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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 13** **CX/CF 13/7/13**
**March 2013**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**Seventh Session**
**Moscow, Russian Federation, 8-12 April 2013**

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

Due to late receipt of the document, comments are not being requested. Codex members and Observers are requested to consider the proposed editorial amendments as described in paragraphs 9 – 25.

## BACKGROUND

1. At the 3rd Session of the Codex Committee on Contaminants in Foods (CCCF) that was held in Rotterdam, Netherlands on 23-27 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 (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 Codex Committee on Contaminants in Foods that was held in Izmir, Turkey on 26-30 April 2010, the Committee agreed to establish an electronic Working Group, working in English, led by the Delegation of the European Union to prepare proposals on description for commodities in the GSCTFF for consideration at the next session of CCCF[2].

3. In preparation of the 6th session of the CCCF, a first draft of the proposed editorial amendments was circulated to the members of the eWG. All comments received have been integrated into a revised version. Due to time constraints, the revised version has not been re-circulated to the members of the eWG for final agreement but has been sent directly to the Codex secretariat for transmission to all Codex members in view of the discussion at the 6th Session of 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 the document to referred back to the working group for further development and comments.

5. The Committee agreed at the 6th Session to re-establish the electronic working group 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.

6. The delegation of Japan provided the Chair of the working group 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 is taken over from the Codex Classification of Foods and Animal Feeds (CAC/MISC 4) or from the Codex 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 working group is of the opinion that it is more appropriate to describe this approach in detail in the explanatory notes to Schedule 1 of the GSCTFF instead of creating a separate list of commodities. This approach has as advantage that every update of Codex Commodity Standards or of the Codex Classification of Foods and Animal Feeds are automatically applicable to the relevant provisions in the GSTFF

8. A list of participants to the eWG is provided in Appendix I to this document. Due to time constraints, the revised version has not been circulated to the members of the eWG for comments but has been sent directly to the Codex secretariat for transmission to all Codex members in view of the discussion at the 7th Session of CCCF.

[1] ALINORM 09/32/41, paragraph 37
[2] ALINORM 10/33/41, paragraph 120

**EXPLANATORY NOTES TO THE PROPOSED AMENDMENTS**

**9. Following general principles were applied to the proposed amendments**

- Proposed changes do not change in substance the current provisions in the GSCTFF.

- Commodity codes are no longer used and the column for commodity codes has been deleted.

- Reference to withdrawn Codex Commodity standards has been deleted.

- Maximum levels or guideline levels which were contained in Codex commodity standards are deleted in case the relevant Codex commodity standard was withdrawn.

- Commodity standards are referred to only in case they are still valid in CODEX and they do contain maximum or guideline levels for contaminants or they provide under the heading contaminants that "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)".

- Standards are referred to by their standard indication CODEX-STAN number-year.

- The column of suffix has been deleted as it was only used for tin and the note it was referring to has been mentioned in the column "Notes/remarks"

- The column of type of level – maximum level (ML) or guideline level (GL) - has been deleted. Instead in the header of the column of the ML or GL it is clearly mentioned if it concerns an ML or a GL.

- As no reference is anymore made to the commodity code nor to the standard CAC/MISC 4 "Codex Classification of Foods and Animal Feeds", a new column has been inserted mentioning the portion of the commodity to which the ML or GL applies. In general, this has been taken over from what is currently foreseen in CAC/MISC 4. In cases there was some specific reference to the portion to which the ML applies already mentioned in the column notes/remarks, this information has been moved to the Portion of the commodity to which the ML applies".

- Nevertheless it might be considered to be appropriate to provide as a general provision in the explanatory notes that in case reference is made to a specific commodity standard, the product to which the maximum level applies is described in the Commodity standard referred to.

- Furthermore in case the maximum level applies to group of products like leafy vegetables, bulb vegetables, etc. the products referred to are provided in the Codex Classification of Foods and Animal Feeds

- Wherever possible, overlap has been provided, clarification provided and the existing provisions simplified without changing the provisions in substance.

**10. Editorial changes to the provisions on <u>aflatoxins total</u>**

- 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 1.

- Inclusion of the definitions for "for further processing" and "ready-to-eat".

- 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 is to include besides hazelnuts also explicitly filberts.

- The standard on the ML for aflatoxin total in dried figs adopted by the Codex Alimentarius Commission in June 2012 with the associated sampling plan has been added to the Standard.

- Provisions re-ordered in alphabetical order.

- The sampling plan for aflatoxin contamination in dried figs as adopted by CODEX refers still 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.

**11. Editorial changes to the provisions on <u>aflatoxin M1</u>**

- Necessary to better define what is meant by milk → proposed to apply the definition for "milks" as provided for in CAC/MISC/4

- The ML applies to milk for human consumption → taken care of the explanatory notes at the beginning of Schedule 1

**12. Editorial changes to the provisions on <u>ochratoxin A</u>**

- 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.

- When deleting the commodity code GC 0654 then it has to be clarified that wheat does not include durum wheat, spelt and emmer. In CAC/MISC/4 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.

Point of discussion: If by having their own Codex commodity codes, durum wheat, spelt and emmer are indeed excluded from the definition of wheat, we support 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 Codex 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.

However it is proposed to apply the ML 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 1.

**13. Editorial changes to the provisions on patulin**

- No specific issues on these provisions.

**14. 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 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 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 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 Codex Standard for Named Animal Fats (CODEX STAN 211-1999); the Codex Standard for Named Vegetable Oils (CODX STAN 210-1999); the Codex 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 Oils and Olive oil it is proposed that they are included in the general group "Edible oils and fats".

- 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"

**15. Editorial changes to the provisions on cadmium**

- Updated with the recent JECFA evaluation in 2010

- It could be considered to exclude besides tomatoes and edible fungi also to exclude leek (as this is in some regions of the world to be considered as stem vegetable) and to include leek into stem vegetables. However this has as consequence of change of the CODEX maximum level of cadmium in leek of 0,05 mg/kg into 0,1 mg/kg and is therefore to be considered as a discussion point.

- Does the term wheat mentioned here relate only to "common wheat" or does it also include "durum wheat, spelt and emmer"?. Given that wheat is referred to by GC 0654 later on it is considered that wheat does not include durum wheat, spelt and emmer and only refers to common wheat. In CAC/MISC/4 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.

In case wheat refers only to "common wheat" (see the discussion on ochratoxin A in § 12) tis would have as consequence that durum wheat, spelt and emmer would fall under "cereal grains" and the stricter level of 0.1 mg/kg would then apply to durum wheat, spelt and emmer. Another solution is to exclude durum wheat, emmer and spelt of the maximum level as is the case for buckwheat, cañihua and quinoa.

- 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 GC0081)

- Polished rice is defined as “having husk or outer brown layers removed”. It appears that polished rice is equal to husked rice as defined in CODEX STAN 198-1995 for rice (in which polished rice is not defined). Husked rice is defined in CODEX STAN 198-1995 as “Husked rice (brown rice or cargo rice) is paddy rice from which the husk only has been removed. The process of husking and handling may result in some loss of bran”. Consequently, it is proposed to replace “Rice, polished” by “Rice, husked”

- 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

**16. 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 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”. Is a simplification, no change in 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 Codex Classification of Foods and Animal Feed for defining which products are to be considered under a group name. In the Codex Classification of Foods and Animal Feed, there is a group “berries and other small fruit”.

- Given that the commodity code is deleted, it can be questioned if fruit juices include also the juices from fruits including fruiting vegetables (in the CAC/MISC 4 it is explicitly foreseen that fruit juices are pressed from fruits (in the strict sense) and from fruits from fruiting vegetables).. Therefore it appears to be appropriate to explicitly mention in the notes that it includes juices from fruits from fruiting vegetables

- It is proposed to replace the commodity name “olive oil, residue oil” into “olive-pomace oil” (in line with CS 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 CS 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.

- In the group of bulb vegetables, in the Codex classification leek is included (while leek is in some/most regions of the world considered as stem vegetable). Therefore it could be considered to include leek into stem vegetables. However this has as consequence of change of the CODEX maximum level of lead in leek of 0.1 mg/kg into no CODEX maximum level for lead in leek and is therefore to be considered as a discussion point.

- The standards CS 15-1981 (canned grapefruit) and CS 68-1981 (canned mandarin oranges) are superseded by the CODEX STAN 254-2007 “CODEX STANDARD FOR CERTAIN CANNED CITRUS FRUITS”. 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) is superseded by the CODEX STAN 296-2009 “CODEX STANDARD FOR JAMS, JELLIES AND MARMELADES”. 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 Codex 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) are superseded by the CODEX STAN 297-2009 “CODEX STANDARD FOR CERTAIN CANNED VEGETABLES”. 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 revoked by the CAC in its 34th meeting in July 2011 (Appendix V of REP11/CAC p. 103). A specific annex on certain mushrooms has been included in the CODEX STAN 297-2009 “CODEX STANDARD FOR CERTAIN CANNED VEGETABLES” (Appendix III, part 2 of REP11/CAC p. 100). 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 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 in CAC/MISC/4 described 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")

- In line with the description of meat in CAC/MISC/4 indicating 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 replace the note "applies also to the fat of meat" by "applies also to the adhering fatty tissues of the meat". While poultry meats are described in CAC/MISC/ 4 as meats which are the muscular tissues including adhering fat and skin form poultry carcases. However 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). This would suggest that the Note/remark to meat of cattle, pigs and sheep "also applies to the fat from meat" refers to MF 0812 cattle fat / MF 0818 pig fat // MF 0822 sheep fat and that it is appropriate to insert in the commodity description the word fat.

- The standards CS 32-1981 (margarine) and CS 135-1981 (minarine) are replaced by CODEX STAN 256-2007 STANDARD FOR FAT SPREADS AND BLENDED SPREADS. 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 standard CODEX STAN 211-199 (named animal fats) 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 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 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 Codex Standard for Named Animal Fats (CODEX STAN 211-1999); the Codex Standard for Named Vegetable Oils (CODX STAN 210-1999); the Codex 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".

**17. Editorial changes to the provisions on <u>mercury</u>**

- Updated with the recent JECFA evaluation in 2010

**18. Editorial changes to the provisions on <u>methylmercury</u>**

- None

**19. Editorial changes to the provisions on <u>tin</u>**

- In CODEX STAN 254-2007 "CODEX STANDARD FOR CERTAIN CANNED CITRUS FRUITS" 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 CODEX STAN 296-2009 "CODEX STANDARD FOR JAMS, JELLIES AND MARMELADES" 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 CODEX STAN 242-2003 “CODEX STANDARD FOR CANNED STONE FRUITS” 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 CODEX STAN 297-2009 “CODEX STANDARD FOR CERTAIN CANNED VEGETABLES” 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 revoked by the CAC in its 34th meeting in July 2011 (Appendix V of REP11/CAC p. 103. A specific annex on certain mushrooms will be included in the CODEX STAN 297-2009 “CODEX STANDARD FOR CERTAIN CANNED VEGETABLES” Appendix III, part 2 of REP11/CAC p. 100. 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 57-1981 (processed tomato concentrates) 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.

**20. Editorial changes to the provisions on radionuclides**

- no particular changes

**21. Editorial changes to the provisions on acrylonitrile**

- no particular changes

**22. Editorial changes to the provisions on chloropropanols**

- no particular changes

**23. 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.

**24. Editorial changes to the provisions on vinyl chloride monomer**

- Codex Alimentarius Commission had adopted CAC/GL 6-1991 on 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 Codex Alimentarius Commission revocation of CAC/GL 6-1991 *Guideline levels for Vinyl Chloride Monomer* and *Acrylonitrile in Food and Packaging Material* as the GLs for these compounds were already transferred into the GSCTFF (REP/12/CF § 106). The Codex Alimentarius Commission adopted the revocation of the CAC/GL 6-1991 (REP12/CAC, Appendix V)

- Furthermore a slight change in the presentation of the GL for vinyl chloride monomer is proposed as the GL for food packaging material is indicated as any other GL and not as a note the GL for the same compound in foods.

**25. Consideration of inclusion into the GSCTFF of maximum levels for hydrocyanic acid established by Codex Commodity Standards**

- Sweet cassava is defined as a raw product containing less than 50 mg/kg hydrocyanic acid (CODEX STAN 238-2003)

- edible cassava flour is defined as a product suitable for direct human consumption and the level of “total hydrocyanic acid” in the flour must not exceed 10 mg/kg (CODEX STAN 176-1989)

- In gari, another product for direct human consumption, the “total hydrocyanic acid” must not exceed 2 mg/kg as free hydrocyanic acid (CODEX STAN 151-1989)

## APPENDIX I

### LIST OF PARTICIPANTS
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## APPENDIX II
## GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

**ANNEX II**

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

***INDEX OF CONTAMINANTS***



**EXPLANATORY NOTES**

| | |
|---|---|
| Reference to JECFA: | References to JECFA meeting in which the contaminant was evaluated and the year of that meeting. |
| Toxicological guidance value: | Toxicological advice about the tolerable intake level of the contaminant for humans, expressed in milligrammes (mg) per kg body weight (bw). The year of recommendations and additional explanation are included. |
| Residue definition: | Definition of the contaminant in the form of which the ML applies or which may or should be analyzed in commodities. |
| Synonyms: | Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant. |

| | |
|---|---|
| Commodity/ product name: | The commodities or products, other than the terms feed or food, are intended for human consumption, unless otherwise specified.<br><br>The maximum levels 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.<br><br>For the other commodities or products the definition of the commodity or product is provided in the Codex Classification of Foods and Animal Feeds (CAC/MISC 4), unless otherwise specified.<br><br>In case a maximum level applies to a product group (e.g. legume vegetables), the ML applies to all individual products belonging to the group as defined in the Codex Classification of Foods and Animal Feeds (CAC/MISC 4) |
| Portion of the Commodity 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 standard CAC/MISC 4 Classification of Foods and Animal Feeds or defined at the establishment of the maximum or guideline level, unless otherwise specified. |
| Type of level: | Indicates whether the value is Codex maximum level (ML) or Codex guideline level (GL). See also the definitions of these terms in the preamble of the GSCTFF. The type of level is provided in the heading to the levels. |

**Definitions of some toxicological terms**

| | |
|---|---|
| PMTDI: | *(Provisional Maximum Tolerable Daily Intake)*<br>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)*<br>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)*<br>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)
Residue 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 | Reference | Portion of the Commodity 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 after removal of shell | The ML applies to shelled Brazil nuts ready-to-eat (**). For sampling plan, see Annex 2 |
| Brazil nuts | 15 | | Whole commodity after removal of shell | The ML applies to shelled Brazil nuts destined for further processing (*) For sampling plan, see Annex 2 |
| Hazelnuts and filberts | 10 | | Whole commodity after removal of shell | The ML applies to hazelnuts "ready to eat" (**) For sampling plan, see Annex 2 |
| Hazelnuts and filberts | 15 | | Whole commodity after removal of shell | The ML applies to hazelnuts intended for further processing (*) For sampling plan, see Annex 2 |
| Peanuts / groundnuts | 15 | | Unless specified, seed or kernels, after removal of shell or husk | The ML applies for peanuts 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 | | | For sampling plan see Annex 3 |
| | | | | |
| (*) "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.

**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 [$(s_R / \bar{X}) \times 100$]
- 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).

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].

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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.

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

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.

Treenuts destined for further processing

Maximum level – 15 µg/kg total aflatoxins

Number of laboratory samples – 1

Laboratory sample size – 20 kg

- Almonds – shelled nuts
- Hazelnuts – shelled 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.

Ready-to-eat treenuts

Maximum level – 10 µg/kg total aflatoxins

Number of laboratory samples – 2

Laboratory sample size – 10 kg

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

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

Analytical method – performance based (see Table 2)

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

The operating characteristic curve describing the performance of the sampling plan for the 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.

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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 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.

**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.

[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.

**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.

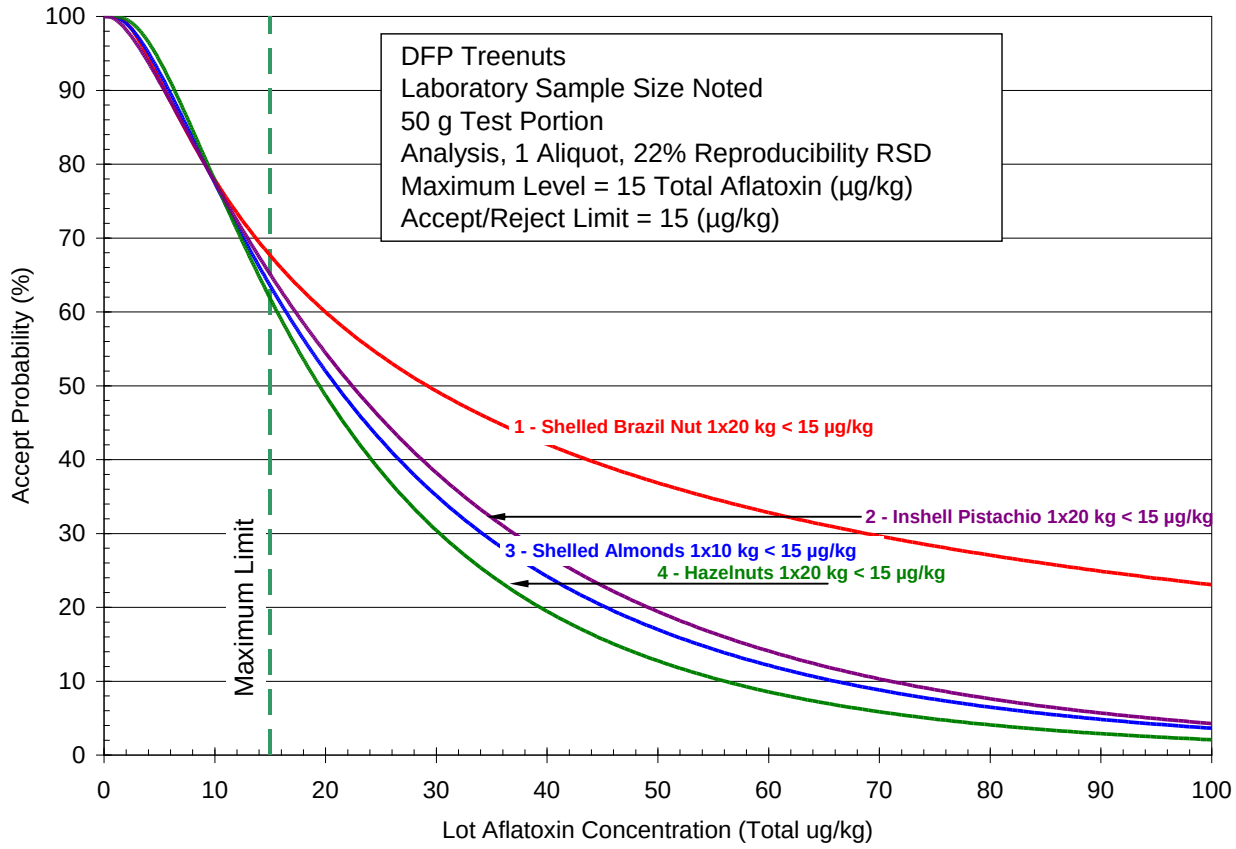
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson[2] (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical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

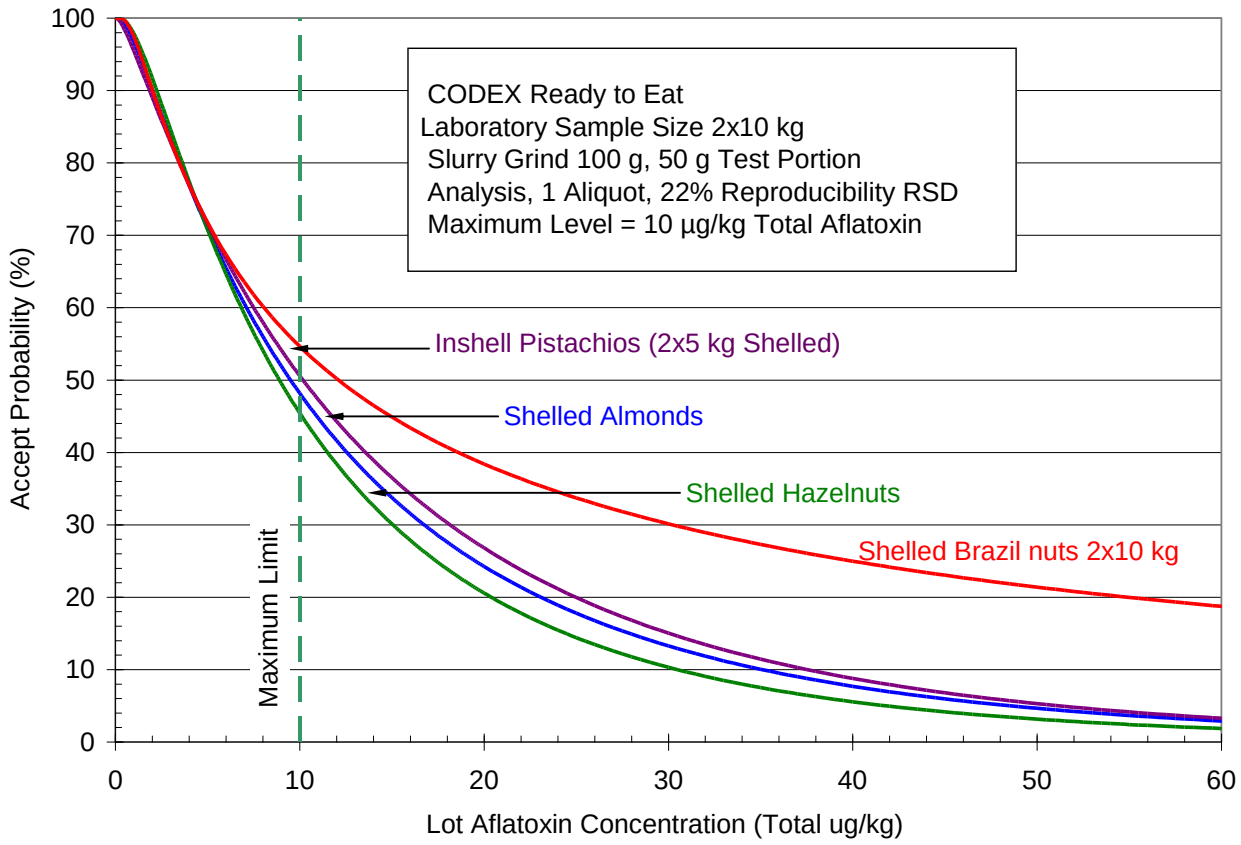
***Treenuts Destined for Further Processing***

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 proposed for only ready-to-eat dried figs.

2. The performance of the proposed draft sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots (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 proposed aflatoxin-sampling plans for dried figs.

4. The analytical variance measured in the sampling study reflects within laboratory variance and was replaced with an estimate of analytical variance 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 proposed maximum level and the aflatoxin test procedure are given below in this section.

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

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

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

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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.

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.

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.

[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.

**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)

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.

[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.

**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 DRAFT AFLATOXIN SAMPLING PLAN FOR READY-TO-EAT DRIED FIGS**

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

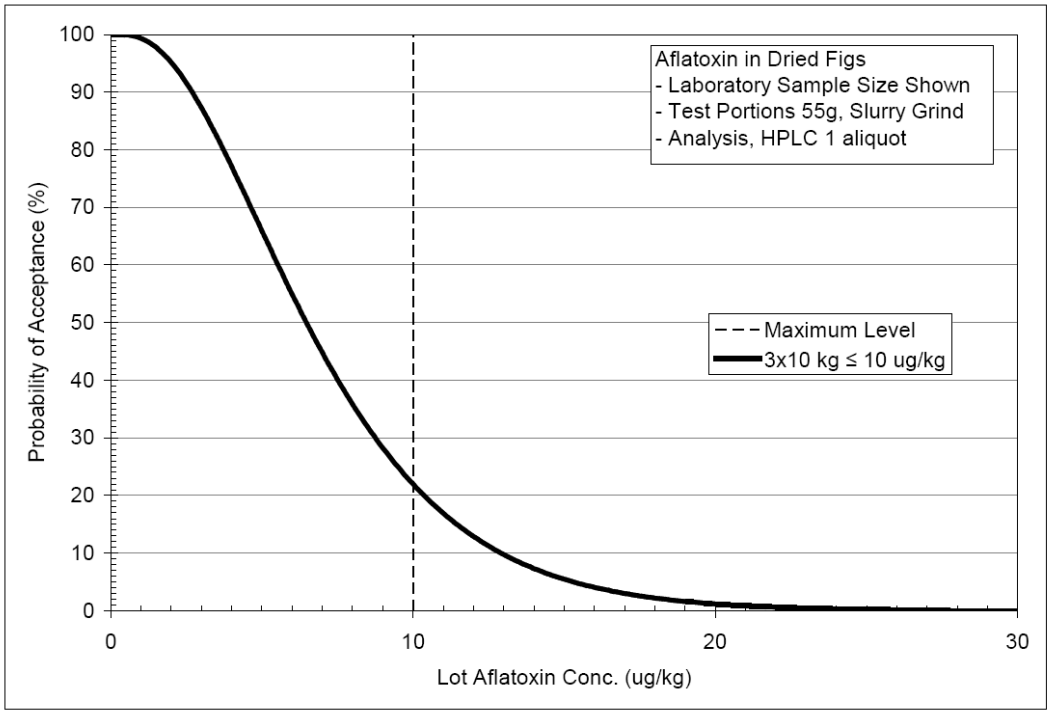


Figure 1. Operating characteristic (OC) curve describing the performance of the aflatoxin sampling plan for ready-to-eat dried figs using three laboratory samples of 10 kg each and a maximum level of 10 ug/kg total aflatoxins, water-slurry comminution method, test portion that reflects 55 g fig mass, 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)
Residue definition: Aflatoxin M1
Synonyms: AFM1

| Commodity / Product Name | Maximum Level (ML) µg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Milk | 0,5 | | Whole commodity | The ML applies to milk, being the mammary secretions of various species of lactating herbivorous ruminant animals usually domesticated. |

## OCHRATOXIN A

Reference to JECFA: 37 (1990), 44 (1995), 56 (2001), 68 (2007)
Toxicological guidance: PTWI 0.0001 mg/kg bw (2001)
Residue 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)

| Commodity / Product Name | Maximum Level (ML) µg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Common wheat | 5 | | Whole commodity | The ML applies to raw common wheat<br>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)
Residue 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 | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Apple juice | 50 | | Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration | The ML applies also to apple juice as ingredient in other beverages |

Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera Aspergillus, Penicillium and Byssochlamys.

## ARSENIC

Reference to JECFA: 5 (1960), 10 (1967), 27 (1983), 33 (1988), 72 (2010)
Toxicological guidance: 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 Committee 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 BMDL0.5 and therefore was no longer appropriate. The Committee withdrew the previous PTWI.
Residue 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 | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Edible oils and fats | 0,1 | CODEX STAN 19-1981<br>CODEX STAN 33-1981<br>CODEX STAN 210-1999<br>CODEX STAN 211-1999 | Whole commodity as prepared for wholesale or retail distribution | |
| Fat spreads and blended spreads | 0,1 | CODEX STAN 256-2007 | | |
| Natural mineral waters | 0,01 | CODEX STAN 108-1981 | | calculated as total As in mg/l |
| Salt, food grade | 0,5 | 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.

## 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, the Committee decided to express the tolerable intake as a monthly value in the form of a provisional tolerable monthly intake (PTMI). The Committee established a PTMI of 25 µg/kg body weight.
Residue 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 | Reference | Portion of the Commodity 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<br>Cauliflower and broccoli: flower heads (immature inflorescence only)<br>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<br>Leeks and spring onions: whole vegetable after removal of roots and adhering soil. | |
| Fruiting vegetables | 0,05 | | Whole commodity after removal of stems<br>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 | |
| Potato | 0,1 | | Peeled potato | |
| 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). | The ML does not apply to potato and celeriac |

| Commodity / Product Name | Maximum Level (ML) mg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| Stalk and stem vegetables | 0,1 | | Whole commodity as marketed after removal of obviously decomposed or withered leaves.<br>Rhubarb: leaf stems only<br>Globe artichoke: flower head only<br>Celery and asparagus: remove adhering soil | |
| Cereal grains | 0,1 | | Whole commodity | The ML does not apply to buckwheat, cañihua, quinoa, wheat (see discussion point in explanatory note § 15) and rice |
| Rice, husked | 0,4 | | Whole commodity as prepared for wholesale or retail distribution | |
| Wheat (see discussion point in explanatory note § 15) | 0,2 | | Whole commodity | |
| Marine bivalve molluscs (clams, cockles and mussels) | 2 | | Whole commodity after removal of shell | The ML does not apply to oysters and scallops |
| Cephalopods (cuttlefishes, octopuses and squids) | 2 | | Whole commodity after removal of shell | The ML applies to cephalopods without viscera |
| Natural mineral waters | 0,003 | CODEX STAN 108-1981 | | The ML is expressed in mg/l |
| Salt, food grade | 0,5 | 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).

## 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, the Committee 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 Committee therefore concluded that the PTWI could no longer be considered health protective and withdrew it.
Residue 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 | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Fruits with the exception of berries and other small fruit | 0,1 | | Whole commodity<br>Pome fruits: whole commodity after removal of stems<br>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<br>Pineapple: whole commodity after removal of crown<br>Avocado, mangos and similar fruit with hard seeds: whole commodity after removal of stone but calculated on whole fruit | |
| Berries and other small fruit | 0,2 | | Whole commodity after removal of caps and stems.<br>Currants: fruit with stem | |
| | | | | |
| Brassica vegetables | 0,3 | | Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves<br>Cauliflower and broccoli: flower heads (immature inflorescence only)<br>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<br>Leeks and spring onions: whole vegetable after removal of roots and adhering soil. | |

| Commodity / Product Name | Maximum Level (ML) mg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| Fruiting vegetables | 0,1 | | Whole commodity after removal of stems<br>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).<br>Potato: peeled potato | |
| | | | | |
| Canned fruit cocktail | 1 | CODEX STAN 78-1981 | | |
| Canned grapefruit | 1 | CODEX STAN 254-2007 | | |
| Canned mandarin oranges | 1 | CODEX STAN 254-2007 | | |
| Canned mangoes | 1 | CODEX STAN 159-1987 | | |
| Canned pineapple | 1 | CODEX STAN 42-1981 | | |
| Canned raspberries | 1 | CODEX STAN 60-1981 | | |
| Canned strawberries | 1 | CODEX STAN 62-1981 | | |
| Canned tropical fruit salad | 1 | CODEX STAN 99-1981 | | |
| Jams (fruit preserves) and jellies | 1 | CODEX STAN 296-2009 | | |
| Mango chutney | 1 | CODEX STAN 160-1987 | | |
| Table olives | 1 | CODEX STAN 66-1981 | | |
| Canned asparagus | 1 | CODEX STAN 297-2009 | | |
| Canned carrots | 1 | CODEX STAN 297-2009 | | |
| Canned green beans and canned wax beans | 1 | CODEX STAN 297-2009 | | |
| Canned green peas | 1 | CODEX STAN 297-2009 | | |
| Canned mature processed peas | 1 | CODEX STAN 297-2009 | | |
| Canned mushrooms | 1 | CODEX STAN 297-2009 | | |
| Canned palmito | 1 | CODEX STAN 297-2009 | | |
| Canned sweet corn | 1 | CODEX STAN 297-2009 | | |

| Commodity / Product Name | Maximum Level (ML) mg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| Preserved tomatoes | 1 | 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. |
| Pickled cucumbers (cucumber pickles) | 1 | CODEX STAN 115-1981 | | |
| Processed tomato concentrates | 1.5 | 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 | CODEX STAN 145-1985 | | |
| Fruit juices | 0,05 | | Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration | The ML applies also to fruit nectars. Fruit juice includes also juices from fruits from fruiting vegetables. |
| | | | | |
| Cereal grains | 0,2 | | Whole commodity | The ML does not apply to buckwheat cañihua and quinoa |
| | | | | |

| Commodity / Product Name | Maximum Level (ML) mg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| Meat and fat of cattle, pigs and sheep | 0,1 | | Whole commodity (without bones) | |
| 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 | |
| | | | | |
| Edible oils and fats | 0,1 | CODEX STAN 19-1981<br>CODEX STAN 33-1981<br>CODEX STAN 210-1999<br>CODEX STAN 211-1999 | Whole commodity as prepared for wholesale or retail distribution | |
| Fat spreads and blended spreads | 0,1 | CODEX STAN 256-2007 | | |
| Milk | 0,02 | | Whole commodity | The ML applies to milk, being the mammary secretions of various species of lactating herbivorous ruminant animals usually domesticated. A concentration factor applies to partially or wholly dehydrated milk. |
| 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 | CODEX STAN 108-1981 | | The ML is expressed in mg/l |
| Salt, food grade | 2 | CODEX STAN 150-1985 | | |
| | | | | |
| Wine | 0,2 | | | |

## MERCURY

Reference to JECFA: 10 (1966), 14 (1970), 16 (1972), 22 (1978), 72 (2010)
Toxicological guidance: The Committee established a PTWI for inorganic mercury of 4 µg/kg bw. The previous PTWI of 5 µg/kg bw for total mercury, established at the sixteenth meeting, was withdrawn. The new PTWI for inorganic mercury was considered applicable to dietary exposure to total mercury from foods other than fish and shellfish. For dietary exposure to mercury from these foods the previously established PTWI for methyl mercury should be applied.
Residue 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 | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Natural mineral waters | 0,001 | CODEX STAN 108-1981 | | The ML is expressed in mg/l |
| Salt food grade | 0,1 | CODEX STAN 150-1981 | | |

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.

## METHYLMERCURY

Reference to JECFA: 22 (1978), 33 (1988), 53 (1999), 61 (2003)
Toxicological guidance: PTWI 0.0016 mg/kg bw (2003)
Residue 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 | Reference | Portion of the Commodity 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.

## 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)
Residue 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 | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Canned foods (other than beverages) | 250 | | | The ML is applicable in canned products only.<br>The ML does not apply to canned strawberries, cooked cured chopped meat, cooked cured ham, cooked cured pork shoulder, corned beef, luncheon meat |
| Canned beverages | 150 | | | The ML is applicable in canned products only. |
| Canned strawberries | 200 | CODEX STAN 62-1981 | | The ML is applicable in canned products only. |
| | | | | |
| Cooked cured chopped meat | 200 | CODEX STAN 98-1981 | | The ML is applicable in canned products only.<br>The ML applies for products in tinplate containers |
| Cooked cured chopped meat | 50 | CODEX STAN 98-1981 | | The ML is applicable in canned products only.<br>The ML applies for products in other containers |
| Cooked cured ham | 200 | CODEX STAN 96-1981 | | The ML is applicable in canned products only.<br>The ML applies for products in tinplate containers |
| Cooked cured ham | 50 | CODEX STAN 96-1981 | | The ML applies for products in other containers |
| Cooked cured pork shoulder | 200 | CODEX STAN 97-1981 | | The ML is applicable in canned products only.<br>The ML applies for products in tinplate containers |
| Cooked cured pork shoulder | 50 | CODEX STAN 97-1981 | | The ML applies for products in other containers |
| Corned beef | 200 | CODEX STAN 88-1981 | | The ML is applicable in canned products only.<br>The ML applies for products in tinplate containers |
| Corned beef | 50 | CODEX STAN 88-1981 | | The ML applies for products in other containers |
| Luncheon meat | 200 | CODEX STAN 89-1981 | | The ML is applicable in canned products only.<br>The ML applies for products in tinplate containers |
| Luncheon meat | 50 | CODEX STAN 89-1981 | | The ML applies for products in other containers |

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

## RADIONUCLIDES

**TABLE 1**

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

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

[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)
Residue 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 | Reference | Portion of the Commodity 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 o.a. 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.

## 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)
Residue 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 | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Liquid condiments containing acid hydrolyzed vegetable proteins 'excluding naturally fermented soy sauce) | 0,4 | | | |

## MELAMINE

Reference to JECFA: FAO/WHO Expert Meeting, 2008
Toxicological guidance: TDI 0.2 mg/kg bw

| Commodity / Product Name | Maximum Level (ML) mg/kg | Reference | Portion of the Commodity to which the ML applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| | | | | |
| Food (other than infant formulae) | 2,5 | | | The ML applies to food other than infant formula<br>The maximum level applies to levels of melamine resulting from its non-intentional and unavoidable presence in feed and food.<br>The maximum level 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<br>- authorised use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine.<br>- migration from food contact materials taking account of any nationally authorised migration limit |
| Feed | 2,5 | | | The maximum level 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 (as consumed) | 0.15 | | | |

## 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
Residue 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 to which the GL applies | Notes/remarks |
|---|---|---|---|---|
| | | | | |
| Food | 0,01 | | | |
| Food packaging material | 1,0 | | | |

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).