for redrafting by an electronic working group led by Denmark with a view to circulation for comments at Step 3 and consideration at Step 4 at its next session (ALINORM 07/30/41, para. 102).

The 2ndCCCF (2008) agreed to forward the proposed draft Code of Practice to the 31st Session of the Codex Alimentarius Commission for adoption at Step 5. (ALINORM 08/31/41, para. 109)The 31st CAC adopted the proposed draft code and advanced it to Step 6 (ALINORM 08.31/REP, para. 65).

The 3rd CCCF (2009) agreed to forward the draft Code to the 32nd CAC for adoption at Step 8 (ALINORM 09/32/41, para. 67 and Appendix V). The 32nd CAC adopted the draft Code at Step 8 (ALINORM 09/32/REP, APPENDIX III).

PAHs in Natural Mineral Waters

The 2nd CCCF (2008) considered the proposed draft amendments to Section 3.2 “Health-Related Limits for Certain Substances” of the Codex Standard for Natural Mineral Waters, referred by the 8th CCNMW. The Committee also considered whether the health-related provision in Section 3.2 should be included in Schedule I of the GSCTF. It was pointed out that iron, zinc and copper had been considered as quality factors rather than safety factors and therefore the levels for those substances had been currently not included in Schedule I of the GSCTF. It was noted that some delegations believed that the level for copper was based on both safety and quality parameters of mineral water. The 2nd CCCF temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41, para. 23-27). After establishment of an EWG by CCCF4, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, paras 89-90).

The Standard contains the following wording for Section 3.2 “Health-related limits for certain substances”:
“The following substances shall be below the limit of quantification when tested, in accordance with the methods prescribed in Section 7: 3.2.20 Polynuclear aromatic hydrocarbons”.

Polycyclic aromatic hydrocarbons (PAHs) constitute a large class of organic compounds containing two or more fused aromatic rings. Foods can be contaminated by two major routes: firstly, by environmental PAHs present in air, soil and water; secondly, PAHs can be formed during processing (drying, smoking) or cooking (grilling, roasting, frying) of foods.

Absorption of dietary PAH is determined by size and lipophilicity of the molecule and the lipid content of the food. PAHs are metabolized by oxidation of the aromatic rings, followed by formation of glutathione, glucuronide and sulfate conjugates. Oxidation can generate electrophilic metabolites that bind covalently to nucleic acids and proteins. Some PAH and PAH metabolites bind to the aryl hydrocarbon (Ah) receptor, resulting in upregulation of enzymes involved in PAH metabolism.

The major foods containing higher concentrations of PAHs are meat and fish products, particularly grilled and barbecued products, oils and fats, cereals and dry foods.

Vinyl chloride monomer

Reference to JECFA:	28 (1984)
Toxicological guidance value:	Provisional Acceptance (1984, the use of food-contact materials from which vinyl chloride may migrate is provisionally accepted, on condition that the amount of the substance migrating into food is reduced to the lowest level technologically
Contaminant definition:	Vinyl chloride monomer
Synonyms:	Monochloroethene, chloroethylene; abbreviation VC or VCM
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the GL applies	Notes/Remarks	Notes for CCCF
Food	0.01	Adopted	2006	FAC		The GL in food packaging material is 1.0 mg/kg.	

Migration of possibly harmful substances from food contact materials has been discussed in the CCFA/CCFAC in the period 1986-1991.

Guideline levels for vinyl chloride monomer and acrylonitrile in food and packaging material were adopted by the CAC at its 19th session (1991) on the understanding that the AOAC International and the ISO would develop appropriate sampling plans and methods of analysis.

The 29th CAC (2006) adopted GSCTF, including Schedule 1 and revoked Guideline Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material (CAC/GL 6-1991) (ALINORM 06/29/41).

Vinyl chloride monomer is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods. Vinyl chloride is not known to occur as a natural product. Residues of vinyl chloride monomer may be still present in the polymer. Vinyl chloride is considered by IARC to be a human carcinogen (as has been shown in occupational exposure situations). IARC Vol. 19, 377-438 (1979)

Radionuclides

^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am

Contaminant definition: ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am

Commodity / Product Name	Guideline Level (GL) (Bq/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the GL applies	Notes/Remarks	Notes for CCCF
Foods other than infant foods	10	Adopted	2006	FAC			
Infant foods	1	Adopted	2006	FAC		The GL applies to foods intended for consumption by infants.	

See the textual part of the Guideline Levels for Radionuclides in Foods Contaminated Following A Nuclear or Radiological Emergency for Use in International Trade below.

The 38th CCFAC (2006) agreed to forward the newly-named proposed draft Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade to the 29th Session of the CAC for adoption at Step 5/8 (with the omission of Steps 6 and 7) and inclusion in the GSCTF. (ALINORM 06/29/12para. 198 and Appendix XXXI)
The 29th CAC (2006) adopted GSCTF, including Schedule 1 and revoked the Guideline Levels for Radionuclides in Foods following accidental Nuclear Contamination for use in International Trade (CAC/GL 5-1989)

Fact Sheet on Codex Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency was prepared by Codex Secretariat on 2 May, 2011.

The 6th CCCF (2012) agreed to establish an electronic Working Group led by the Netherlands and co-chaired by Japan to start new work on levels for radionuclides in food for comment at Step 3 and further consideration by the next session, subject to approval by the 35th Session of the Commission. The Working Group would:
• review the current guideline levels for radionuclides in food; and
• develop in connection with the review of the guideline levels, a clear guidance on the interpretation and application of the guideline levels (REP12/CF, paras. 169-171).

The 35th CAC (2012) approved new work on the proposed draft levels for radionuclides in food (REP12/CAC, para.145 and Appendix VI).

The 7th CCCF (2013) agreed not to change the current GLs to MLs for radionuclides in the GSCTFF as GLs provide countries flexibility to determine whether and under what conditions food could be distributed within their territory or jurisdiction; not to change the present approach using GLs for groups of radionuclides to be assessed independently; and not to change the current GL values in the GSCTFF and therefore to discontinue work on the revision of the GLs for radionuclides in food in the GSCTFF. Based on the information provided by the IAEA Representative on the ongoing work of the Inter-agency Working Group, the 7th CCCF further decided to discontinue work on the development of guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF. Along these lines, the 7th CCCF also agreed not to consider the appropriateness to develop additional GLs for drinking water for inclusion in the GSCTFF.
The 7th CCCF noted that after completion of the work carried out by the Inter-agency Working Group, the CCCF could decide to start new work on radionuclides as necessary (REP12/CF, paras. 51-53).

The 36th CAC (2013) approved discontinuation of work as summarized in Appendix VII (REP13/CAC, para. 130 and Appendix VII).

Radionuclides

^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am

The 8th CCCF (2014) agreed to establish an EWG led by the Netherlands and co-chaired by Japan to follow-up on the conclusions and recommendations of the Inter-Agency Working Group led by IAEA to determine the need and feasibility to pursue work on the following matters;
(i) the stage of food production to which the Codex guideline levels apply,
(ii) the period of time these GLs should apply in food trade following a nuclear or radiological emergency,
(iii) the identification of internationally validated methods of analysis for radionuclides in foods and
(iv) the development of sampling plans to enhance the implementation of the Codex GLs.
The Committee further agreed to request the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF for consideration at its 9th session. If further work is identified, proposals e.g. analytical methods, sampling plans, guidance, should be presented for consideration by the Committee (REP 14/CF, paras. 15-18).

The 9th CCCF (2015) welcomed the activities of IAEA in support of member countries to better deal with nuclear/radiological contamination at the national level and noted that the information contained in the TECDOC could be useful for future work on radionuclides within CCCF. The Committee further noted that the International Commission on Radiological Protection (ICRP) was reviewing dose coefficients for ingestion of radionuclides to assess public exposure and the associated health risk from intake of radionuclides in food. The review was expected to be finalised within 2-3 years. The Committee agreed to consider in future any work on guideline levels for radionuclides in food in the GSCTFF pending the outcome of the work of the ICPR on the review of dose coefficients for ingestion of radionuclides to assess public exposure and associated health risk due to intake of radionuclides in food (REP 15/CF, paras. 132-134)

Radionuclides

^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U

Contaminant definition: ^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U

Commodity / Product Name	Guideline Level (GL) (Bq/kg)	Step	Reference or Adoption year	Ref to CC Portion of the Commodity/Product to which the GL applies	Notes/Remarks	Notes for CCCF
Foods other than infant foods	100	Adopted	2006	FAC		
Infant foods	100	Adopted	2006	FAC	The GL applies to foods intended for consumption by infants.	

See the textual part of the Guideline Levels for Radionuclides in Foods Contaminated Following A Nuclear or Radiological Emergency for Use in International Trade below.

The 38th CCFAC (2006) agreed to forward the newly-named proposed draft Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade to the 29th Session of the CAC for adoption at Step 5/8 with the omission of Steps 6 and 7 and inclusion in the GSCTF (ALINORM 06/29/12, para. 198 and Appendix XXXI).
The 29th CAC (2006) adopted GSCTF, including Schedule 1 and revoked the Guideline Levels for Radionuclides in Foods following accidental Nuclear Contamination for use in International Trade (CAC/GL 5-1989).

Fact Sheet on Codex Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency was prepared by Codex Secretariat on 2 May, 2011.

The 6th CCCF (2012) agreed to establish an electronic Working Group led by the Netherlands and co-chaired by Japan to start new work on levels for radionuclides in food for comment at Step 3 and further consideration by the next session, subject to approval by the 35th Session of the Commission. The Working Group would:
• review the current guideline levels for radionuclides in food; and
• develop in connection with the review of the guideline levels, a clear guidance on the interpretation and application of the guideline levels (REP12/CF, paras. 169-171).

The 35th CAC (2012) approved new work on the proposed draft levels for radionuclides in food (REP12/CAC, para.145 and Appendix VI).

The 7th CCCF (2013) agreed not to change the current GLs to MLs for radionuclides in the GSCTFF as GLs provide countries flexibility to determine whether and under what conditions food could be distributed within their territory or jurisdiction; not to change the present approach using GLs for groups of radionuclides to be assessed independently; and not to change the current GL values in the GSCTFF and therefore to discontinue work on the revision of the GLs for radionuclides in food in the GSCTFF. Based on the information provided by the IAEA Representative on the ongoing work of the Inter-agency Working Group, the 7th CCCF further decided to discontinue work on the development of guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF. Along these lines, the 7th CCCF also agreed not to consider the appropriateness to develop additional GLs for drinking water for inclusion in the GSCTFF.
The 7th CCCF noted that after completion of the work carried out by the Inter-agency Working Group, the CCCF could decide to start new work on radionuclides as necessary (REP12/CF, paras. 51-53).

The 36th CAC (2013) approved discontinuation of work as summarized in Appendix VII (REP13/CAC, para. 130 and Appendix VII).

Radionuclides

^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U

The 8th CCCF (2014) agreed to establish an EWG led by the Netherlands and co-chaired by Japan to follow-up on the conclusions and recommendations of the Inter-Agency Working Group led by IAEA to determine the need and feasibility to pursue work on the following matters;
(i) the stage of food production to which the Codex guideline levels apply,
(ii) the period of time these GLs should apply in food trade following a nuclear or radiological emergency,
(iii) the identification of internationally validated methods of analysis for radionuclides in foods and
(iv) the development of sampling plans to enhance the implementation of the Codex GLs..
The Committee further agreed to request the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF for consideration at its 9th session. If further work is identified, proposals e.g. analytical methods, sampling plans, guidance, should be presented for consideration by the Committee (REP 14/CF, paras. 15-18).

The 9th CCCF (2015) welcomed the activities of IAEA in support of member countries to better deal with nuclear/radiological contamination at the national level and noted that the information contained in the TECDOC could be useful for future work on radionuclides within CCCF. The Committee further noted that the International Commission on Radiological Protection (ICRP) was reviewing dose coefficients for ingestion of radionuclides to assess public exposure and the associated health risk from intake of radionuclides in food. The review was expected to be finalised within 2-3 years. The Committee agreed to consider in future any work on guideline levels for radionuclides in food in the GSCTFF pending the outcome of the work of the ICPR on the review of dose coefficients for ingestion of radionuclides to assess public exposure and associated health risk due to intake of radionuclides in food (REP 15/CF, paras. 132-134)

Radionuclides

^{35}S, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir

Contaminant definition: ^{35}S, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir; ^{35}S represents the value for organically bound sulphur.

Commodity / Product Name	Guideline Level (GL) (Bq/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Foods other than infant foods	1000	Adopted	2006	FAC			
Infant foods	1000	Adopted	2006	FAC		The GL applies to foods intended for consumption by infants.	

See the textual part of the Guideline Levels for Radionuclides in Foods Contaminated Following A Nuclear or Radiological Emergency for Use in International Trade below.

The 38th CCFAC (2006) agreed to forward the newly-named proposed draft Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade to the 29th Session of the CAC for adoption at Step 5/8 (with the omission of Steps 6 and 7) and inclusion in the GSCTF. (ALINORM 06/29/12para. 198 and Appendix XXXI)
The 29th CAC (2006) adopted GSCTF, including Schedule 1 and revoked the Guideline Levels for Radionuclides in Foods following accidental Nuclear Contamination for use in International Trade (CAC/GL 5-1989).

Fact Sheet on Codex Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency was prepared by Codex Secretariat on 2 May, 2011.

The 6th CCCF (2012) agreed to establish an electronic Working Group led by the Netherlands and co-chaired by Japan to start new work on levels for radionuclides in food for comment at Step 3 and further consideration by the next session, subject to approval by the 35th Session of the Commission. The Working Group would:
• review the current guideline levels for radionuclides in food; and
• develop in connection with the review of the guideline levels, a clear guidance on the interpretation and application of the guideline levels (REP12/CF, paras. 169-171).

The 35th CAC (2012) approved new work on the proposed draft levels for radionuclides in food (REP12/CAC, para.145 and Appendix VI).

The 7th CCCF (2013) agreed not to change the current GLs to MLs for radionuclides in the GSCTFF as GLs provide countries flexibility to determine whether and under what conditions food could be distributed within their territory or jurisdiction; not to change the present approach using GLs for groups of radionuclides to be assessed independently; and not to change the current GL values in the GSCTFF and therefore to discontinue work on the revision of the GLs for radionuclides in food in the GSCTFF. Based on the information provided by the IAEA Representative on the ongoing work of the Inter-agency Working Group, the 7th CCCF further decided to discontinue work on the development of guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF. Along these lines, the 7th CCCF also agreed not to consider the appropriateness to develop additional GLs for drinking water for inclusion in the GSCTFF.
The 7th CCCF noted that after completion of the work carried out by the Inter-agency Working Group, the CCCF could decide to start new work on radionuclides as necessary (REP12/CF, paras. 51-53).

The 36th CAC (2013) approved discontinuation of work as summarized in Appendix VII (REP13/CAC, para. 130 and Appendix VII).

Radionuclides

^{35}S, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir

The 8th CCCF (2014) agreed to establish an EWG led by the Netherlands and co-chaired by Japan to follow-up on the conclusions and recommendations of the Inter-Agency Working Group led by IAEA to determine the need and feasibility to pursue work on the following matters;
(i) the stage of food production to which the Codex guideline levels apply,
(ii) the period of time these GLs should apply in food trade following a nuclear or radiological emergency,
(iii) the identification of internationally validated methods of analysis for radionuclides in foods and
(iv) the development of sampling plans to enhance the implementation of the Codex GLs..
The Committee further agreed to request the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF for consideration at its 9th session. If further work is identified, proposals e.g. analytical methods, sampling plans, guidance, should be presented for consideration by the Committee (REP 14/CF, paras. 15-18).

The 9th CCCF (2015) welcomed the activities of IAEA in support of member countries to better deal with nuclear/radiological contamination at the national level and noted that the information contained in the TECDOC could be useful for future work on radionuclides within CCCF. The Committee further noted that the International Commission on Radiological Protection (ICRP) was reviewing dose coefficients for ingestion of radionuclides to assess public exposure and the associated health risk from intake of radionuclides in food. The review was expected to be finalised within 2-3 years. The Committee agreed to consider in future any work on guideline levels for radionuclides in food in the GSCTFF pending the outcome of the work of the ICPR on the review of dose coefficients for ingestion of radionuclides to assess public exposure and associated health risk due to intake of radionuclides in food (REP 15/CF, paras. 132-134)

Radionuclides

^{3}H, ^{14}C, ^{99}Tc

Contaminant definition: ^{3}H, ^{14}C, ^{99}Tc; ^{3}H represents the value for organically bound tritium.

Commodity / Product Name	Guideline Level (GL) (Bq/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the GL applies	Notes/Remarks	Notes for CCCF
Foods other than infant foods	10000	Adopted	2006	FAC			
Infant foods	1000	Adopted	2006	FAC		The GL applies to foods intended for consumption by infants.	

See the textual part of the Guideline Levels for Radionuclides in Foods Contaminated Following A Nuclear or Radiological Emergency for Use in International Trade below.

The 38th CCFAC (2006) agreed to forward the newly-named proposed draft Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency for Use in International Trade to the 29th Session of the CAC for adoption at Step 5/8 (with the omission of Steps 6 and 7) and inclusion in the GSCTF (ALINORM 06/29/12para. 198 and Appendix XXXI).
The 29th CAC (2006) adopted GSCTF, including Schedule 1 and revoked the Guideline Levels for Radionuclides in Foods following accidental Nuclear Contamination for use in International Trade (CAC/GL 5-1989).

Fact Sheet on Codex Guideline Levels for Radionuclides in Foods Contaminated Following a Nuclear or Radiological Emergency was prepared by Codex Secretariat on 2 May, 2011.

The 6th CCCF (2012) agreed to establish an electronic Working Group led by the Netherlands and co-chaired by Japan to start new work on levels for radionuclides in food for comment at Step 3 and further consideration by the next session, subject to approval by the 35th Session of the Commission. The Working Group would:
• review the current guideline levels for radionuclides in food; and
• develop in connection with the review of the guideline levels, a clear guidance on the interpretation and application of the guideline levels (REP12/CF, paras. 169-171).

The 35th CAC (2012) approved new work on the proposed draft levels for radionuclides in food (REP12/CAC, para.145 and Appendix VI).

The 7th CCCF (2013) agreed not to change the current GLs to MLs for radionuclides in the GSCTFF as GLs provide countries flexibility to determine whether and under what conditions food could be distributed within their territory or jurisdiction; not to change the present approach using GLs for groups of radionuclides to be assessed independently; and not to change the current GL values in the GSCTFF and therefore to discontinue work on the revision of the GLs for radionuclides in food in the GSCTFF. Based on the information provided by the IAEA Representative on the ongoing work of the Inter-agency Working Group, the 7th CCCF further decided to discontinue work on the development of guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF. Along these lines, the 7th CCCF also agreed not to consider the appropriateness to develop additional GLs for drinking water for inclusion in the GSCTFF.
The 7th CCCF noted that after completion of the work carried out by the Inter-agency Working Group, the CCCF could decide to start new work on radionuclides as necessary (REP12/CF, paras. 51-53).

The 36th CAC (2013) approved discontinuation of work as summarized in Appendix VII (REP13/CAC, para. 130 and Appendix VII).

Radionuclides

^{3}H, ^{14}C, ^{99}Tc

The 8th CCCF (2014) agreed to establish an EWG led by the Netherlands and co-chaired by Japan to follow-up on the conclusions and recommendations of the Inter-Agency Working Group led by IAEA to determine the need and feasibility to pursue work on the following matters;

(i) the stage of food production to which the Codex guideline levels apply,
(ii) the period of time these GLs should apply in food trade following a nuclear or radiological emergency,
(iii) the identification of internationally validated methods of analysis for radionuclides in foods and
(iv) the development of sampling plans to enhance the implementation of the Codex GLs..
The Committee further agreed to request the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF for consideration at its 9th session. If further work is identified, proposals e.g. analytical methods, sampling plans, guidance, should be presented for consideration by the Committee (REP 14/CF, paras. 15-18).

The 9th CCCF (2015) welcomed the activities of IAEA in support of member countries to better deal with nuclear/radiological contamination at the national level and noted that the information contained in the TECDOC could be useful for future work on radionuclides within CCCF. The Committee further noted that the International Commission on Radiological Protection (ICRP) was reviewing dose coefficients for ingestion of radionuclides to assess public exposure and the associated health risk from intake of radionuclides in food. The review was expected to be finalised within 2-3 years. The Committee agreed to consider in future any work on guideline levels for radionuclides in food in the GSCTFF pending the outcome of the work of the ICPR on the review of dose coefficients for ingestion of radionuclides to assess public exposure and associated health risk due to intake of radionuclides in food (REP 15/CF, paras. 132-134).

Radionuclides

Scope: The Guideline Levels apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency[19]. These guideline levels apply to food after reconstitution or as prepared for consumption, i.e., not to dried or concentrated foods, and are based on an intervention exemption level of 1 mSv in a year.

Application: As far as generic radiological protection of food consumers is concerned, when radionuclide levels in food do not exceed the corresponding Guideline Levels, the food should be considered as safe for human consumption. When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. National governments may wish to adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply, e.g., in the case of wide-spread radioactive contamination. For foods that are consumed in small quantities, such as spices, that represent a small percentage of total diet and hence a small addition to the total dose, the Guideline Levels may be increased by a factor of 10.

Radionuclides: The Guideline Levels do not include all radionuclides. Radionuclides included are those important for uptake into the food chain; are usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods, and; could be accidentally released into the environment from typical installations or might be employed in malevolent actions. Radionuclides of natural origin are generally excluded from consideration in this document.

In the Table, the radionuclides are grouped according to the guideline levels rounded logarithmically by orders of magnitude. Guideline levels are defined for two separate categories “infant foods” and “other foods”. This is because, for a number of radionuclides, the sensitivity of infants could pose a problem. The guideline levels have been checked against age-dependent ingestion dose coefficients defined as committed effective doses per unit intake for each radionuclide, which are taken from the “International Basic Safety Standards” (IAEA, 1996)[20].

Multiple radionuclides in foods: The guideline levels have been developed with the understanding that there is no need to add contributions from radionuclides in different groups. Each group should be treated independently. However, the activity concentrations of each radionuclide within the same group should be added together[21].

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19 For the purposes of this document, the term “emergency” includes both accidents and malevolent actions.

20 Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Office, OECD Nuclear Energy Agency, Pan American Health Organization, World Health Organization (1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA, Vienna.

21 For example, if ^{134}Cs and ^{137}Cs are contaminants in food, the guideline level of 1000 Bq/kg refers to the summed activity of both these radionuclides.

ANNEX 1

SCIENTIFIC JUSTIFICATION FOR PROPOSED DRAFT REVISED GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Guideline Levels for Radionuclides in Foods and specifically the values presented in Table 1 above are based on the following general radiological considerations and experience of application of the existing international and national standards for control of radionuclides in food.

Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the Guideline Levels were issued by the Codex Alimentarius Commission in 1989[22] (CAC/GL 5-1989).

Infants and adults: The levels of human exposure resulting from consumption of foods containing radionuclides listed in Table 1 at the suggested guideline levels have been assessed both for infants and adults and checked for compliance with the appropriate dose criterion.

In order to assess public exposure and the associated health risks from intake of radionuclides in food, estimates of food consumption rates and ingestion dose coefficients are needed. According to Ref. (WHO, 1988) it is assumed that 550 kg of food is consumed by an adult in a year. The value of infant food and milk consumption during first year of life used for infant dose calculation equal to 200 kg is based on contemporary human habit assessments (F. Luykx, 1990[23]; US DoH, 1998[24]; NRPB, 2003[25]). The most conservative values of the radionuclide-specific and age-specific ingestion dose coefficients, i.e. relevant to the chemical forms of radionuclides which are most absorbed from the gastro-intestinal tract and retained in body tissues, are taken from the (IAEA, 1996).

Radiological criterion: The appropriate radiological criterion, which has been used for comparison with the dose assessment data below, is a generic intervention exemption level of around 1 mSv for individual annual dose from radionuclides in major commodities, e.g. food, recommended by the International Commission on Radiological Protection as safe for members of the public (ICRP, 1999)[26].

Naturally occurring radionuclides: Radionuclides of natural origin are ubiquitous and as a consequence are present in all foodstuffs to varying degrees. Radiation doses from the consumption of foodstuffs typically range from a few tens to a few hundreds of microsieverts in a year. In essence, the doses from these radionuclides when naturally present in the diet are unamenable to control; the resources that would be required to affect exposures would be out of proportion to the benefits achieved for health. These radionuclides are excluded from consideration in this document as they are not associated with emergencies.

One-year exposure assessment: It is conservatively assumed that during the first year after major environmental radioactive contamination caused by a nuclear or radiological emergency it might be difficult to readily replace foods imported from contaminated regions with foods imported from unaffected areas. According to FAO statistical data the mean fraction of major foodstuff quantities imported by all the countries worldwide is 0.1. The values in Table 1 as regards foods consumed by infants and the general population have been derived to ensure that if a country continues to import major foods from areas contaminated with radionuclides, the mean annual internal dose of its inhabitants will not exceed around 1 mSv (see Annex 2). This conclusion might not apply for some radionuclides if the fraction of contaminated food is found to be higher than 0.1, as might be the case for infants who have a diet essentially based on milk with little variety.

Long-term exposure assessment: Beyond one year after the emergency the fraction of contaminated food placed on the market will generally decrease as a result of national restrictions (withdrawal from the market), changes to other produce, agricultural countermeasures and decay.

Experience has shown that in the long term the fraction of imported contaminated food will decrease by a factor of a hundred or more. Specific food categories, e.g. wild forest products, may show persistent or even increasing levels of contamination. Other categories of food may gradually be exempted from controls. Nevertheless, it must be anticipated that it may take many years before levels of individual exposure as a result of contaminated food could be qualified as negligible.

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22 The Codex Alimentarius Commission at its 18th Session (Geneva 1989) adopted Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989) applicable for six radionuclides (^{90}Sr, ^{131}I, ^{137}Cs, ^{134}Cs, ^{239}Pu and ^{241}Am) during one year after the nuclear accident.

23 F. Luykx (1990) Response of the European Communities to environmental contamination following the Chernobyl accident. In: Environmental Contamination Following a Major Nuclear Accident, IAEA, Vienna, v.2, 269-287.

24 US DoHHS (1998) Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. Food and Drug Administration, Rockville.

25 K. Smith and A. Jones (2003) Generalized Habit Data for Radiological Assessments. NRPB Report W41.

26 International Commission on Radiological Protection (1999). Principles for the Protection of the Public in Situations of Prolonged Exposure. ICRP Publication 82, Annals of the ICRP.

ANNEX 2

ASSESSMENT OF HUMAN INTERNAL EXPOSURE WHEN THE GUIDELINE LEVELS ARE APPLIED

For the purpose of assessment of the mean public exposure level in a country caused by the import of food products from foreign areas with residual radioactivity, in implementing the present guideline levels the following data should be used: annual food consumption rates for infants and adults, radionuclide- and age-dependent ingestion dose coefficients and the import/production factors. When assessing the mean internal dose in infants and adults it is suggested that due to monitoring and inspection the radionuclide concentration in imported foods does not exceed the present guideline levels. Using cautious assessment approach it is considered that all the foodstuffs imported from foreign areas with residual radioactivity are contaminated with radionuclides at the present guideline levels.

Then, the mean internal dose of the public, E (mSv), due to annual consumption of imported foods containing radionuclides can be estimated using the following formula:

$$E = GL(A) \cdot M(A) \cdot e_{ing}(A) \cdot IPF$$

where:

GL(A) is the Guideline Level (Bq/kg)

M(A) is the age-dependent mass of food consumed per year (kg)

$e_{ing}(A)$ is the age-dependent ingestion dose coefficient (mSv/Bq)

IPF is the import/production factor[27] (dimensionless).

Assessment results presented in Table 2 both for infants and adults demonstrate that for all the twenty radionuclides doses from consumption of imported foods during the 1st year after major radioactive contamination do not exceed 1 mSv. It should be noted that the doses were calculated on the basis of a value for the IPF equal to 0.1 and that this assumption may not always apply, in particular to infants who have a diet essentially based on milk with little variety.

It should be noted that for ^{239}Pu as well as for a number of other radionuclides the dose estimate is conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life (ICRP, 2005[28]). For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for ^{3}H, ^{14}C, ^{35}S, iodine and cesium isotopes.

As an example, dose assessment for ^{137}Cs in foods is presented below for the first year after the area contamination with this nuclide.

For adults: $E = 1000 \text{ Bq/kg} \cdot 550 \text{ kg} \cdot 1.3 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.7 \text{ mSv}$;
For infants: $E = 1000 \text{ Bq/kg} \cdot 200 \text{ kg} \cdot 2.1 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.4 \text{ mSv}$

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27 The import/production factor (***IPF***) is defined as the ratio of the amount of foodstuffs imported per year from areas contaminated with radionuclides to the total amount produced and imported annually in the region or country under consideration.

28 International Commission on Radiological Protection (2005) Doses to Infants from Radionuclides Ingested in Mothers Milk. To be published.

TABLE2.

ASSESSMENT OF EFFECTIVE DOSE FOR INFANTS AND ADULTS FROM INGESTION OF IMPORTED FOODS IN A YEAR

Radionuclide	Guideline Level (Bq/kg)		Effective dose (mSv)	
	Infant foods	Other foods	1st year after major contamination	
			Infants	Adults
^{238}Pu	1	10	0.08	0.1
^{239}Pu			0.08	0.1
^{240}Pu			0.08	0.1
^{241}Am			0.07	0.1
^{90}Sr	100	100	0.5	0.2
^{106}Ru			0.2	0.04
^{129}I			0.4	0.6
^{131}I			0.4	0.1
^{235}U			0.7	0.3
^{35}S*	1000	1000	0.2	0.04
^{60}Co			1	0.2
^{89}Sr			0.7	0.1
^{103}Ru			0.1	0.04
^{134}Cs			0.5	1
^{137}Cs			0.4	0.7
^{144}Ce			1	0.3
^{192}Ir			0.3	0.08
^{3}H**	1000	10000	0.002	0.02
^{14}C			0.03	0.3
^{99}Tc			0.2	0.4

* This represents the value for organically bound sulphur.

** This represents the value for organically bound tritium.

See for “Scientific justification for the Guideline Levels” (Annex 1) and the “Assessment of human internal exposure when the Guideline Levels are applied” (Annex 2).

Quality factors

Copper

Reference to JECFA: 10 (1966), 14 (1970), 26 (1982)
Toxicological guidance value: PMTDI 0.05-0.5 mg/kg bw (1982)
Contaminant definition: Copper, total
Synonyms: Cu

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Edible fats and oils, refined (not covered by individual standards)	0.1	Adopted	CS 19-1981	FO		This quality factors is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Edible fats and oils, virgin(not covered by individual standards)	0.4	Adopted	CS 19-1981	FO		This quality factors is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Edible fats and oils, cold pressed fats and oils (not covered by individual standards)	0.4	Adopted	CS 19-1981	FO		This quality factors is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Named animal fats	0.4	Adopted	CS 211-1999	FO		Lard, rendered pork fat, premier jus and edible tallow. This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.	1)
Vegetable oils, Crude	0.4	Adopted	CS 210-1999,	FO		Named vegetable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	OC 0172

Quality factors

Copper

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Named Vegetable oils, refined	0.1	Adopted	CS 210-1999	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	OR 0172 1)
Named vegetable oils, virgin	0.4	Adopted	CS 210-1999	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Olive oils and olive-pomace oils	0.1	Adopted	CS 33-1981	FO		These quality and composition factors are supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet these supplementary factors, may still conform to the standard.	
Milkfat products	0.05	Adopted	CS 280-1973	MMP		This limit applys to anhydrous milkfat, milkfat, anhydrous butteroil and butter oil and ghee.	
Casein products	5	Adopted	CS 290-1995	MMP		This limit appys to edible acid casein, edible rennet caein and edible caseinate, intented for direct consumption or further processing.	
Natural mineral waters	1 mg/l	Adopted	CS 108-1981	NMW, CF			

1) The revised Standards for oils and fats contain the following wording for the mentioned contaminant MLs: “The products covered by the provisions of this Standard shall comply with MLs being established by the CAC but in the meantime the following limits will apply.”

Copper as cupric sulfate has been evaluated by JECFA in 1966, 1970, and 1982. The PMTDI was established to be 0.05-0.5 mg/kg bw. A provisional guidance value of 0.5 mg/kg bw/day was proposed in 1966 on the understanding that a very considerable margin appeared to exist between normal intakes and those that could lead to chronic copper poisoning, and that the dietary levels of those constituents such as molybdenum and zinc, which are known to affect copper metabolism, lie within normal limits. The 26th JECFA concluded in 1970 from more recent food analyses that the daily intake of 20 mg was likely to be exceeded by significant sections of the population with no apparent deleterious effects. On this basis the tentative assessment of the maximum acceptable daily load of 0.5 mg/kg bodyweight was retained. The 26th JECFA reaffirmed the provisional value based on the same rationale.

Quality factors

Copper

In EHC 200 (1998)it was concluded that the upper limit of the acceptable range of oral intake (AROI) in adults is uncertain but is most likely in the range of several but not many mg/day in adults (several meaning more than 2 or 3 mg/day). This evaluation was based solely on studies of gastrointestinal effects of copper-contaminated drinking water. The available data on toxicity in animals were not considered helpful in establishing the upper limit of the AROI due to uncertainty about an appropriate model for humans, but they help to establish a mode of action for the response.

WHO established a drinking water guideline of 2 mg/liter in 2003, based on the 1993 Guidelines for Drinking Water Quality, 2nd edition, where a provisional health-based guideline value of 2 mg/liter for copper was derived from the PMTDI of 0.5 mg/kg bw/day as proposed by JECFA in 1982. The document mentioned that this PMTDI was based on a rather old study in dogs, that did not take into account differences in copper metabolism between infants and adults, but this rationale could not be found in the JECFA evaluation of 1982 (see above).

Copper in Natural Mineral Waters

The 2nd CCCF (2008) considered the proposed draft amendments to Section 3.2 “Health-Related Limits for Certain Substances” of the Codex Standard for Natural Mineral Waters, referred by the 8th CCNMW. The Committee also considered whether the health-related provision in Section 3.2 should be included in Schedule I of the GSCTF. It was pointed out that iron, zinc and copper had been considered as quality factors rather than safety factors and therefore the levels for those substances had been currently not included in Schedule I of the GSCTF. It was noted that some delegations believed that the level for copper was based on both safety and quality parameters of mineral water. The 2nd CCCF temporarily endorsed the section pending elaboration of appropriate methods of analyses by CCMAS and decided to postpone the decision on inclusion of those substances in the GSCTF (ALINORM 08/31/41, para. 23-27). After establishment of an EWG by 4th CCCF, the 5th CCCF (2011) agreed to inform the Commission to remove the footnote which indicated the temporary endorsement (footnote 3) from the Standard on Natural Mineral Waters (CODEX STAN 108-1981) as there was no need for the endorsement of these sections since there was no safety concern associated with these compounds at the proposed levels. The Committee did not integrate the levels in the GSCTFF (REP11/CF, para 89-90).

Copper is both an essential nutrient and a drinking-water contaminant. It has many commercial uses. It is used to make pipes, valves and fittings and is present in alloys and coatings. Copper sulfate pentahydrate is sometimes added to surface water for the control of algae. Dissolved copper can sometimes impart a light blue or blue-green colour and an unpleasant metallic, bitter taste to drinking-water.

Dietary copper intake will vary with the types of food consumed, the condition of the soils the foods are produced on (e.g. copper content) and drinking-water characteristics. Copper is ubiquitously distributed in foods, but the richest sources of copper in food are liver, seafood (especially shellfish and crustaceans), grains, cereal products and potatoes, which contribute to about 65% of total dietary intake. Also, drinking-water may contribute for a considerable part to the total daily intake of copper. The average daily intake of copper has been estimated to range from 0.5 to 0.7 mg for infants 6 months of age or less up to 2-3 mg for adults, however this level is likely to be exceeded in arid areas where there may be a high intake of water containing high levels of copper.

Sensitivity to the toxic effects of excess dietary copper is influenced by its chemical form, species, and interaction with other dietary minerals. High levels can cause symptoms of acute toxicity, including nausea, abdominal discomfort (diarrhea), emesis, haemoglobinuria and/or haematuria, jaundice, oliguria/anuria, hypotension, coma and death. Histopathological effects were observed in the gastrointestinal tract, liver and kidney. WHO (1974) concluded that the fatal oral human dose is about 200 mg/kg. There is limited information on chronic copper toxicity. However, copper does not appear to be a cumulative toxic hazard for man, except for individuals suffering from Wilson’s disease. Copper is not considered to be mutagenic, carcinogenic or affect reproduction. Teratogenicity/embryotoxicity is observed in some animal studies.

Quality factors

Iron

Reference to JECFA: 27 (1983)

Toxicological guidance value: PMTDI 0.8 mg/kg bw (1983, Group PMTDI, applies to iron from all sources except for iron oxides used as colouring agent, supplemental iron taken during pregnancy and lactation, and supplemental iron for specific clinical requirements)

Contaminant definition: Iron, total

Synonyms: Fe

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Edible fats and oils, refined (not covered by individual standards)	2.5	Adopted	CS 19-1981	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Edible fats and oils, virgin (not covered by individual standards)	5.0	Adopted	CS 19-1981	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Edible fats and oils, cold pressed (not covered by individual standards)	5.0	Adopted	CS 19-1981	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Named vegetable oils, virgin	5.0	Adopted	CS 210-1999	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	OC 0172

Quality factors

Iron

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
Named vegetable oils, refine	1.5	Adopted	CS 210-1999	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	OR 0172
Crude palm kernel olein	5.0	Adopted	CS 210-1999	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Crude palm kernel stearin	7.0	Adopted	CS 210-1999	FO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Olive oils and olive-pomace oils	3	Adopted	CS 33-1981	PO		This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Named animal fats	1.5	Adopted	CS 211-199	FO		Lard, rendered pork fat, premier jus and edible tallow. This quality factor is supplementary information to the essential composition and quality factors of the standard. A product, which meets the essential quality and composition factors but does not meet this supplementary factor, may still conform to the standard.	
Milkfat products	0.2	Adopted	CS 280-1973	MMP		This limit applys to anhydrous milkfat, milkfat, anhydrous butteroil and butter oil and ghee.	
Casein products	20	Adopted	CS 290-1995	MMP		50 mg/kg in roller dried caseinates. This limit appys to edible acid casein, edible rennet caein and edible caseinate, intented for direct consumption or further processing.	

Quality factors

Iron

Iron has been evaluated by JECFA in 1983. The PMTDI is established to 0.8 mg/kg bw as a precaution against storage in the body of excessive iron. (Hydrated) iron oxides have been evaluated by JECFA in 1974, 1978 and 1979 (based on their use as colouring agents). An ADI of 0.5 mg/kg bw was established for these iron forms.

WHO did not propose a health-based guideline value for iron in drinking-water 1993 Guidelines for Drinking Water Quality, but it was mentioned that a value of about 2 mg/litre can be derived from the PMTDI established in 1983 by JECFA as a precaution against storage in the body of excessive iron.

Iron is one of the most abundant metals in the Earth's crust. It is found in natural fresh waters at levels ranging from 0.5 to 50 mg/liter. Iron may also be present in drinking-water as a result of the use of iron coagulants or the corrosion of steel and cast iron pipes during water distribution.

Iron is an essential trace element required by all forms of life. In man it is required for the synthesis of haem proteins and in many enzyme systems. Various groups (male, female, children, pregnant, lactating) differ in requirement for iron, iron deficiency is one of the most common nutritional deficiencies in children, in women of child bearing age, and pregnant women. It rarely occurs in adult men, except in cases of chronic bleeding.

Iron occurs as a natural constituent of all foods of plant and animal origin, and may also be present in drinking water. In food it occurs as iron oxides, inorganic and organic salts or organic complexes such as haem iron. Processing may affect the chemical form of iron. Levels of iron range from low for many fruits, vegetables and fats, to medium for red meats, chicken, eggs, whole wheat flower, to high for organ tissues, fish, green vegetables and tomatoes. Meat and grain contribute to a great part of diet-derived iron. Other important dietary sources include water, beverages and iron medication. The average daily intake of iron has been estimated to be 17 mg/day for males and 9-12 mg/day for females. Iron fortification of food, but also contamination of food during its preparation (iron-rich soil) could increase the intake of iron. The chemical form of the dietary iron is important for determining the amount of iron available for absorption, but also the source of iron (plant or animal), its interaction with other food components and the body's need for iron (mucosal regulation) affect absorption.

The effects of toxic doses of iron in animal studies are characterized by initial depression, coma, convulsion, respiratory failure and cardiac arrest. Post-mortem examination reveals adverse effects on the gastrointestinal tract. No long-term feeding studies are available, however, injection-site tumors have been observed in several animal studies after injection with iron preparations. Some iron-forms were found positive in mutagenicity tests. No teratogenic effects or effects on reproduction were observed.

In human, acute toxicity of iron ingested from normal dietary sources has not been reported; the amount of iron absorbed in normal subjects is subject to mucosal regulation so that excessive iron is not stored in the body. However, subjects with impaired ability to regulate iron absorption (i.e. suffering from idiopathic haemochromatosis), will be at risk from excessive exposure to iron. Excess iron intake may result in siderosis (deposition of iron in tissue) in liver, pancreas, adrenals, thyroid, pituitary and heart depending on the chemical form. Haemochromatosis patients suffer from liver cirrhosis, adrenal insufficiency, heart failure or diabetes. It is unknown whether excessive iron in the diet of individuals with impaired ability to regulate iron absorption will accelerate the clinical symptoms of the disease or increase the incidence of preclinical haemochromatosis.

Quality factors

Zinc

Reference to JECFA:	10 (1966), 26 (1982)
Toxicological guidance value:	PMTDI 0.3-1 mg/kg bw (1982)
Contaminant definition:	Zinc, total
Synonyms:	Zn

Commodity / Product Name	Level (mg/kg)	Step	Reference or Adoption year	Ref to CC	Portion of the Commodity/Product to which the ML applies	Notes/Remarks	Notes for CCCF
	No ML						

Zinc has been evaluated by JECFA in 1966 and 1982. The PMTDI is established to 0.3-1 mg/kg bw, based on clinical studies in which up to 600 mg of zinc sulfate (equivalent to 200 mg elemental zinc) has been administered daily in divided doses for a period of several months, without any reported adverse effects, including effects on blood counts and serum biochemistry. There is a wide margin between nutritionally required amounts of zinc and toxic levels.

WHO proposed in 2003 that, taking into account recent studies on humans, the derivation of a guideline value was not required at the time. It was stated however, that drinking-water containing zinc at levels above 3 mg/litre may not be acceptable to consumers based on taste considerations.

Zinc is a ubiquitous metal present in the environment, most rocks and many minerals contain zinc which can be used for the zinc industry. Zinc is utilized as protective coating of other metals, dye casting, construction industry, for alloys, dry cell batteries, dental, medical and household applications, fungicide, topical antibiotics and lubricants. Natural emissions results from erosion and forest fires. Anthropogenic sources are mining, zinc production facilities, iron and steel production, corrosion of galvanized structures, coal and fuel combustion, waste disposal and the use of zinc-containing fertilizers and pesticides.

Zinc is an essential trace element; the requirement for zinc changes throughout life and health effects associated with zinc deficiency are numerous. Zinc occurs as a natural constituent in all plant and animal tissues and functions as an integral part of several enzyme systems. Protein foods are important dietary sources of zinc. Levels range from high for oysters with lesser amounts in other seafood, muscle meats, nuts, whole cereals. Sugar, citrus fruits and non-leafy vegetables are poor sources of zinc. The interaction with other dietary factors affects the absorption of zinc. The average daily intake of zinc has been estimated to be maximally 20 mg/day for adults.

In animal studies, zinc in toxic doses caused weakness, anorexia, anemia, diminished growth, loss of hair, lowered food utilization, changes in the levels of liver and serum enzymes, morphological and enzymatic changes in the brain, and histological and functional changes in the kidney. The haematopoietic system, kidney and pancreas were found to be the target organs after long-term oral exposure to zinc. Genotoxicity tests failed to prove that zinc is mutagenic and only (very) high levels of zinc showed teratogenic effects or effects on reproduction.

In human, high levels of zinc cause acute effects such as vomiting and gastrointestinal irritation (nausea, cramps, diarrhea), however when bound to food components (i.e. meat, oysters) these effects are expected to be less. No information is available on toxic effects in man due to chronic excessive intake of zinc, however impaired copper uptake in humans has been noted following the chronic elevated intake of zinc. Some effects of zinc therefore may be secondary to impaired copper utilization (i.e. anemia).