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CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 12 **CX/CF 14/8/12**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Eighth Session
The Hague, The Netherlands, 31 March – 4 April 2014

EDITORIAL AMENDMENTS TO THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

BACKGROUND

1. At the 3rd Session of the Committee on Contaminants in Foods (CCCF) (March 2009), the Committee agreed to discontinue work on the food categorization system to be used for the purpose of the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) (GSCTFF), but to instead provide a clear description of the food/feed for which a maximum level (ML) or guideline level (GL) applies and to screen the existing MLs and GLs provided for in Schedule I of the GSCTFF to provide where necessary a clearer description of the food/feed to which the ML or GL applies.[1]

2. At the 4th Session of the CCCF (April 2010), the Committee agreed to establish an electronic Working Group (eWG), working in English, led by the European Union to prepare proposals on description for commodities in the GSCTFF for consideration at the next session of the CCCF.[2]

3. In preparation of the 6th Session of the CCCF (March 2012), a first draft of the proposed editorial amendments was circulated to the members of the eWG. All comments received were integrated into a revised version. Due to time constraints, the revised version were not re-circulated to the members of the eWG for final agreement but was sent directly to the Codex Secretariat for transmission to all Codex members in view of the discussion at the 6th Session of the CCCF.

4. At the 6th Session, several delegations noted that some editorial changes were not necessarily editorial and that due to the late distribution of the document they had not had an opportunity to consider all the changes proposed and to ascertain their implications on the MLs listed in the GSCTFF and therefore proposed that the document be referred back to the eWG for further development and comments.

5. The Committee therefore agreed to re-establish the eWG led by the European Union to work on the above-mentioned issues including those indicated in working document CX/CF 12/6/11 in order to present a revised proposal for consideration by the next session of the Committee.[3]

6. For the elaboration of the working document to be discussed at the 7th session of the CCCF (April 2013), the delegation of Japan provided the Chair of the eWG with a proposal for a separate list with an extensive description of all the different commodities and or products referred to in the GSCTFF with a reference number for the different commodities. The detailed definition of the commodities or products was taken from the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) or from the commodity standards. In the GSCTFF, a new column would be created for referring to the reference number of the separate list with an extensive description of all different commodities and or products.

7. The Chair of the eWG was of the opinion that it would be more appropriate to describe this approach in detail in the explanatory notes to Schedule I of the GSCTFF instead of creating a separate list of commodities. This approach has as advantage that every update of commodity standards or of the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) are automatically applicable to the relevant provisions in the GSTFF.

8. Due to time constraints, the revised version was not circulated to the members of the eWG for comments prior to the 7th session of the CCCF but was sent directly to the Codex Secretariat for transmission to all Codex members in view of the discussion at the 7th Session of the CCCF.

9. At the 7th Session, the Committee generally supported the recommendations of the in-session working group (in-session WG) provided for in CRD 28 related to the application of the current approach to describe commodities in the GSCTFF; the need for time to consider the amendments proposed in CX/CF 13/7/13 while recognizing that progress had already been made in the revision of the food descriptors; and the need to re-establish the eWG to continue work on the editorial revision with a view to their finalization at the next session of the CCCF.

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[1] ALINORM 09/32/41, para. 37.
[2] ALINORM 10/33/41, paras. 119 - 123.
[3] REP12/CF, paras. 97 – 106.

10. The following the recommendations of the in-session WG (and of immediate relevance for the elaboration of this document) were submitted to the Plenary for discussion:

a) to agree that the clear description of the feed/food is achieved by:

- in case reference is made to a commodity standard in the column "Reference", the ML/GL applies to the commodity (ies)/product within the scope of the commodity standard and the definition of the commodity/product is the definition as provided in the commodity standard.
- in case of raw agricultural commodities the definition of the commodity or product is provided in the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993), unless otherwise specified. The portion of the feed and food to which the ML or GL applies, is the portion defined in the Classification, unless otherwise specified in the Schedule I of GSCTFF.
- for the other products/commodities, in case of need, the clear description has to be provided in the Schedule I of GSCTFF.

b) to discuss the appropriateness of referring in certain cases to the commodity codes as used in the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) in the "reference" column of the Schedule I of the GSCTFF and to conclude on it.

11. The Committee generally supported the recommendations of the in-session WG related to the application of the current approach to describe commodities in the GSCTFF.

12. The Committee agreed to re-establish the eWG led by the European Union and co-chaired by the Netherlands, working in English, to prepare a revised version of the editorial amendments to the GSCTFF for comments and consideration at the next session of the CCCF. The document should be revised taking into account changes suggested by the Committee, and should be circulated as soon as possible to the members of the eWG for comments. A revised draft GSCTFF would then be circulated to all members and observers for comments by end of September 2013.[4]

13. The revised relevant parts of the GSCTFF (Annexes II and III) are presented in Appendix I. The list of participants is provided in Appendix II.

14. The Committee is invited to consider the editorial amendments proposed by the Electronic Working Group in particular those points for discussion highlighted in the document in order to finalize the editorial amendments to the GSCTFF.

EXPLANATORY NOTES TO THE PROPOSED AMENDMENTS

15. The following general principles were applied to the proposed amendments:

- Proposed changes are editorial and do not change the substance of the current provisions in the GSCTFF.
- Commodity codes are no longer used and the column titled "commodity codes" has been deleted from the tables.
- Reference to withdrawn commodity standards has been deleted.
- Maximum levels (MLs) or guideline levels (GLs) which were established in the commodity standard have been deleted in cases where the relevant commodity standards were withdrawn.
- Commodity standards are referred to only if they are still valid in Codex and contain MLs or GLs for contaminants or if they contain a general reference to the GSCTFF.
- Commodity standards are referred to by the Codex reference number (e.g. CODEX STAN number-year adopted).
- The column titled "Suffix" has been deleted as it was only used for tin and the information has been included in the column titled "Notes/remarks".
- The column titled "Type" has been replaced by the column titled "Maximum Level (ML) or Guideline Level (GL)" depending on the type of level established by Codex.
- As no reference is made to the commodity code nor to the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993), a new column has been inserted titled "Portion of the Commodity/Product to which the ML or GL Applies." In cases where there was specific reference to the portion to which the ML applies in the column titled "Notes/remarks", this information has been moved to the column titled "Portion of the Commodity/Product to which the ML Applies".
- A general provision has been included in the explanatory notes section that indicates that when reference is made to a specific commodity standard, the product to which the ML or GL applies is described in the referenced commodity standard.
- Furthermore, in case the ML applies to group of products (e.g. leafy vegetables, bulb vegetables, etc.), the products referred to are described in the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993).
- Wherever possible, overlap and clarification has been provided and the existing provisions simplified without changing the substance of the provisions.

[4] REP13/CF paras. 97 - 103.

- Decisions made by the Codex Alimentarius Commission at its 36th meeting (July 2013) are included in the draft proposal.
- **Given that abovementioned amendments to the GSCTFF include changes to the format of the GSCTFF there is a need to amend the Annex II of the GSCTFF which determines the elements which the format for Schedule shall contain. A proposal for a revised Annex II to the GSCTFF is provided in ANNEX II to this document.**
- **A proposal for a revised Schedule I to the GSCTFF is provided in ANNEX III to this document.**

Point of discussion: Necessity of keeping the (short) information notes on the substance provided at the end of the provisions of certain contaminants in Schedule I

- In the case of aflatoxins total, patulin, arsenic, cadmium, mercury, methylmercury, tin, acrylonitrile and vinylchloride Monomer a short information note is given at the end of the provisions on the substance.
- Such information is not provided for aflatoxin M1, ochratoxin A, lead, chloropropanols, hydrocyanic acid and melamine. The need to maintain these information notes was questioned as they are not necessary for the Schedule I, there is no information note in Schedule I for each contaminant covered by Schedule I, the information notes provided are divergent in the nature of the information provided (sometimes very basic, sometimes a bit more extensive).
- At each CCCF meeting, a document is presented namely "Document for information and use in discussions related to contaminants and toxins of the GSCTFF" (reference of the document at the 8th session of the CCCF is CF/8 INF/1, general reference is CF/Number of the CCCF session INF/1) which contains that information.
- This information is not of immediate relevance for the provisions in Schedule I.
- Within the eWG, there were divergent views as regards the necessity to keep the information notes. A majority of the views expressed within the eWG was in favour of keeping the information notes.

16. Editorial changes to the provisions on aflatoxins total

- Necessary to define that ML applies to peanuts for human consumption, although less relevant maybe also appropriate for the tree nuts → taken care of the explanatory notes at the beginning of Schedule I.
- Inclusion of the definitions for "for further processing" and "ready-to-eat". It is found appropriate to maintain the definitions in the table given the importance for the application of the maximum level. One member of the eWG was of the opinion that it was not necessary to mention the definitions again as the definitions are already mentioned in the sampling plan.
- Definition of intended for further processing is not foreseen for peanuts → proposed to align it with the definition of intended for further processing as foreseen for tree nuts.
- Proposed to include besides hazelnuts also explicitly filberts and make reference to it in the column "Notes/Remarks".
- The ML for aflatoxin total in dried figs adopted by the Codex Alimentarius Commission at its 35th Session (July 2012) with the associated sampling plan has been added to the Standard.
- Comment was made to delete the term "shelled" for Brazil nuts as the portion to be analysed is mentioned as "Whole commodity after removal of shell". However following the discussions in the CCCF, it was clear that the ML only applies to shelled Brazil nuts (and not to Brazil nuts in shell). Therefore, despite the views from one member of the eWG, it is proposed to keep "shelled Brazil nuts" but the portion to be analysed in that case "Whole commodity" (as the ML refers only to shelled Brazil nuts).
- Provisions re-ordered in alphabetical order.
- The sampling plan for aflatoxin contamination in dried figs as adopted by Codex still refers on several occasions to the "proposed draft sampling plan". It seems appropriate to delete each time "proposed draft" as suggested in Annex 3 to the maximum levels for aflatoxin total.
- **Point of discussion:** The following comment was made as regards the sampling plans for aflatoxins. For almonds, hazelnuts, pistachios and shelled Brazil nuts and for dried figs operating characteristic curves describing the performance of the sampling plans are provided. No such operating characteristic curve is provided for the sampling plan for peanuts intended for further processing. These operating characteristic curves are very important when discussing the appropriate sampling plan, but it is **questioned to which extent these operating characteristic curves are still necessary in the adopted sampling plan**. The views within the eWG were divergent but the majority of the eWG was in favour of keeping the operating characteristic curves describing the performance of the sampling plans in the sampling plans.
- **Point of discussion: The need for keeping the references to the scientific studies in the sampling plans was questioned.** The following comment was made: In the adopted Codes of Practice it is usual to delete the references to scientific literature/studies. It is questioned to which extent the references (in footnotes) to scientific studies/reports in the adopted sampling plans can be deleted with minor adaptation of the text of the sampling plan (removal of reference/ replacing by some wording /or by a link) and without a change in substance.

  The views within the eWG were divergent but the majority of the eWG was in favour of keeping the references in the sampling plans.

17. Editorial changes to the provisions on aflatoxin M1

- Addition of a related Code of Practice
- Necessary to better define what is meant by milk → proposed to apply the definition for "milk" as provided for in the *Standard for the use of Dairy Terms* (CODEX STAN 206-1999).
- The ML applies to milk for human consumption → taken care of the explanatory notes at the beginning of Schedule I

18. Editorial changes to the provisions on ochratoxin A

- Adding the reference to the *Code of Practice for the prevention and reduction of ochratoxin A contamination in cocoa* (CAC/RCP 72-2013)).
- Adding the reference to the *Code of Practice for the prevention and reduction of ochratoxin A contamination in coffee* (CAC/RCP 69-2009).
- While for wheat it is explicitly mentioned that the ML applies to raw wheat, there is no specific reference to "raw" in the case of barley and rye. It seems appropriate to align this.
- **Point of discussion:** When deleting the commodity code GC 0654, it has to be clarified that wheat does not include durum wheat, spelt and emmer. In the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) there is also the entry "GC 4723 Durum wheat, see wheat ssp *Triticum durum* Desf" and the entry "GC 4625 Emmer, see Wheat ssp *Triticum dicoccum* Schubl" and also "GC 4673 Spelt, see Wheat *Triticum spelta* L".

  By having their own commodity codes, it appears that durum wheat, spelt and emmer are indeed excluded from the definition of wheat, and therefore it is suggested to put under notes/remarks: "excluding durum wheat, emmer and spelt".

  (However, in the current Classification, the reference "see wheat" is made for durum wheat, spelt and emmer. Also, in the proposed revision of the Classification, all the above wheat are combined in one category. This could plead for not excluding durum wheat, spelt and emmer from the ML for wheat.)

  The views as regards if wheat covers only common wheat or if wheat includes common wheat, durum wheat, emmer and spelt were divergent in the eWG. The majority of views expressed agreed that the ML for "wheat" applies only to raw common wheat.
- Necessary to explicitly mention that for the three cereals covered, the ML applies only to these three cereals intended for human consumption → taken care of the explanatory notes at the beginning of Schedule I.

19. Editorial changes to the provisions on patulin

- No specific issues on these provisions.

20. Editorial changes to the provisions on arsenic

- Updated with the JECFA evaluation in 2010.
- As the CS 32-1981 (margarine) and CS 135-1981 (minarine) have been replaced by the *Standard for Fat Spreads and Blended Spreads* (CODEX STAN 256-2007) and as that standard establishes a ML of 0.1 mg/kg for arsenic for all products covered by the standard, it seems logic to replace the current maximum level of 0.1 mg/kg for margarine and minarine by a ML of 0.1 mg/kg for fat spread and blended spreads in line with the scope of the standard.
- It is proposed to replace the commodity names "olive oil, residue oil" into "olive-pomace oil" (in line with the terminology used in the *Standard for Olive Oils and Olive Pomace Oils* (CODEX STAN 33-1981) and to delete the note/remark (not of immediate relevance as it is included in the general entry "Edible oils and fats" and not specifically mentioned).
- It is proposed to group vegetable oils, crude and edible together as the same ML applies and the *Standard for Named Vegetable Oils* (CODEX STAN 210-1999) covers both. Furthermore it is proposed in case "crude" is put versus "edible" that the word "edible" is changed in "refined" as crude oils can also to (a limited) extent be consumed without refining.

  The CS 19-1981 applies to oils and fats and mixtures thereof in a state for human consumption. It includes oils and fats that have been subjected to processes of modification (such as trans-esterification or hydrogenation) or fractionation. This Standard does not apply to any oil or fat which is covered by one of the following: the *Standard for Named Animal Fats* (CODEX STAN 211-1999); the *Standard for Named Vegetable Oils* (CODEX STAN 210-1999); the *Standard for Olive Oils and Olive-Pomace Oils* (CODEX STAN 33-1981). It is furthermore clarified in the *Standard for Edible Fats and Oils nor covered by Individual Standards* (CODEX STAN 19-1981) that "*Edible fats and oils are foodstuffs which are composed of glycerides of fatty acids. They are of vegetable, animal or marine origin. They may contain small amounts of other lipids such as phosphatides, of unsaponifiable constituents and of free fatty acids naturally present in the fat or oil. Fats of animal origin must be produced from animals in good health at the time of slaughter and be fit for human consumption*".

As the same maximum level is established for named animal fats, named vegetable oils (crude and edible /refined) and olive oil (virgin, refined and pomace oil) it is proposed for reasons of simplification that they are included in the general group "edible oils and fats" and that these fats and oils do not need to be mentioned separately. Reference is made in the column "Notes/Remarks" to the commodity standards.

- One member of the eWG does not agree with the merging of commodity names for reasons of simplification.
- For mineral water, as it concerns a commodity standard, it is appropriate to take over the exact wording of CS 108-1991 in the note/remark i.e. "calculated as total As in mg/l"

21. Editorial changes to the provisions on cadmium

- Updated with the recent JECFA evaluation in 2010
- As the ML level is explicitly applicable to cereal grains, the exclusion of germ and bran seems not to be consistent/needed as it could (erroneously) suggest that all other derived products are included such as flour, etc. (for bran CM 0081 is foreseen for unprocessed cereal bran; CF0081 for processed cereal bran and consequently clearly not covered by GC 0081). Also germ would fall under Group 065 cereal grain milling fractions identified with code CF and does also clearly not fall within GC 0081).
- **Wheat: see discussion point § 16.**
- The two entries "Fruiting vegetables, cucurbits" and "Fruiting vegetables, other than cucurbits" both with the same maximum level have been merged for reasons of simplification (no change in substance)
- One member of the eWG does not agree with the merging of commodity names for reasons of simplification.
- For the entry on cephalopods given that no reference is made anymore to the commodity code it is appropriate to add cuttlefishes, octopuses, squids for the food for which the ML applies

22. Editorial changes to the provisions on lead

- Updated with the recent JECFA evaluation in 2010
- Given that no reference is anymore given to the commodity codes, the term "assorted (sub) tropical fruits" is not well defined and might lead to disputes. A citation of all fruits involved will make the standard very complex and is therefore not appropriate. However given that the 6 fruit classes for the ML of lead referred to in the standard do encompasses all fruits and that for 5 of the 6 classes the same ML (0.1 mg/kg) applies with the exception of berries and other small fruits, for which an ML of 0.2 ppm applies. **Therefore it seems appropriate for reasons of simplification that with the deletion of the commodity codes the standard could be simplified to "fruits -ML of 0.1 ppm, excluding berries and other small fruit" and a second entry "berries and other small fruits - ML of 0.2 ppm". It is a simplification, no a change in substance as no change in the existing levels - the only point that needs to be clarified if there is a need to further define "berries and other small fruits". However this seems to be addressed by the general reference to the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) for defining which products are to be considered under a group name. In the Classification, there is a group "berries and other small fruit".**
- The two entries "Fruiting vegetables, cucurbits" and "Fruiting vegetables, other than cucurbits" both with the same maximum level have been merged for reasons of simplification (no change in substance).
- One member of the eWG does not agree with the merging of commodity names for reasons of simplification.

*The following detailed information on the different commodity standards as regards canned fruits and vegetables is provided:

- The standards CS 15-1981 (canned grapefruit) and CS 68-1981 (canned mandarin oranges) have been superseded by the *Standard for Certain Canned Citrus Fruits* (CODEX STAN 254-2007). In CODEX STAN 254-2007 no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by the provisions of this Standard shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for these products*".
- The standard CS 79-1981 (jams (fruit preserves) and jellies) has been superseded by the *Standard for Jams, Jellies and* Marmalades (CODEX STAN 296-2009). In CODEX STAN 296-2009 no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by this Standard shall comply with the maximum levels of the General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)*".
- The standards CS 16-1981 (canned green beans and canned wax beans), CS 18-1981 (canned sweet corn), CS 56-1981 (canned asparagus), CS 58-1981 (canned green peas), CS 81-1981 (canned mature processed peas), CS 116-1981 (canned carrots) and CS 144-1985 (canned palmito) have been superseded by the *Standard for Certain Canned Vegetables (*CODEX STAN 297-2009). In CODEX STAN 297-2009 no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)*".

- The standard CS 55-1981 (canned mushrooms) has been superseded by *Standard for Certain Canned Vegetables* (CODEX STAN 197-2009) by including a specific annex on certain mushrooms. In CODEX STAN 297-2009 no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)*".
- The standard CS 13-1981 (canned tomatoes) has been revised in 2007 and refers to "preserved tomatoes" instead of "canned tomatoes". In the revision, the specific ML established for lead has been replaced by "*5.2 OTHER CONTAMINANTS - 5.2.1. The product covered by the provisions of this Standard shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for this product. 5.2.2 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.*"
- The standard CS 57-1981 (processed tomato concentrates) has been revised in 2007. In the revision the specific ML established for lead has been replaced by "*5.2 OTHER CONTAMINANTS - 5.2.1. The product covered by the provisions of this Standard shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for this product. 5.2.2. 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.*"
- Fruit juices are described in the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) as juices pressed from various mature fruits, either from the whole fruits or from the pulp ("juices from Type 1 - fruits but also including juices from fruits from fruiting vegetables (cucurbits/other than cucurbits"). This is in line with what is foreseen in the *Standard for Fruit Juices and Nectars* (CODEX STAN 247-2005) on fruit juices. So no need for specific reference to juices from fruits from fruiting vegetables.
- In line with the description of meat in the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) which indicates that meats are the muscular tissues, including adhering fatty tissues such as intramuscular, intermuscular and subcutaneous fat from animal carcases or cuts. Therefore, it seems appropriate to keep the note "applies also to the fat of meat".
- Poultry meats are described in the *Classification of Foods and Animal Feeds* (CAC/MISC 4-1993) as meats which are the muscular tissues including adhering fat and skin form poultry carcases. In this case, no reference is made to the fat in the note/remarks column. However there is a specific maximum limit for poultry fat (PF 0111).
- The standards CS 32-1981 (margarine) and CS 135-1981 (minarine) are replaced by the *Standard for Fat Spreads and Blended Spreads* (CODEX STAN 256-2007). For margarine the fat content needs to be equal to or more than 80%. Minarine is defined as a fat spread with a fat content from 39-41%.
- The CS 19-1981 applies to oils and fats and mixtures thereof in a state for human consumption. It includes oils and fats that have been subjected to processes of modification (such as trans-esterification or hydrogenation) or fractionation. This Standard does not apply to any oil or fat which is covered by one of the following: the *Standard for Named Animal Fats* (CODEX STAN 211-1999); the *Standard for Named Vegetable Oils* (CODEX STAN 210-1999); the *Standard for Olive Oils and Olive-Pomace Oils* (CODEX STAN 33-1981). It is furthermore clarified in CODEX STAN 19-1981 that "*Edible fats and oils are foodstuffs which are composed of glycerides of fatty acids. They are of vegetable, animal or marine origin. They may contain small amounts of other lipids such as phosphatides, of unsaponifiable constituents and of free fatty acids naturally present in the fat or oil. Fats of animal origin must be produced from animals in good health at the time of slaughter and be fit for human consumption". As the same maximum level is proposed for Named animal fats, Named vegetable oil and olive oil, it is proposed that they are included in the general group "Edible oils and fats*".
- The *Standard for Named Animal Fats* (CODEX STAN 211-199) provides for detailed definitions of the products covered by the standard (lard, rendered pork fat, premier jus and edible tallow).
- It is proposed to replace the commodity names "olive oil, residue oil" into "olive-pomace oil" (in line with the terminology used in the *Standard for Olive Oils and Olive-Pomace Oils* (CODEX STAN 33-1981) and to delete the note/remark (not of immediate relevance as it is included in the general entry "edible oils and fats" and not specifically mentioned).
- It is proposed to group vegetable oils, crude and edible together as the same ML applies and the *Standard for Named Vegetable Oils* (CODEX STAN 210-1999) covers both. Furthermore, it is proposed in case "crude" is put versus "edible" that the word "edible" is changed in "refined" as "crude" oils can also to (a limited) extent be consumed without refining.
- **As the same maximum level is established for named animal fats, named vegetable oils (crude and edible /refined) and olive oil (virgin, refined and pomace oil) it is proposed <u>for reasons of simplification</u> that they are included in the general group "edible oils and fats" and that these fats and oils do not need to be mentioned separately. Reference is made in the column "Notes/Remarks" to the commodity standards.**
- Necessary to better define what is meant by milk → proposed to apply the definition for "milk" as provided for in the *Standard for the use of Dairy Terms* (CODEX STAN 206-1999).

23. Editorial changes to the provisions on mercury

- Updated with the recent JECFA evaluation in 2010.

24. Editorial changes to the provisions on methylmercury

- None.

25. Editorial changes to the provisions on tin

- In the *Standard for Certain Canned Citrus Fruits* (CODEX STAN 254-2007) no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by the provisions of this Standard shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for these products*".
- In the *Standard for Jams, Jellies and Marmalades* (CODEX STAN 296-2009) no specific ML is established but the following standard sentence under the heading contaminants is provided "*5 CONTAMINANTS 5.1 The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)*".
- In the *Standard for Canned Stone Fruits* (CODEX STAN 242-2003) no specific ML is established but the following standard sentence under the heading contaminants is provided "*5 CONTAMINANTS 5.1 HEAVY METALS The products covered by the provisions of this Standard shall comply with those maximum levels for heavy metals established by the Codex Alimentarius Commission for these products*".
- In the *Standard for Certain Canned Vegetables* (CODEX STAN 297-2009) no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995).*"
- The standard CS 55-1981 (canned mushrooms) has been supersedes by the *Standard for Certain Canned Vegetables* (CODEX STAN 297-2009) by including a specific annex on certain mushrooms. In CODEX STAN 297-2009 no specific ML is established but the following standard sentence under the heading contaminants is provided "*The products covered by this Standard shall comply with the maximum levels of the Codex General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)*".
- The standard CS 13-1981 (canned tomatoes) has been revised in 2007 and refers to "preserved tomatoes" instead of "canned tomatoes". However, in the revision the specific ML established for tin has been replaced by "*5.2 OTHER CONTAMINANTS - 5.2.1 The product covered by the provisions of this Standard shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for this product. 5.2.2 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.*"
- The *Standard for Processed Tomato Concentrates* (CODEX STAN 57-1981) has been revised in 2007. In the revision the specific ML established for tin has been replaced by "*5.2 OTHER CONTAMINANTS - 5.2.1. The product covered by the provisions of this Standard shall comply with those maximum levels for contaminants established by the Codex Alimentarius Commission for this product. 5.2.2. 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.*"
- All specified canned foods with a maximum level of 250 mg/kg are no longer specifically mentioned as they are covered by the ML of 250 mg/kg for "all canned foods (other than beverages)". All specified beverages with a maximum level of 150 mg/kg are no longer specifically mentioned as they are covered by the ML of 150 mg/kg for "all canned beverages".

Specified canned foods (and beverages) with a deviating maximum level are still specifically mentioned.

- The suffix "C" has been replaced by the meaning "The ML is applicable in canned products only" in the column of notes/remarks. However in most cases the mention seems to be superfluous as "canned" is already specifically mentioned in the food to which the ML of tin applies.
- **Point of discussion:** The questions raises if the Maximum Levels for Tin in Canned Foods (Other than Beverages) and in Canned Beverages (250 mg/kg and 150 mg/kg, respectively) automatically supersedes the already existing (lower) maximum levels for certain products (i.e., canned strawberries, CODEX STAN 62-1981; cooked cured chopped meat CODEX STAN 98-1981; cooked cured ham, CODEX STAN 96-1981; cooked cured pork shoulder, CODEX STAN 97-1981; corned beef, CODEX STAN 88-1981; and luncheon meat, CODEX STAN 89-1981) or if it is necessary to formally revoke these Codex provisions.

  Referring to the discussions in the CCCF and CAC in 2007 (bold and italic added):

CCCF (2007) (extract from ALINORM 07/30/41)

"Status of the draft Maximum Levels for Tin in Canned Foods (other than beverages) and in Canned Beverages

82. The Committee agreed to forward the draft Maximum Levels in Tin to the 30th Session of the Codex Alimentarius Commission for adoption at Step 8. The Delegations of the European Community and Switzerland reserved their position to this decision. ***The Committee also noted that the eventual adoption by the Commission of the draft Maximum Level for Tin in Canned Foods (other than beverages) would result in consequential changes to maximum levels for tin in certain canned products (i.e. products in tin-layered cans), currently included in Schedule I of the General Standard for Contaminants and Toxins in Foods (GSCTF)."***

CAC (2007) (extract from ALINORM 07/30/REP)

"Contaminants in Foods

Draft Maximum Levels for Tin in Canned Foods (other than beverages) and in Canned Beverages

41. The Committee ***adopted*** *the draft Maximum Levels and agreed to include them in Schedule I of the General Standard for Contaminants and Toxins in Foods (GSCTF),* ***with the understanding that the existing maximum levels for tin in certain canned foods included in Schedule I of the GSCTF would be replaced by the adopted maximum levels.***

42. The Delegation of the European Community maintained its reservation expressed at the First Session of the Codex Committee on Contaminants in Foods, stating that the proposed maximum levels for tin might lead to the PTWI set by JECFA being exceeded in certain vulnerable groups, that the maximum levels for tin should be set as low as reasonably achievable and that the technological need did not justify the proposed levels."

The eWG was of the opinion that the adopted general MLs adopted in 2007 supersede all the existing maximum levels, the products for which the same maximum level was already established and the other products in tin-layered cans. No formal revocation needed for the MLs is needed. The ML for tin in non-tinplate cans remain.

26. Editorial changes to the provisions on radionuclides

- No particular changes.

27. Editorial changes to the provisions on acrylonitrile

- No particular changes.

28. Editorial changes to the provisions on chloropropanols

- No particular changes.

29. Inclusion into the GSCTFF the MLs for hydrocyanic acid (decision from the 7th Session of CCCF (REP13/CF), approved by the 36th session of CAC)

***** Maximum levels for hydrocyanic acid of 2 mg/kg (expressed as free hydrocyanic acid) in gari and of 10 mg/kg (expressed as total hydrocyanic acid) in cassava flour (REP13/CF, para. 88, Appendix V).

***** Reference to the Code of Practice for the reduction of hydrocyanic acid (HCN) in cassava and cassava products (CAC/RCP 73-2013).

(inserted between chloropropanols and melamine)

30. Editorial changes to the provisions on melamine

- The maximum level for melamine in liquid infant formula, adopted by the Codex Alimentarius Commission in June 2012 has been added to the Standard.

31. Editorial changes to the provisions on vinyl chloride monomer

- The Codex Alimentarius Commission had adopted the *Guidelines Levels for Vinyl Chloride Monomer and Acrylonitrile in Food and Packaging Material* (CAC/GL 6-1991). This Guidance was adopted when the GSCTFF was not yet adopted. When all MLs for contaminants were transferred into the GSCTFF some associated individual standards and related texts like CAC/GL 6-1991 were forgotten to be revoked. Therefore the CCCF at its 6th session recommended to the 35th Session of the Commission revocation of CAC/GL 6-1991 as the GLs for these compounds were already transferred into the GSCTFF (REP/12/CF, para. 106). The Commission adopted the revocation of the CAC/GL 6-1991 (REP12/CAC, Appendix V).

Discussion point

Changes needed to the Preamble following the change of the definition of contaminant

Extract from CX/CF 13/7/2 – Matters arising from the 35th Session of the Codex Alimentarius Commission (CAC) for consideration by the 7th Session of the CCCF (April 2013)

"MATTERS FOR ACTION

Definition of "contaminant"

4. When considering the adoption of the revised definition of "contaminant", a delegation requested clarification as to whether the revised definition excluded substances intentionally added to feed and whether residues of veterinary drugs in food of animal origin as carry over from feed (i.e. medicated feed) would be included in the revised definition. The Delegation also suggested a review of the Section on contaminants in the Format of Commodity Standards may be needed, with the revision of the definition.

5. The Commission noted that the Committee on Residues of Veterinary Drugs in Foods had the responsibility for feed additives when establishing maximum residue limits for veterinary drugs in food of animal origin arising from the addition of veterinary drugs to feed (i.e. medicated feed).

6. The Commission adopted the revised definition of "contaminant" as proposed by the Committee and endorsed by the Committee on General Principles. ***In addition, as part of the ongoing editorial revision of the GSCTFF, the Commission requested the Committee to look into relevant sections of the General Standard e.g. Section 1.1 (Scope) and 1.2.2 (List of substances that meet the definition of contaminant) to fix any possible discrepancy in relation to the revised definition and the issue of feed additives/feed additive residues.***

7. The Committee is invited to consider this matter under Agenda Item 13."

Agenda item 13 related the discussion on editorial amendments to the "*General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). However the point was not discussed under this agenda item (an oblivion) but the point needs to be discussed. In order to prepare the discussion at the 8th Session of the CCCF, the Codex Secretariat requested to submit it to the eWG to collect the views and to eventually a common position from the eWG to be presented at the Plenary session.

Relevant extract from the 35th Session of the CAC (July 2012) (REP12/CAC, paras. 21-24)

"Definition of "Contaminant"

21. The Commission recalled that the revision of the definition of contaminant followed the revision of the Risk Analysis Principles applied by the Codex Committee on Contaminants in Foods and the revision of the Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals to make it more explicit as regards its applicability to feed as recommended by the 33rd Session of the Commission.

22. A Delegation requested clarification as to whether the revised definition excluded substances intentionally added to feed and whether residues of veterinary drugs in food of animal origin as carry over from feed (i.e. medicated feed) would be included in the revised definition. The Delegation also suggested that a review of the Section on contaminants in the Format of Commodity Standards may be needed, with the revision of the definition (Procedural Manual, 20th edition, page 52).

23- 24 are identical to the paragraphs 5 and 6 of CX/CF 13/7/2 above."

REVISED DEFINITION FOR CONTAMINANT (6th Session of the CCCF, March 2012, REP12/CF para. 38, Appendix IV), as adopted by CAC at its 35th meeting (bold are the additions to the former definition of contaminant)

"**Contaminant** means any substance not intentionally added to food ***or feed*** **for food producing animals**, which is present in such food ***or feed*** as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food ***or feed***, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter."

FROM THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS

3. This document also applies to contaminants and toxins in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health. This excludes feed additives, processing aids and agricultural and veterinary chemical residues that are the responsibility of other relevant Codex committees.

DISCUSSION AT THE 6th CCCF (REP12/CF, paras. 33 – 36)

Codex responsibility for feed additives

33. The Committee considered the question on whether it should be the responsibility of the CCCF to deal with the issues related to feed additives/feed additive residues.

34. In this regard, the Committee considered a revised definition of contaminant as proposed by the working group which includes a reference to feed to make more clear that the definition of contaminant applies to food and feed for consistency with the terms of reference and the scope of the GSCTFF.

35. In this regard, the Committee noted that the terms of reference of the Committee on Residues of Veterinary Drugs in Foods covered feed additives when establishing maximum residue limits for veterinary drugs in food of animal origin arising from the addition of veterinary drugs to feed (i.e. medicated feed) and that the same applied when establishing maximum residue limits for pesticides as a result of phytosanitary treatments. In addition, the Committee noted the view of several delegations that any feed additive/feed additive residues that may result in its unavoidable / unintentional presence in food due to the carry over of the substance from the feed into food being relevant to food safety was already covered by the definition of contaminant. Based on these considerations, the Committee agreed with the revised definition of contaminant as proposed by the working group.

36. The Delegation of Japan indicated that the inclusion of "or feed" in the revised definition of contaminant, which referred to "contaminant" as any substance "not intentionally" added to food "or feed", introduced a discrepancy between the definition and section 1.2.2 of the General Standard for Contaminants and Toxins in Food and Feed which did not explicitly exclude feed additives (intentionally added to feed) from the indicated application of the term "contaminant" as opposed to compounds governed by other Codex committees such as pesticide or veterinary drugs residues. The Delegation further noted that, if the definition of contaminant would be limited to the "unintentional/unavoidable" presence of substance in foods and "feed", the scope of the preamble in the GSCTFF would still allow for interpretation that feed additives "intentionally" added to feed are covered by the definition of contaminant as not explicitly excluded in the list as other substances like veterinary drugs and pesticide residues."

SECTION 1.1. of the GSCTFF (CODEX STAN 193-1995)

" **1.1 SCOPE**

This Standard contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed, and lists the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed which are recommended by the CAC to be applied to commodities moving in international trade.

This Standard includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health."

SECTION 1.2.2. of the GSCTFF (CODEX STAN 193-1995)

"**1.2.2 Contaminant**

Codex Alimentarius defines a contaminant as follows:

"Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

This standard applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

1) Contaminants having only food and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Codex Committee on Contaminants in Foods (CCCF) has the objective to protect public health.

2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR).

3) Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).

5) Residues of processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA)[1]"

Proposed changes, supported by the EWG, to section 1.1. and 1.2.2. of the GSCTFF following the revised definition of contaminant to fix any possible discrepancies

1.1 SCOPE *(no changes needed → no changes proposed)*

This Standard contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed, and lists the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed which are recommended by the CAC to be applied to commodities moving in international trade.

This Standard includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health. '"

"**1.2.2 Contaminant (some changes/ additions needed)**

Codex Alimentarius defines a contaminant as follows:

"Any substance not intentionally added to food **or feed for food producing animals**, which is present in such food **or feed** as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food **or feed,** or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

This standard applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

1) Contaminants having only food and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Codex Committee on Contaminants in Foods (CCCF) has the objective to protect public health.

2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR).

3) Residues of veterinary drugs, as defined by the Codex definition, **and residues of feed additives (*),** that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).

5) Residues of processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA)(**) "

(*) Feed additives as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054-2004): "Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products. Micro-organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration."

Residues of feed additives include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the feed additive concerned.

(**) Processing aids are any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product."

APPENDIX I

FORMAT OF THE GSCTFF

Introduction

The format for Schedule I shall contain the following elements:

- ***Name of the contaminant***
- ***Synonyms:*** symbols, synonyms, abbreviations, scientific descriptions shall be mentioned.
- ***Reference to JECFA meetings*** (in which the contaminant was discussed).
- ***PMTDI, PTWI or similar toxicological guidance value:*** when the situation is complex a short statement and further references may be necessary here.
- ***Contaminant definition:*** definition of the contaminant as it shall be analyzed and to which the maximum level or guideline level applies.
- ***Reference*** to a source-directed measure or a related code of practice for the contaminant, if appropriate.
- ***List of Codex maximum levels or guideline levels for that contaminant;*** this list shall be composed of the following elements, in columns:
  - feed/food commodity/product name;
  - Numerical value of maximum level or guideline level and units in which it is expressed;
  - Portion of the Commodity/Product to which the maximum level or guideline level applies;
  - Notes/Remarks, including reference to relevant Codex commodity standards

ANNEX II

SCHEDULE I - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOODS

INDEX OF CONTAMINANTS

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 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.
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. For the other commodities or products not contained in Codex commodity standards the definition of the commodity or product is provided in the Codex 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
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 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)* 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.

AFLATOXINS, TOTAL

Reference to JECFA: 31 (1987), 46 (1996), 49 (1997), 68 (2007)
Toxicological guidance: Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible)
Contaminant definition: Aflatoxins total (B1 +B2 + G1 + G2)
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 Feedingstuffs 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)

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Almonds	10	Whole commodity after removal of shell.	The ML applies to almonds "ready-to-eat"(**) For sampling plan, see Annex 2.
Almonds	15	Whole commodity after removal of shell.	The ML applies to almonds intended for further processing (*) For sampling plan, see Annex 2.
Brazil nuts	10	Whole commodity.	The ML applies to shelled Brazil nuts ready-to-eat (**). For sampling plan, see Annex 2.
Brazil nuts	15	Whole commodity.	The ML applies to shelled Brazil nuts intended for further processing (*) For sampling plan, see Annex 2.
Hazelnuts	10	Whole commodity after removal of shell.	The ML applies to hazelnuts, also known as filberts, "ready to eat"(**) For sampling plan, see Annex 2.
Hazelnuts	15	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.
Peanuts	15	Unless specified, seed or kernels, after removal of shell or husk.	The ML applies for peanuts, also known as groundnuts, intended for further processing (*). For sampling plan, see Annex 1.
Pistachios	10	Whole commodity after removal of shell.	The ML applies to pistachios "ready to eat"(**). For sampling plan, see Annex 2.
Pistachios	15	Whole commodity after removal of shell.	The ML applies to pistachios intended for further processing (*) For sampling plan, see Annex 2.
Dried figs	10	Whole commodity.	The Ml applies to dried figs "ready-to-eat"(**) For sampling plan see Annex 3.

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
(*)"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"			

(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 AFM in Group 2B (probable human carcinogen). The liver is the primary target organ. **→ see discussion point)**

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: 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 homogenisation 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

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 a 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.

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 20 kg.

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.

Homogenisation – Grinding

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

23. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation 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 homogenisation (finer grind – slurry) can be obtained by more sophisticated equipment, resulting in a lower sample preparation variance.

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. Utilising 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 generalised 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 - 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.

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 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.
4. Uncertainty estimates associated with sampling, sample preparation, and analysis, shown in Annex I, and the negative binomial distribution[1,2,3] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans (Annex II).

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1 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.

5. In Annex I, 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[2]. 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 four treenuts. The within laboratory analytical uncertainty for almonds, hazelnuts and pistachios can be found at the website http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[3].

6. 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

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 four 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.

<u>Treenuts destined for further processing</u>

Maximum level – 15 µg/kg total aflatoxins

Number of laboratory samples – 1

Laboratory sample size – 20 kg

- Almonds – shelled nuts
- Hazelnuts – shelled nuts
- Pistachios – 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.

<u>Ready-to-eat treenuts</u>

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

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2 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.

3 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).

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 four 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.

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	2000	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 grams 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[4]. 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[5].

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.

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.

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4 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.

5 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.

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, ISO) 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[6], respectively.

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

Equation 5: $RSD_R = 2^{(1-0.5\log c)}$ (for $C > 120$ µg/kg 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 = $0.66RSD_R$
- 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.

6 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.

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, Iran and Brazil, 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[3].

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) $5.759C^{1.561}$	S^2_s = (10,000/ns) $4.291C^{1.609}$	S^2_s = 8,000/ns) $7.913C^{1.475}$	s_s^2 = (1,850/ns) $4.8616C^{1.889}$
Sample Prep[d]	S^2_{sp} = (100/nss) $0.170C^{1.646}$	S^2_{sp} = (50/nss) $0.021C^{1.545}$	S^2_{sp} = (25/nss) $2.334C^{1.522}$	s_{ss}^2 = (50/nss) $0.0306C^{0.632}$
Analytical[e]	S^2_a = (1/na) $0.0484C^{2.0}$	S^2_a = (1/na) $0.0484C^{2.0}$	S^2_a = (1/na) $0.0484C^{2.0}$	experimental s_a^2 = (1/n) $0.0164C^{1.117}$ or FAPAS s_a^2 = (1/n) $0.0484C^{2.0}$
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 µg/kg total aflatoxin.

c/ Shelled nut count/kg for almonds, hazelnuts, pistachios and Brazil nuts is 773, 1,000, 1,600 and 185, respectively.

d/ Sample preparation for almonds, hazelnuts, and pistachios reflect Hobart, Robot Coupe, Marjaan Khatman and Turrax 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 nut/water 1/1 w/w.

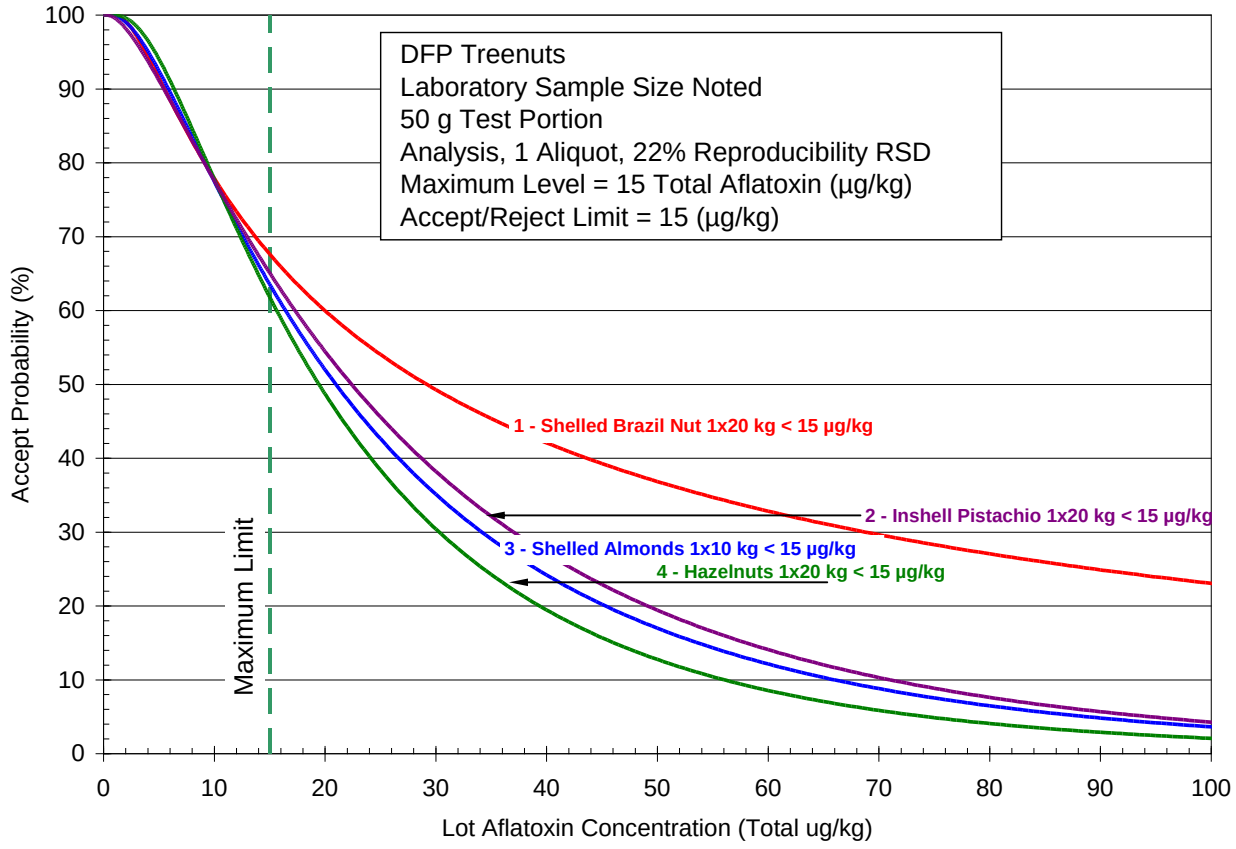
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson[2] (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the four treenuts.

Annex II

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

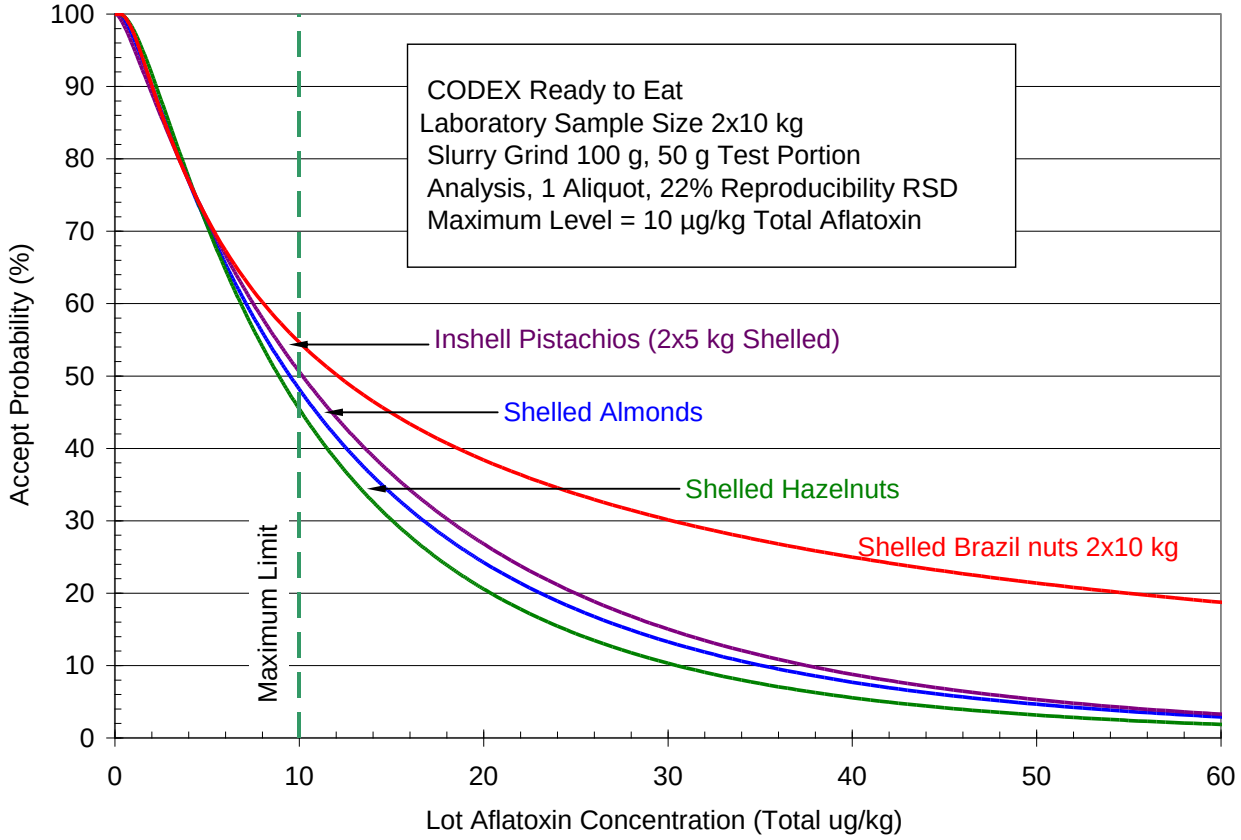
Treenuts Destined for Further Processing

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 µg/kg 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 10 kg shelled nuts) for pistachios with dry grind with a vertical cutter mixer type mill almonds, hazelnuts and pistachios and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



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 µg/kg for total aflatoxins, with dry grind with a vertical cutter mixer type mill almonds, hazelnuts and 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 - 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.

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 established only for ready-to-eat dried figs.
2. The performance of the sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots (Annex IV). 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[1] are used to calculate operating characteristic (OC) curves that describe the performance of the 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 reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data[2]. 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. The within laboratory analytical uncertainty for dried figs can be found in study results described in Annex IV.
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 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 ng/g total aflatoxins.

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1 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.

2 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.

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 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 section 47 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.

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 30 kg[a] as a function of lot (or sublot) weight.

Lot or Sublot Weight [b] (T in Tonnes)	Minimum Number of Incremental Samples	Minimu 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 = 30000/100

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 (2400 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.

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[3]. 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[4].

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.

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3 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.

4 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.

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.

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[2] and Horwitz and Albert[5], 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)

5 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.

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. Variances[a] 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)

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 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 dried figs.

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

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

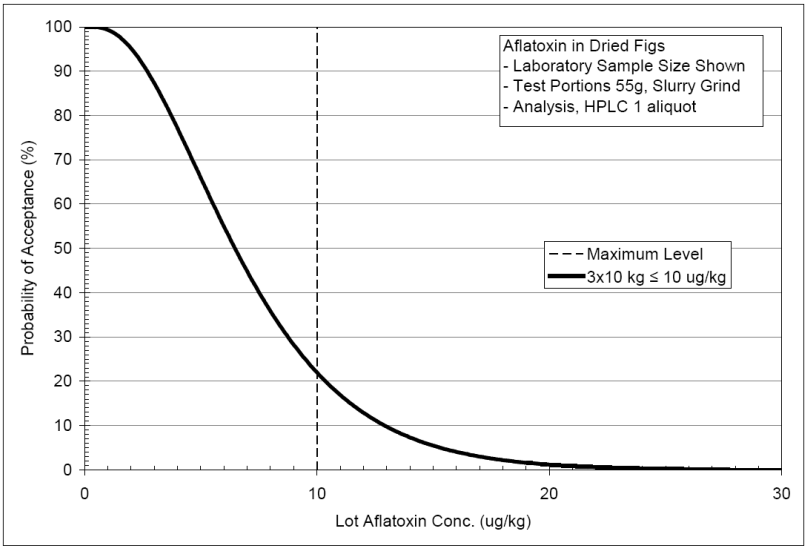

Figure 1. Operating characteristic (OC) curve describing the performance of the aflatoxin sampling plan for ready-to-eat dried figs using three laboratory samples of 10 kg each and a maximum level of 10 ug/kg total aflatoxins, water-slurry comminution method, test portion that reflects 55 g fig mass,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

AFLATOXIN M1

Reference to JECFA: 56 (2001)

Toxicological guidance: 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 M1

Synonyms: AFM1

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	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Milks	0.5	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.

OCHRATOXIN A

Reference to JECFA: 37 (1990), 44 (1995), 56 (2001), 68 (2007)
Toxicological guidance: PTWI 0.0001 mg/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, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes (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 - 2013)

Commodity / Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Wheat	5	Whole commodity.	The ML applies to raw common wheat. The ML does not apply to durum wheat, spelt and emmer.
Barley	5	Whole commodity.	The ML applies to raw barley.
Rye	5	Whole commodity.	The ML applies to raw rye.

PATULIN

Reference to JECFA: 35 (1989), 44 (1995)
Toxicological guidance: 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	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Apple juice	50	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration.	Relevant Codex commodity standard include CODEX STAN 247-2005 (apple products only). The ML applies also to apple juice used as an ingredient in other beverages.

(Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera Aspergillus, Penicillium and Byssochlamys → **see discussion point**)

ARSENIC

Reference to JECFA: 5 (1960), 10 (1967), 27 (1983), 33 (1988), 72 (2010)

Toxicological guidance: At the 72nd meeting of JECFA (2010), the inorganic arsenic lower limit on the benchmark dose for a 0.5% increased incidence of lung cancer (BMDL0.5) was determined from epidemiological studies 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) using a range of assumptions to estimate total dietary exposure to inorganic arsenic from drinking-water and food. The JECFA noted that the provisional tolerable weekly intake (PTWI) of 15 µg/kg bw (equivalent to 2.1 µg/kg bw per day) is in the region of the BMDL 0.5 and therefore was no longer appropriate. The JECFA withdrew the previous PTWI.

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 Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Edible fats and oils	0.1	Whole commodity.	Relevant Codex commodity standards include CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999 and CODEX STAN 211-1999.
Fat spreads and blended spreads	0.1		Relevant Codex commodity standards include CODEX STAN 256-2007.
Natural mineral waters	0.01		Relevant Codex commodity standards include CODEX STAN 108-1981. Calculated as total As in mg/l.
Salt, food grade	0.5		Relevant Codex commodity standards include CODEX STAN 150-1985.

(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 ug/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. 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 6x 10-4. **→ see discussion point)**

CADMIUM

Reference to JECFA: 16 (1972), 33 (1988), 41 (1993), 55 (2000), 61 (2003), 64 (2005), 73 (2010)

Toxicological guidance: In view of the long half-life of cadmium, daily ingestion in food has a small or even a negligible effect on overall exposure. In order to assess long- or short-term risks to health due to cadmium exposure, dietary intake should be assessed over months, and tolerable intake should be assessed over a period of at least 1 month. To encourage this view, at the 73rd meeting (2010) the JECFA decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI) and established a PTMI of 25 µg/kg body weight.

Contaminant definition: Cadmium, total

Synonyms: Cd

Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Brassica vegetables	0.05	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.
Bulb vegetables	0.05	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.	
Fruiting vegetables	0.05	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.
Leafy vegetables	0.2	Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.	The ML also applies to Brassica leafy vegetables.
Legume vegetables	0.1	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	
Pulses	0.1	Whole commodity.	The ML does not apply to soya bean (dry).
Root and tuber vegetables	0.1	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.
Stalk and stem vegetables	0.1	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.	

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Cereal grains	0.1	Whole commodity.	The ML does not apply to buckwheat, cañihua, quinoa, wheat and rice.
Rice, polished	0.4	Whole commodity.	
Wheat	0.2	Whole commodity.	The ML does not apply to durum wheat, spelt and emmer.
Marine bivalve molluscs	2	Whole commodity after removal of shell.	The ML applies to clams, cockles and mussels but not to oysters and scallops.
Cephalopods	2	Whole commodity after removal of shell.	The ML applies to cuttlefishes, octopuses and squids without viscera
Natural mineral waters	0.003		Relevant Codex commodity standards include CODEX STAN 108-1981. The ML is expressed in mg/l.
Salt, food grade	0.5		Relevant Codex commodity standards include CODEX STAN 150-1985.

(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). **→ see discussion point)**

LEAD

Reference to JECFA: 10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999), 73 (2010)

Toxicological guidance: Based on the dose–response analyses, at the 73rd meeting (2010), JECFA estimated that the previously established PTWI of 25 µg/kg body weight is associated with a decrease of at least 3 intelligence quotient (IQ) points in children and an increase in systolic blood pressure of approximately 3 mmHg (0.4 kPa) in adults. While such effects may be insignificant at the individual level, these changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population. The JECFA therefore concluded that the PTWI could no longer be considered health protective and withdrew it.

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 Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Fruits with the exception of berries and other small fruits	0.1	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.	
Berries and other small fruits	0.2	Whole commodity after removal of caps and stems. Currants: fruit with stem.	
Brassica vegetables	0.3	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
Bulb vegetables	0.1	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Fruiting vegetables	0.1	Whole commodity after removal of stems Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to mushrooms
Leafy vegetables	0.3	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.
Legume vegetables	0.2	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	
Pulses	0.2	Whole commodity.	
Root and tuber vegetables	0.1	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.	
Canned fruit cocktail	1		Relevant Codex commodity standards include CODEX STAN 78-1981.
Canned grapefruit	1		Relevant Codex commodity standards include CODEX STAN 254-2007.
Canned mandarin oranges	1		Relevant Codex commodity standards include CODEX STAN 254-2007.
Canned mangoes	1		Relevant Codex commodity standards include CODEX STAN 159-1987.
Canned pineapple	1		Relevant Codex commodity standards include CODEX STAN 42-1981.
Canned raspberries	1		Relevant Codex commodity standards include CODEX STAN 60-1981.
Canned strawberries	1		Relevant Codex commodity standards include CODEX STAN 62-1981.
Canned tropical fruit salad	1		Relevant Codex commodity standards include CODEX STAN 99-1981.
Jams (fruit preserves),jellies and marmelades	1		Relevant Codex commodity standards include CODEX STAN 296-2009.
Mango chutney	1		Relevant Codex commodity standards include CODEX STAN 160-1987.
Preserved tomatoes	1		Relevant Codex commodity standards include CODEX STAN 297-2009. 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.
Table olives	1		Relevant Codex commodity standards include CODEX STAN 66-1981.
Canned asparagus	1		Relevant Codex commodity standards include CODEX STAN 297-2009.

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Canned carrots	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned green beans and canned wax beans	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned green peas	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned mature processed peas	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned mushrooms	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned palmito	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned sweet corn	1		Relevant Codex commodity standards include CODEX STAN 297-2009.
Canned tomatoes	1		Relevant Codex commodity standards include CODEX STAN 13-1981.
Pickled cucumbers (cucumber pickles)	1		Relevant Codex commodity standards include CODEX STAN 115-1981
Processed tomato concentrates	1.5		Relevant Codex commodity standards include CODEX STAN 57-1981. In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.
Canned chestnuts and canned chestnuts puree	1		Relevant Codex commodity standards include CODEX STAN 145-1985.
Fruit juices	0.05	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 standards include CODEX STAN 247-2005
Cereal grains	0.2	Whole commodity	The ML does not apply to buckwheat cañihua and quinoa
Meat of cattle, pigs and sheep	0.1	Whole commodity (without bones).	The ML also applies to fat from the meat.
Meat and fat of poultry	0.1	Whole commodity (without bones).	
Cattle, edible offal of	0.5	Whole commodity.	
Pig, edible offal of	0.5	Whole commodity.	
Poultry, edible offal of	0.5	Whole commodity.	

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/remarks
Edible fats and oils	0.1	Whole commodity as prepared for wholesale or retail distribution.	Relevant Codex commodity standards include CODEX STAN 19-1981, CODEX STAN 33-1981, CODEX STAN 210-1999 and CODEX STAN 211-1999.
Fat spreads and blended spreads	0.1		Relevant Codex commodity standards include CODEX STAN 256-2007.
Milk	0.02	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.
Secondary milk products	0.02	Whole commodity.	The ML applies to the food as consumed.
Infant formula	0.02	Whole commodity.	The ML applies to infant formula ready to use.
Fish	0.3	Whole commodity (in general after removing the digestive tract).	
Natural mineral waters	0.01		Relevant Codex commodity standards include CODEX STAN 108-1981. The ML is expressed in mg/l.
Salt, food grade	2		Relevant Codex commodity standards include CODEX STAN 150-1985.
Wine	0.2		

MERCURY

Reference to JECFA: 10 (1966), 14 (1970), 16 (1972), 22 (1978), 72 (2010)

Toxicological guidance: At the 72rd meeting (2010), JECFA 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.

Contaminant definition: Mercury, Total

Synonyms: Hg

Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Natural mineral waters	0.001		Relevant Codex commodity standards include CODEX STAN 108-1981. The ML is expressed in mg/l.
Salt food grade	0.1		Relevant Codex commodity standards include CODEX STAN 150-1985.

(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. **→ see discussion point***)*

METHYLMERCURY

Reference to JECFA: 22 (1978), 33 (1988), 53 (1999), 61 (2003), 67(2006)
Toxicological guidance: 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 Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) mg/kg	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks
Fish	0.5	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.
Predatory fish	1	Whole commodity (in general after removing the digestive tract).	Predatory fish such as shark, swordfish, tuna, pike and others. The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.

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.

(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. **→ see discussion point***).*

TIN

Reference to JECFA: 10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26(1982), 33(1988), 55 (2000), 64 (2005)
Toxicological guidance: 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 Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Maximum Level mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/rRemarks
Canned foods (other than beverages)	250		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		Relevant Codex commodity standards include CODEX-STAN 247-2005
Cooked cured chopped meat	50		The ML is applicable to canned products only. The ML applies to products in non-tinplate cans Relevant Codex commodity standards include CODEX STAN 98-1981
Cooked cured ham	50		The ML is applicable to canned products only. The ML applies to products in non-tinplate cans Relevant Codex commodity standards include CODEX STAN 96-1981
Cooked cured pork shoulder	50		The ML is applicable to canned products only. The ML applies to products in non-tinplate cans Relevant Codex commodity standards include CODEX STAN 97-1981
Corned beef	50		The ML is applicable to canned products only. The ML applies to products in non-tinplate cans Relevant Codex commodity standards include CODEX STAN 88-1981
Luncheon meat	50		The ML is applicable to canned products only. The ML applies to products in non-tinplate cans Relevant Codex commodity standards include CODEX STAN 89-1981

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 anticarcinogenic 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). **→ see discussion point).**

RADIONUCLIDES

TABLE 1

Commodity / Product Name	Guideline Level (GL) Bq/kg	Representative radionuclides	Portion of the Commodity/Product to which the GL applies	Notes/Remarks
Infant foods	1	Pu-238, Pu-239, Pu-240, Am-241	Whole commodity.	The GL applies to foods intended for consumption by infants.
Infant foods	100	Sr-90, Ru-106, I-129, I-131, U-235	Whole commodity.	The GL applies to foods intended for consumption by infants.
Infant foods	1000	S-35 (*), Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192	Whole commodity.	The GL applies to foods intended for consumption by infants.
Infant foods	1000	H-3(**), C-14, Tc-99	Whole commodity.	The GL applies to foods intended for consumption by infants.
Foods other than infant foods	10	Pu-238, Pu-239, Pu-240, Am-241	Whole commodity.	
Foods other than infant foods	100	Sr-90, Ru-106, I-129, I-131, U-235	Whole commodity.	
Foods other than infant foods	1000	S-35 (*), Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192	Whole commodity.	
Foods other than infant foods	10000	H-3(**), C-14, Tc-99	Whole commodity.	

(*) This represents the value for organically bound sulphur

(**) This represents the value for organically bound tritium

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[1]. 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)[2].

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1 For the purposes of this document, the term “emergency” includes both accidents and malevolent actions.

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[3].

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2 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.

3 For example, if ^{134}Cs and ^{137}Cs are contaminants in food, the guideline level of 1,000 Bq/kg refers to the summed activity of both these radionuclides.

Annex 1

SCIENTIFIC JUSTIFICATION FOR THE 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[1] (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[2]; US DoH, 1998[3]; NRPB, 2003[4]). 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)[5].

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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1 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.

2 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.

3 US DoHHS (1998) Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. Food and Drug Administration, Rockville.

4 K. Smith and A. Jones (2003) Generalised Habit Data for Radiological Assessments. NRPB Report W41.

5 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:

$$E = GL(A)\ M(A) \cdot e_{ing}(A)\ IPF$$

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[1] (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[2]). 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 caesium 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 = 1,000 Bq/kg·550 kg·$1.3 \cdot 10^{-5}$ mSv/Bq·0.1 = 0.7 mSv

For infants: E = 1,000 Bq/kg 200 kg·$2.1 \cdot 10^{-5}$ mSv/Bq·0.1 = 0.4 mSv

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1 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.

2 International Commission on Radiological Protection (2005) Doses to Infants from Radionuclides Ingested in Mothers Milk. To be published.

TABLE 2

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*	1,000	1,000	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**	1,000	10,000	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).

ACRYLONITRILE

Reference to JECFA: 28 (1984)
Toxicological guidance: 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 Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) mg/kg	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks
Food	0.02		

(Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as packaging material for e.g. 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 → **see discussion point***).*

CHLOROPROPANOLS

Reference to JECFA: 41 (1993; for 1,3-dichloro-2-propanol only), 57 (2001), 67 (2006)

Toxicological guidance: 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, 65000 (general population), 2400 (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 Proteins (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64 – 2008)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Liquid condiments containing acid hydrolyzed vegetable proteins	0.4		The ML does not apply to naturally fermented soy sauce;

HYDROCYANIC ACID/CYANOGENIC GLYCOSIDES

Reference to JECFA: 39 (1992), 74 (2011)
Toxicological guidance: 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 -2013)

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Gari	2	Whole commodity.	The ML is expressed as free hydrocyanic acid. Relevant Codex commodity standards include CODEX STAN 151-1989.
Cassava flour	10		The ML is expressed as total hydrocyanic acid Relevant Codex commodity standards include CODEX STAN 176-1989.

MELAMINE

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

Commodity / Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Food (other than infant formulae)	2.5		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.
Feed	2.5		The ML does not apply to melamine that could be present in the following feed ingredients / additives: guanidine acetic acid (GAA), urea and biuret, as a result of normal production processes.
Powdered infant formula	1		
Liquid infant formula	0.15		The ML applies to liquid infant formula as consumed.

VINYL CHLORIDE MONOMER

Reference to JECFA: 28 (1984)
Toxicological guidance: 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: Vinylchloride monomer
Synonyms: Monochloroethene, chloroethylene; abbreviation VC or VCM
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity / Product Name	Guideline Level (GL) mg/kg	Reference	Portion of the Commodity/Product to which the GL Applies	Notes/Remarks
Food	0.01			The GL in food packaging material is 1.0 mg/kg.

Vinylchloride 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 VCM 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). → **see discussion point**

APPENDIX II

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