CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

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World Health Organization

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GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

CXS 193-1995

Adopted in 1995
Revised in 1997, 2006, 2008, 2009
Amended in 2010, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019

1.1 SCOPE

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

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

1.2 DEFINITION OF TERMS

1.2.1 General

The definitions for the purpose of the Codex Alimentarius, as mentioned in the Procedural Manual of the Codex Alimentarius Commission, are applicable to the *General Standard for Contaminants and Toxins in Food and Feed* (GSCTFF) and only the most important ones are repeated here. Some new definitions are introduced, where this seems warranted to obtain optimal clarity. When reference is made to foods, this also applies to animal feed, in those cases where this is appropriate.

1.2.2 Contaminant

Codex Alimentarius defines a contaminant as follows:

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

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

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

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

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

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

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

(*) Feed additives as defined in the *Code of Practice on Good Animal Feeding* (CXC 54-2004): "Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products.

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

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

1.2.3 Natural toxins included in this Standard

The Codex definition of a contaminant implicitly includes naturally occurring toxicants including toxic metabolites of certain microfungi that are not intentionally added to food and feed (mycotoxins).

Toxins that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish (phycotoxins) are also included in this Standard. Mycotoxins and phycotoxins are both subclasses of contaminants.

Endogenous natural toxicants, such as e.g. solanine in potatoes, that are implicit constituents of food and feed resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s), i.e. phytotoxins are not generally considered within the scope of this Standard. They are, however, within the terms of reference of CCCF and will be dealt with on a case-by-case basis.

1.2.4 Maximum level and related terms[1]

The ***Codex maximum level (ML)*** for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity.

1.3 PRINCIPLES REGARDING CONTAMINANTS IN FOOD AND FEED

1.3.1 General

Contamination of food and feed may pose a risk to human (and/or animal health). Moreover, in some cases they may also have a negative impact on the quality of the food or feed. Food and feed can become contaminated by various causes and processes.

Contaminant levels in food and feed shall be as low as reasonably achievable through best practice such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP) following an appropriate risk assessment. The following actions may serve to prevent or to reduce contamination of feed and food[2]:

- Preventing food and feed contamination at the source, e.g. by reducing environmental pollution.
- Applying appropriate technology control measure(s) in food and feed production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding.
- Applying measures aimed at decontamination of contaminated feed or food and measures to prevent contaminated feed or food to be marketed for consumption.

To ensure that adequate action is taken to reduce contamination of food and feed a Code of Practice shall be elaborated comprising source related measures and Good Manufacturing Practice as well as Good Agricultural Practice in relation to the specific contamination problem.

The degree of contamination of food and feed and the effect of actions to reduce contamination shall be assessed by monitoring, survey programs and more specialized research programs, where necessary.

When there are indications that health hazards may be involved with consumption of food that is contaminated, it is necessary that a risk assessment should be undertaken. When health concerns can be substantiated, a risk management measure must be applied, based on a thorough evaluation of the situation and consideration of a range of risk management options. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish MLs or other measures to control the contamination of food and feed. In special cases, specific advice on dietary recommendations may also have to be considered to complement other regulatory measures, when the measures are not sufficiently adequate to protect public health and safety.

National measures regarding food and feed contamination should avoid the creation of unnecessary barriers to international trade in food and feed commodities. The purpose of the GSCTFF is to provide guidance about possible approaches to eliminate or reduce the contamination problem and to promote international harmonization through recommendations, which in turn may prevent trade barriers and disputes.

For all contaminants, which may be present in more than one feed or food item, a broad approach shall be applied, considering all relevant information that is available, for the assessing of risks and for developing recommendations and control measures, including the setting of maximum levels.

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1 For the contaminants radionuclides, acrylonitrile and vinylchloride monomer a **Codex guideline level (GL)** has been established.
A ***Codex guideline level*** (***GL)*** is the maximum level of a substance in a food or feed commodity which is recommended by the Codex Alimentarius Commission to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.
Because the Commission has decided that the preferred format of a Codex standard in food or feed is a maximum level, the present existing or proposed guideline levels shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by JECFA, if appropriate.

2 In addition, reference is made to the *Code of Practice for source Directed measures to reduce contamination of food with chemicals* (CXC 49-2001) and the *Code of Practice on Good Animal Feeding* (CXC 54-2004).

1.3.2 Principles for establishing maximum levels in food and feed

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

The maximum levels shall be set in such a way that the consumer is adequately protected. At the same time the other legitimate factors need to be considered. This will be performed in accordance with the *Working Principles for Risk Analysis for Food Safety for Application by Governments*.

The principles of Good Manufacturing Practice and Good Agricultural Practice as defined by Codex shall be used. Maximum levels shall be based on sound scientific principles leading to levels, which are acceptable worldwide, so that there is no unjustified barrier to international trade. MLs shall be clearly defined with respect to status and intended use.

1.3.3 Specific criteria

The following criteria should (not preventing the use of other relevant criteria) be considered when developing MLs and/or other measures in connection with the *General Standard for Contaminants and Toxins in Food and Feed* (Further details about these criteria are given in Annex I).

Toxicological information

- identification of the toxic substance(s);
- metabolism by humans and animals, as appropriate;
- toxicokinetics and toxicodynamics including information on possible carry-over of the toxic substance from feed to edible animal tissue/products;
- information about acute and long-term toxicity and other relevant toxicity data; and
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are especially vulnerable.

Analytical data

- validated qualitative and quantitative data on representative samples; and
- appropriate sampling procedures.

Intake data

- presence in food of dietary significance for the contaminant;
- presence in food that are widely consumed;
- presence in feed and feed components;
- food intake data for average and most exposed/high consumer groups;
- results from total diet studies;
- calculated contaminant intake data from food consumption models;
- data on intake by susceptible groups; and
- data on intake by food producing animals.

Technological considerations

- Information about contamination processes, technological possibilities, production and manufacturing practices and economic aspects related to contaminant level management and control.

Risk assessment and risk management considerations (cf. *Working Principles for Risk Analysis for Food Safety for Application by Governments*)

- risk management options and considerations;
- consideration of possible maximum levels in food and feed based on the criteria mentioned above; and
- consideration of alternative solutions.

1.4 FORMAT OF THE GENERAL STANDARD FOR CONTAMINANTS IN FOOD AND FEED

A full description of the format is provided in Annex II.

Annex I

CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED

Introduction

In this Annex criteria are mentioned regarding information, which is considered necessary for evaluating contaminant problems in food and feed and for the establishment of maximum levels. The criteria mentioned here are elaborated in more detail than in Section 1.3.3 of the Preamble. Only those aspects that need further clarification are detailed; however, criteria or aspects that are not specifically detailed here should not be ruled out in the evaluation process.

Toxicological information

Integrated toxicological expert advice regarding a safe/tolerable intake level of a contaminant is essential when decisions about maximum levels in foods are considered. A recommendation from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological database, should be the main basis for decisions by Codex members. In urgent cases, it may be possible to rely on less developed evaluations from JECFA or on toxicological expert advice from other international or national bodies.

When toxicological information is presented in relation to proposals for maximum levels for contaminants in food and feed, information about the following aspects is desirable:

- identification of the toxic substance(s);
- metabolism in humans and animals, as appropriate;
- toxicokinetics and toxicodynamics including information on possible carry-over of the contaminant from feed to edible animal tissue/products;
- information about acute and long-term toxicity in animals and humans, including epidemiological data on humans and other relevant toxicity data;
- conclusions and advice of toxicological expert(s) (groups), with references, including information on especially vulnerable population groups or animals.

Analytical data

Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativeness of the samples for the contamination of the product in general (e.g. on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related contaminant regulation.

Information on appropriate sampling procedures should be supplied. Special attention to this aspect is necessary in the case of contaminants that may not be homogeneously distributed in the product (e.g. mycotoxins in some commodities).

Intake data

It is desirable to have information about the contaminant concentrations in those foods or food groups that (together) are responsible for at least half and preferably 80% or more of the total dietary intake of the contaminant, both for consumers with average and high consumption patterns.

Information about the ***presence of the contaminant in foods that are widely consumed*** (staple foods) is desirable in order to be able to make a satisfactory assessment of the contaminant intake and of risks associated with food trade.

For the contaminants, which can be present in food of animal origin as a consequence of the carry-over from feed, information about the presence of the contaminant in the feed and feed components should be given. Furthermore, the intake of contaminants by the different food producing animals and the resulting levels of the contaminant in the food of animal origin should be estimated.

Food consumption data for average, most exposed (high consumers) and susceptible consumer groups are desirable for evaluations of (potential) intake of contaminants. This problem, however, has to be addressed differently on a national and on an international scale. It is therefore important to have information about both average and high consumption patterns regarding a wide variety of foodstuffs, so that for every contaminant the most exposed consumer groups may be identified for every contaminant. Detailed information about high consumption patterns is desirable, both regarding group identification criteria (e.g. age or sex differences, vegetarian or regional dietary customs, etc.) and statistical aspects.

***Dietary intake of contaminants*:** Reference is made to the *Guidelines for the Study of Dietary Intake of Chemical Contaminants* (WHO, 1985 - http://whqlibdoc.who.int/offset/WHO_OFFSET_87.pdf). It is important to supply all relevant details, such as the type of study (duplicate diet, total diet or market basket study, selective study), and statistical details. Calculated contaminant intake data from food consumption models may also be useful. When results about food groups and about effects of preparation and cooking etc. are available, these should also be supplied.

Technological considerations

Information about the source of the contaminant and the way in which the food and feed is contaminated, possibly including information, if available, about contamination being present in parts only of the product, is essential for assessing the possibilities to control the contamination process and to be able to guarantee a desired product safety and quality. Where possible ***Source-related measures*** should be proposed. ***Good Manufacturing Practice (GMP)*** and/or ***Good Agricultural Practice (GAP)*** should also be adapted to control a contamination problem. When this is possible, maximum levels may be based on GMP or GAP considerations to establish at a level as low as reasonably achievable and necessary to protect the consumer. Considerations regarding the technological possibilities to control a contamination problem, e.g. by cleaning, should also be considered when a primary risk assessment model (theoretical maximum daily intake) shows possible intakes exceeding the toxicological reference value. In such a case the possibilities of lower contamination levels need further careful examination. Then a detailed study about all the aspects involved is necessary, so that decisions about maximum levels can be based on a thorough evaluation of both the public health arguments and the potential problem with complying with the proposed standard.

Risk assessment and risk management considerations

Risk assessment and risk management are conducted in accordance with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CXG 62-2007).

Establishment of maximum levels

In case it is decided that, on the basis of the outcome of the risk assessment, there is no need to establish a maximum level to protect public health as the level of hazard/risk does not pose a public health problem, this should be communicated in a transparent and accessible manner (e.g. by using the full format as provided for Schedule I and to mention in the box of Maximum level “not necessary”).

The ***establishment of maximum levels (MLs) of contaminants in food and feed*** involves several principles, some of which have already been mentioned in this Preamble. Briefly stated, the following criteria will help in maintaining a consistent policy in this matter:

- MLs should be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.
- MLs should be set only for food that is significant for the total exposure of the consumer to the contaminant. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in Section 3 of the *Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* (Section IV of the Procedural Manual) should be consulted.
- MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake.
- Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.
- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.

- Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.
- MLs should apply to representative samples per lot. If necessary, appropriate methods of sampling should be specified.
- MLs should not be lower than a level which can be analyzed with methods of analysis that can readily be set up and applied in food and feed control laboratories, unless public health considerations necessitate a lower ML which can only be controlled by means of a more elaborate and sensitive method of analysis with an adequate lower detection limit. In all cases, a validated method of analysis should be available with which a ML can be controlled.
- The contaminant as it should be analyzed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants.
- The product as it should be analyzed and to which the ML applies, should be clearly defined. In general, MLs are set on primary products. MLs should in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some cases, however, there may be valid arguments to prefer expression on a dry weight basis (this might be in particular the case for contaminants in feed) or on a fat weight basis (this might be in particular the case for fat soluble contaminants). Preferably the product should be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might interfere with the preparation and the analysis of the sample. The product definitions used by CCPR and contained in the *Classification of Food and Feed* (CXM 4-1989) may serve as guidance on this subject; other product definitions should only be used for specified reasons. For contaminant purposes, however, analysis and consequently MLs should preferably be on the basis of the edible part of the product.

  For fat-soluble contaminants, which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).
- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food and feed can likewise be calculated from the composition of the food and feed. Information regarding the behavior of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general, however, MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors. When these factors are sufficiently known, they should be mentioned in the suffix to the maximum level following the format of list of MLs as defined in Annex II.
- MLs should preferably not be set higher than is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

Procedure for risk assessment in relation to (proposed) MLs

It is more difficult to control food and feed contamination problems than in the case of food additives and pesticide residues. Proposed MLs will inevitably be influenced by this situation. In order to promote acceptance of Codex MLs, it is therefore important that assessments of the impact of those MLs on dietary exposure are done in a consistent and realistic way. The procedure involves assessment of the dietary intake in relation to the proposed or existing MLs and the toxicological reference value.

In case a contaminant is carried over from feed to food of animal origin, the intake of a contaminant by the different food producing animal species and the resulting levels in the food of animal origin should be estimated.

The best estimate of dietary intake involves the national dietary pattern and corrections for concentration changes during transport, storage, food preparation, for known levels in foods as consumed, etc. Caution is recommended when using other than average food consumption values, although it is considered appropriate to use relevant average food consumption data for identifiable subgroups of the population. Food consumption patterns with a higher intake of critical foods may be used in the intake calculations when this is part of an accepted national or international health protection and risk management policy. A harmonized approach using an appropriate intake estimation model that is as realistic as possible is recommended. (cf. the *Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* - Section IV of the Procedural Manual). Calculated data should where possible always be compared with measured intake data. Proposals for MLs should be accompanied by intake calculations and risk assessment conclusions regarding their impact on dietary intake and use. The intake calculations should follow the methodology described in the Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups (see Sections 2 and 4 of the *Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* – Section IV of the Procedural Manual). Statements from Governments about the non-acceptance of (proposed) Codex MLs should refer to specified intake calculations and risk management conclusions, which support this position.

Annex II

FORMAT OF THE GSCTFF

Introduction

The format for the Schedule shall contain the following elements:

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

SCHEDULE
MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOODS

INDEX OF CONTAMINANTS

EXPLANATORY NOTES

Reference to JECFA	References to the JECFA meeting in which the contaminant was evaluated and the year of that meeting.
Toxicological guidance value	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed per kg body weight (bw). The year of recommendations and additional explanation are included.
Contaminant definition	Definition of the contaminant in the form of which the ML or GL applies or which may or should be analyzed in commodities/products.
Synonyms	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity / product name	The commodities or products, to which the ML or GL applies, other than the terms feed or food, are those that are intended for human consumption, unless otherwise specified. The ML or GL contained in Codex commodity standards apply to the commodities within the scope of the Codex commodity standard. Reference to the Codex Standard is provided and the definition of the commodity/product is the definition as provided in the Codex commodity standard. When the ML or GL applies only to the commodity within the scope of the Codex commodity standard then the reference is mentioned as “Relevant Codex commodity standard(s) is (are) …”. In case the reference to Codex commodity standards is provided as example for commodities to which the ML or GL applies then the reference is mentioned as “Relevant Codex Commodity standards include …” For the other commodities or products not contained in Codex commodity standards the definition of the commodity or product is provided in the *Classification of Food and Feed* (CXM 4), unless otherwise specified. In case a ML or GL applies to a product group (e.g. legume vegetables), the ML or GL applies to all individual products belonging to the group as defined in CXM 4 For any other commodities or products other than those described above, where necessary, the definition of the commodity/product is provided in “Notes/Remarks”.
Portion of the Commodity/Product to which the maximum level (ML) or guideline level (GL) applies	The portion of the feed or food to which the ML or GL applies, is the portion defined in the Codex commodity standard or CXM 4 or defined at the establishment of the ML or GL, unless otherwise specified.

DEFINITIONS OF SOME TOXICOLOGICAL TERMS

PMTDI	**Provisional Maximum Tolerable Daily Intake** The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.
PTWI	**Provisional Tolerable Weekly Intake** An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.
PTMI	**Provisional Tolerable Monthly Intake** An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods.

AFLATOXINS, TOTAL

Reference to JECFA: 31 (1987), 46 (1996), 49 (1997), 68 (2007)

Toxicological guidance value: Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible)

Contaminant definition: Aflatoxins total (B_1 + B_2 + G_1 + G_2)

Synonyms: Abbreviations, AFB, AFG, with numbers, to designate specific compounds

Related code of practice: *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CXC 55-2004)

Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CXC 59-2005)

Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CXC 45-1997)

Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (CXC 65-2008)

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

Commodity/Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Pistachios	15	Whole commodity after removal of shell.	The ML applies to pistachios intended for further processing (*). For sampling plan, see Annex 2.
Dried figs	10	Whole commodity	The ML applies to dried figs “ready-to-eat” (**). For sampling plan see Annex 3.
(*) “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 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.			
(**) “ready-to-eat” means “not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as ingredient in foodstuffs, otherwise processed or offered for human consumption.			

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 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 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	It is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum level.
Incremental sample	A quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples taken from the lot or sublot. The aggregate sample has to be at least as large as the 20 kg laboratory sample.
Laboratory sample	The smallest quantity of peanuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenization as possible.
Test portion	A 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. Considering 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 – ton (T)	Weight or number of sublots	Number of incremental samples	Laboratory sample weight (kg)
Peanuts	≥ 500	100 tons	100	20
	> 100 and < 500	5 sublots	100	20
	≥ 25 and ≤ 100	25 tones	100	20
	> 15 and <= 25	--1 sublot	100	20

Number of incremental samples for lots of less than 15 tons

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 tones – (T)	N° of incremental samples
$T \leq 1$	10
$1 < T \leq 5$	40
$5 < T \leq 10$	60
$10 < T < 15$	80

Incremental sample selection

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

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

Static lots

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

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

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

    Equation 1: $SF = (LT \times IS) / (AS \times IP)$

    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 g 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.

Homogenization – Grinding

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

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

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

Test portion

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

D. ANALYTICAL METHODS

Background

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

Performance criteria for methods of analysis

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

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

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

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

where:

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

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

Annex 2

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

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

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers may commercially classify treenuts as either "ready-to-eat" (RTE) or "destined for further processing" (DFP). As a result, maximum levels and sampling plans are proposed for both commercial types of treenuts. Maximum levels need to be defined for treenuts destined for further processing and ready-to-eat treenuts before a final decision can be made about a sampling plan design.

2. Treenuts can be marketed either as in-shell or shelled nuts. For example, pistachios are predominately marketed as in-shell nuts while almonds are predominately marketed as shelled nuts.

3. Sampling statistics, shown in Annex, 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, 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, and the negative binomial distribution are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans.

5. In Annex, the analytical variance reflects a reproducibility relative standard deviation of 22%, which is based upon Food Analysis Performance Assessment Scheme (FAPAS) data. 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.

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 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 – in-shell 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.

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 – in-shell 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.

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

SAMPLE SELECTION

MATERIAL TO BE SAMPLED

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

13. Considering that the weight of the lot is not always an exact multiple of 25 tone 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 tons. 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 tons)	Minimum number of incremental samples	Minimum incremental sample size [c] (g)	Minimum aggregate sample size (Kg)
T < 1	10	2 000	20
1 ≤ T < 5	25	800	20
5 ≤ T < 10	50	400	20
10 ≤ T < 15	75	267	20
15 ≤T	100	200	20

a / Minimum aggregate sample size = laboratory sample size of 20 kg

b / 1 Ton = 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 ton, 2 000 g = 20 000/10

WEIGHT OF THE INCREMENTAL SAMPLE

20. The suggested minimum weight of the incremental sample should be approximately 200 g for lots of 25 metric tons (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 mould 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. 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.

TEST PORTION

38. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 g. 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.

Table 2. Specific requirements with methods of analysis should comply with

Criterion	Concentration range (ng/g)	Recommended value	Maximum permitted value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 100%	n/a
	> 15	80 to 110%	n/a
Precision or relative standard deviation RSD_R (Reproducibility)	1 to 120	Equation 4	2 x value derived from Equation 4
	> 120	Equation 5	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.

Equation 4: $RSD_R = 22.0$ (for $C \leq 120$ µg/kg or $c \leq 120 \times 10^{-9}$)

Equation 5: $RSD_R = 2^{(1-0.5\log c)}$ (for $C > 120$ µg/kg or $c > 120 \times 10^{-9}$)

where:

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

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

45. Results should be reported on the edible portion of the sample.

Annex

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.

Sampling, sample preparation, and analytical variances associated with testing almonds, hazelnuts, pistachios and shelled Brazil nuts are shown in Table 1 below.

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%, which is based upon FAPAS data, is considered, 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 3

SAMPLING PLAN FOR AFLATOXIN CONTAMINATION IN DRIED FIGS

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

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers commercially classify dried figs mostly as "ready-to-eat" (RTE). As a result, maximum levels and sampling plans are established only for ready-to-eat dried figs.
2. The performance of the sampling plan was computed using the variability and aflatoxin distribution among laboratory samples of dried figs taken from contaminated lots. 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 are used to calculate operating characteristic (OC) curves that describe the performance of the aflatoxin-sampling plans for dried figs.
4. The analytical variance measured in the sampling study reflects within laboratory variance and was replaced with an estimate of analytical variance reflects a reproducibility relative standard deviation of 22%, which is based upon Food Analysis Performance Assessment Scheme (FAPAS) data. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for dried figs.

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

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

6. An aflatoxin sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the 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 aflatoxin sampling plan uses three 10 kg aggregate samples of dried figs.

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

Maximum level	–	10 µg/kg total aflatoxins
Number of laboratory samples	–	3
Laboratory sample size	–	10 kg
Sample preparation	–	water-slurry grind and a test portion that represents 55 g mass of dried figs
Analytical method	–	performance based (see Table 2)
Decision rule	–	If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxins for all three 10 kg laboratory samples, then accept the lot. Otherwise, reject the lot.

10. To assist member countries implement the above 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 tons should be subdivided into sublots to be sampled separately. If a lot is greater than 15 tons, the number of sublots is equal to the lot weight in tons divided by 15 tons. It is recommended that a lot or a sublot should not exceed 15 tons.

12. Considering that the weight of the lot is not always an exact multiple of 15 tons, 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 tons, 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 tons)	Minimum number of incremental samples	Minimum incremental sample size[c] (g)	Minimum aggregate sample size (Kg)	Laboratory sample size (Kg)	Number of laboratory samples
15.0 ≥T > 10.0	100	300	30	10	3
10.0 ≥T > 5.0	80	300	24	8	3
5.0 ≥T > 2.0	60	300	18	9	2
2.0 ≥T > 1.0	40	300	12	6	2
1.0 ≥T > 0.5	30	300	9	9	1
0.5 ≥T > 0.2	20	300	6	6	1
0.2 ≥T > 0.1	15	300	4.5	4.5	1
0.1 ≥T	10	300	3	3	1

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

b/ 1 Ton = 1 000 kg

c/ Minimum incremental sample size = laboratory sample size (30 kg)/minimum number of incremental samples,
i.e. for 10 < T ≤ 15 tons, 300 g = 30 000/100

19. The suggested minimum weight of the incremental sample is 300 g 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: $S = (D \times LT) / (T \times V)$

    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: $SF = (S \times V) / (D \times MR)$

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.

    $T = (5.0 \text{ cm} \times 20\,000 \text{ kg}) / (30 \text{ kg} \times 20 \text{ cm/sec}) = 167 \text{ sec}.$

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

PACKAGING AND TRANSPORTATION OF SAMPLES

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

SEALING AND LABELLING OF SAMPLES

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

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 mould 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. 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.

TEST PORTION

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

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

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

ANALYTICAL METHODS

BACKGROUND

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

PERFORMANCE CRITERIA FOR METHODS OF ANALYSIS

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

Table 2. Specific requirements with which methods of analysis should comply with

Criterion	Concentration range (ng/g)	Recommended value	Maximum permitted value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 100%	n/a
	> 15	80 to 110%	n/a
Precision or relative standard deviation RSD_R (Reproducibility)	1 to 120	Equation 4	2 x value derived from Equation 4
	> 120	Equation 5	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.

Equation 4: $RSD_R = 22.0$

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

where:

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

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

44. Results should be reported on the sample.

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

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

Table 3. Variances[a] associated with the aflatoxin test procedure for 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 based upon FAPAS data and considered 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.

AFLATOXIN M_1

Reference to JECFA: 56 (2001)

Toxicological guidance value: Cancer potency estimates at specified residue levels (2001, Using worst-case assumptions, the additional risks for liver cancer predicted with use of proposed maximum levels of aflatoxin M_1 of 0.05 and 0.5 µg/kg are very small. The potency of aflatoxin M_1 appears to be so low in HBsAg- individuals that a carcinogenic effect of M_1 intake in those who consume large quantities of milk and milk products in comparison with non-consumers of these products would be impossible to demonstrate. Hepatitis B virus carriers might benefit from a reduction in the aflatoxin concentration in their diet, and the reduction might also offer some protection in hepatitis C virus carriers).

Contaminant definition: Aflatoxin M_1

Synonyms: AFM_1

Related code of practice: *Code of Practice for the Reduction of Aflatoxin B_1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals* (CXC 45-1997)

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

DEOXYNIVALENOL (DON)

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

Commodity/Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Cereal-based foods for infants and young children	200	ML applies to the commodity on a dry matter basis.	All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).
Flour, meal, semolina and flakes derived from wheat, maize or barley	1 000		
Cereal grains (wheat, maize and barley) destined for further processing	2 000		"Destined for further processing" means intended to undergo an additional processing/treatment that has proven to reduce levels of DON before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels.

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

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

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

Cereal-based foods for infants and young children

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

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

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

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 larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	It is defined by a DON test procedure and an accept/reject level. A DON test procedure consists of three steps: sample selection, sample preparation and analysis or DON quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).

Incremental sample	The quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	The smallest quantity of shelled cereal comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample in such a way to ensure that the laboratory sample is still representative of the sublot sampled.
Test portion	A portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the DON for chemical analysis.

SAMPLING PLAN DESIGN CONSIDERATIONS

MATERIAL TO BE SAMPLED

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

Table 1. Subdivision of cereal sublots according to lot weight

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

* see table 2

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

INCREMENTAL SAMPLE

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

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

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

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

STATIC LOTS

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

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

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

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

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

DYNAMIC LOTS

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

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

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

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

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

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

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

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

PACKAGING AND TRANSPORTATION OF SAMPLES

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

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

SAMPLE PREPARATION

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

17. As the distribution of DON 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.

18. 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 DON cross-contamination.

TEST PORTION

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

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

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

ANALYTICAL METHODS

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

Table 3. Proposed method criteria for DON in cereals.

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

FUMONISINS ($B_1 + B_2$)

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

Commodity/Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Raw maize grain	4 000	Whole commodity	
Maize flour and maize meal	2 000	Whole commodity	

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

Maize grain, unprocessed

Maximum level	4 000 µg/kg FB1 + FB2
Increments	increments of 100 g, depending on the lot weight (≥ 0.5 tons)
Sample preparation	dry grind with a suitable mill (particles smaller than 0.85 mm - 20 mesh)
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result for the laboratory samples is equal or less than 4 000 µg/kg, accept the lot. Otherwise, reject the lot.

Maize flour and maize meal

Maximum level	2 000 µg/kg FB1 + FB2
Increments	10 x 100 g
Sample preparation	None
Laboratory sample weight	≥ 1 kg
Number of laboratory samples	1
Test portion	25 g test portion
Method	HPLC
Decision rule	If the fumonisin-sample test result is equal or less than 2 000 µg/kg, accept the lot. Otherwise, reject the lot.

DEFINITION

Lot	An identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor, or markings.
Sublot	The designated part of a larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.
Sampling plan	It is defined by a fumonisin test procedure and an accept/reject level. A fumonisin test procedure consists of three steps: sample selection, sample preparation and analysis or fumonisin quantification. The accept/reject level is a tolerance usually equal to the Codex maximum level (ML).
Incremental sample	The quantity of material taken from a single random place in the lot or sublot.
Aggregate sample	The combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.
Laboratory sample	The smallest quantity of shelled maize comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample in such a way to ensure that the laboratory sample is still representative of the sublot sampled.
Test portion	A portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the fumonisin for chemical analysis.

SAMPLING PLAN DESIGN CONSIDERATIONS

MATERIAL TO BE SAMPLED

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

Table 1. Subdivision of maize sublots according to lot weight

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

* see table 2

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

INCREMENTAL SAMPLE

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

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

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

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

STATIC LOTS

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

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

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

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

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

DYNAMIC LOTS

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

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

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

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

    $S = (D \times LT) / (T \times V)$,

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

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

    $SF = (S \times V) / (D \times MR)$.

PACKAGING AND TRANSPORTATION OF SAMPLES

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

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

SAMPLE PREPARATION

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

17. As the distribution of fumonisin 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.

18. 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 fumonisin cross-contamination.

TEST PORTION

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

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

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

ANALYTICAL METHODS

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

Table 3. Performance criteria for Fumonisin B1+ B2.

Maize Grain

Analyte	**ML** (mg/Kg)	**LOD** (mg/Kg)	**LOQ** (mg/Kg)	**RSD_R**	**Recovery (%)**
FB1 + FB2	4.0	-	-	-	-
FB1		≤ 0.3*	≤ 0.6*	HorRat ≤ 2 (< 27%)	80 - 110
FB2		≤ 0.15*	≤ 0.3*	HorRat ≤ 2 (< 32%)	80 - 110

* - The LOD and LOQ were derived based upon typical B1:B2 ratio of 5:2 in naturally-contaminated samples

Maize Flour/Meal

Analyte	**ML** (mg/Kg)	**LOD** (mg/Kg)	**LOQ** (mg/Kg)	**RSD_R**	**Recovery (%)**
FB1 + FB2	2.0	-	-	-	-
FB1		≤ 0.15*	≤ 0.3*	HorRat ≤ 2 (< 30%)	80 – 110
FB2		≤ 0.06*	≤ 0.15*	HorRat ≤ 2 (< 34%)	80 – 110

* - The LOD and LOQ were derived based upon typical B1:B2 ratio of 5:2 in naturally-contaminated samples

OCHRATOXIN A

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

Commodity/Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Wheat	5	Whole commodity	The ML applies to raw common wheat, raw durum wheat, raw spelt and raw 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 value: PMTDI 0.0004 mg/kg bw (1995)
Contaminant definition: Patulin
Related code of practice: *Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages* (CXC 50-2003)

Commodity/Product Name	Maximum Level (ML) µg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Apple juice	50	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration.	Relevant Codex commodity standard include CXS 247-2005 (apple products only). The ML applies also to apple juice used as an ingredient in other beverages.

ARSENIC

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

Toxicological guidance value: At the 72nd meeting of JECFA (2010), the inorganic arsenic lower limit on the benchmark dose for a 0.5% increased incidence of lung cancer (BMDL 0.5) was determined from epidemiological studies to be 3.0 µg/kg bw/day (2–7 µg/kg bw/day based on the range of estimated total dietary exposure) using a range of assumptions to estimate total dietary exposure to inorganic arsenic from drinking-water and food. The JECFA noted that the provisional tolerable weekly intake (PTWI) of 15 µg/kg bw (equivalent to 2.1 µg/kg bw/day) is in the region of the BMDL 0.5 and therefore was no longer appropriate. The JECFA withdrew the previous PTWI.

Contaminant definition: Arsenic: total (As-tot) when not otherwise mentioned; inorganic arsenic (As-in); or other specification

Synonyms: As

Related code of practice: *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals* (CXC 49-2001)
Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice (CXC 77-2017)

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Edible fats and oils	0.1	Whole commodity	Relevant Codex commodity standards are CXS 19-1981, CXS 33-1981, CXS 210-1999, CXS 211-1999 and CXS 329-2017. For fish oils covered by CXS 329-2017, the ML is for fish oils (As-in). Countries or importers may decide to use their own screening when applying the ML for As-in in fish oils by analyzing total arsenic (As-tot) in fish oils. If the As-tot concentration is below the ML for As-in, no further testing is required, and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.
Fat spreads and blended spreads	0.1		Relevant Codex commodity standard is CXS 256-2007.
Natural mineral waters	0.01		Relevant Codex commodity standard is CXS 108-1981. Calculated as total As in mg/l.
Rice, husked	0.35	Whole commodity	The ML is for inorganic arsenic (As-in). Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analyzing total arsenic (As-tot) in rice. If the As-tot concentration is below or equal to the ML for As-in, no further testing is required, and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Rice, polished	0.2	Whole commodity	The ML is for inorganic arsenic (As-in). Countries or importers may decide to use their own screening when applying the ML for As-in in rice by analyzing total arsenic (As-tot) in rice. If the As-tot concentration is below or equal to the ML for As-in, no further testing is required, and the sample is determined to be compliant with the ML. If the As-tot concentration is above the ML for As-in, follow-up testing shall be conducted to determine if the As-in concentration is above the ML.
Salt, food grade	0.5		Relevant Codex commodity standard is CXS 150-1985.

CADMIUM

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

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

Contaminant definition: Cadmium, total

Synonyms: Cd

Related code of practice: *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals* (CXC 49-2001)

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Brassica vegetables	0.05	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: “buttons” only.	The ML does not apply to Brassica leafy vegetables.
Bulb vegetables	0.05	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.	
Fruiting vegetables	0.05	Whole commodity after removal of stems. Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to tomatoes and edible fungi.
Leafy vegetables	0.2	Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.	The ML also applies to Brassica leafy vegetables.
Legume vegetables	0.1	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	
Pulses	0.1	Whole commodity	The ML does not apply to soya bean (dry).

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Root and tuber vegetables	0.1	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.	The ML does not apply to celeriac.
Stalk and stem vegetables	0.1	Whole commodity as marketed after removal of obviously decomposed or withered leaves. Rhubarb: leaf stems only. Globe artichoke: flower head only. Celery and asparagus: remove adhering soil.	
Cereal grains	0.1	Whole commodity	The ML does not apply to buckwheat, cañihua, quinoa, wheat and rice.
Rice, polished	0.4	Whole commodity	
Wheat	0.2	Whole commodity	The ML applies to common wheat, durum wheat, spelt and emmer.
Marine bivalve mollusks	2	Whole commodity after removal of shell.	The ML applies to clams, cockles and mussels but not to oysters and scallops.
Cephalopods	2	Whole commodity after removal of shell.	The ML applies to cuttlefishes, octopuses and squids without viscera.
Natural mineral waters	0.003		Relevant Codex commodity standard is CXS 108-1981. The ML is expressed in mg/l.
Salt, food grade	0.5		Relevant Codex commodity standard is CXS 150-1985.
Chocolate containing or declaring ≥ 50% to < 70% total cocoa solids on a dry matter basis	0.8	Whole commodity as prepared for wholesale or retail distribution	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate / chocolate flakes, and bitter table chocolate.
Chocolate containing or declaring ≥ 70% total cocoa solids on a dry matter basis	0.9	Whole commodity as prepared for wholesale or retail distribution	Including sweet chocolate, Gianduja chocolate, semi – bitter table chocolate, Vermicelli chocolate / chocolate flakes, and bitter table chocolate.

LEAD

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

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

Contaminant definition: Lead, total

Synonyms: Pb

Related code of practice: *Code of Practice for the Prevention and Reduction of Lead Contamination in Foods* (CXC 56-2004)

Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CXC 49-2001)

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Berries and other small fruits	0.1	Whole commodity after removal of caps and stems.	The ML does not apply to cranberry, currant and elderberry.
Cranberry	0.2	Whole commodity after removal of caps and stems.	
Currants	0.2	Fruit with stem.	
Elderberry	0.2	Whole commodity after removal of caps and stems.	
Fruits	0.1	Whole commodity. Berries and other small fruits: whole commodity after removal of caps and stems. Pome fruits: whole commodity after removal of stems. Stone fruits, dates and olives: whole commodity after removal of stems and stones, but the level calculated and expressed on the whole commodity without stem. Pineapple: whole commodity after removal of crown. Avocado, mangos and similar fruit with hard seeds: whole commodity after removal of stone but calculated on whole fruit.	The ML does not apply to cranberry, currant and elderberry.

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Brassica vegetables	0.1	Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: “buttons” only.	The ML does not apply to kale and leafy Brassica vegetables.
Bulb vegetables	0.1	Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached.	
Fruiting vegetables	0.05	Whole commodity after removal of stems Sweet corn and fresh corn: kernels plus cob without husk.	The ML does not apply to fungi and 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	0.1	Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	
Fresh farmed mushrooms (common mushrooms (*Agaricus bisporous*), shiitake mushrooms (*Lentinula edodes*), and oyster mushrooms (*Pleurotus ostreatus*))	0.3	Whole commodity	Relevant Codex commodity standard is CXS 38-1981.
Pulses	0.1	Whole commodity	
Root and tuber vegetables	0.1	Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.	

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Canned fruits	0.1	The ML applies to the product as consumed.	Relevant Codex commodity standards are CXS 242-2003, CXS 254-2007, CXS 78-1981, CXS 159-1987, CXS 42-1981, CXS 99-1981, CXS 60-1981, CXS 62-1981
Jams, jellies and marmalades	0.4		Relevant Codex commodity standard is CXS 296-2009 (for jams and jellies only).
Mango chutney	0.4		Relevant Codex commodity standard is CXS 160-1987.
Canned vegetables	0.1	The ML applies to the product as consumed.	Relevant Codex commodity standard is CXS 297-2009.
Preserved tomatoes	0.05		Relevant Codex commodity standard is CXS 13-1981. In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall consider the natural total soluble solids, the reference value being 4.5 for fresh fruit.
Table olives	0.4		Relevant Codex commodity standard is CXS 66-1981.
Pickled cucumbers (cucumber pickles)	0.1		Relevant Codex commodity standard is CXS 115-1981.
Canned chestnuts and canned chestnuts puree	0.05		Relevant Codex commodity standard is CXS 145-1985.
Fruit juices	0.03	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	The ML does not apply to juices exclusively from berries and other small fruit. Relevant Codex commodity standard is CXS 247-2005.
Fruit juices obtained exclusively from berries and other small fruits	0.05	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	The ML does not apply to grape juice. Relevant Codex commodity standard is CXS 247-2005.
Grape juice	0.04	Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to drink. The ML applies also to nectars, ready to drink.	Relevant Codex commodity standard is CXS 247-2005.
Cereal grains	0.2	Whole commodity	The ML does not apply to buckwheat cañihua and quinoa.

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Infant formula, formula for special medical purposes intended for infants and follow-up formula	0.01	Whole commodity	Relevant Codex commodity standards are CXS 72-1981 and CXS 156-1987. The ML applies to formula as consumed.
Fish	0.3	Whole commodity (in general after removing the digestive tract)	
Meat of cattle, pigs and sheep	0.1	Whole commodity (without bones)	The ML also applies to fat from the meat.
Meat and fat of poultry	0.1	Whole commodity (without bones)	
Cattle, edible offal of	0.2	Whole commodity.	Edible offal means such offal as have been passed as fit for human consumption, but not including lungs, ears, scalp, snout (including lips and muzzle), mucous membranes, sinews, genital system, udders, intestines and urinary bladder (CXM 4-1989). The ML applies to the following edible offal: Brain, head, heart, kidney, liver, tongue and stomach.
Pig, edible offal of	0.15	Whole commodity.	Edible offal means such offal as have been passed as fit for human consumption, but not including lungs, ears, scalp, snout (including lips and muzzle), mucous membranes, sinews, genital system, udders, intestines and urinary bladder (CXM 4-1989). The ML applies to the following edible offal: Blood, heart, kidney, liver and tongue.
Poultry, edible offal of	0.1	Whole commodity.	Poultry edible offal are such edible tissues and organs, other than poultry meat and poultry fat, from slaughtered poultry as have been passed fit for human consumption (CXM 4-1989). The ML applies to the following edible offal: Heart, kidney, liver, stomach and thymus.
Edible fats and oils	0.08	Whole commodity as prepared for wholesale or retail distribution.	Relevant Codex commodity standards are CXS 19-1981, CXS 33-1981, CXS 210-1999, CXS 211-1999 and CXS 329-2017.
Fat spreads and blended spreads	0.04	Whole commodity as prepared for wholesale or retail distribution.	Relevant Codex commodity standard is CXS 256-2007.

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Milk	0.02	Whole commodity	Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing. A concentration factor applies to partially or wholly dehydrated milks.
Secondary milk products	0.02	Whole commodity	The ML applies to the food as consumed.
Natural mineral waters	0.01		Relevant Codex commodity standard is CXS 108-1981. The ML is expressed in mg/l.
Salt, food grade	1	Whole commodity as prepared for wholesale or retail distribution	Relevant Codex commodity standard is CXS 150-1985. Excluding salt from marshes.
Wine (wine and fortified / liqueur wine)	0.2	Whole commodity	The ML applies to wines and fortified / liqueur wines made from grapes harvested before (CAC42, July 2019)
Wine	0.1	Whole commodity	The ML applies to wine made from grapes harvested after the date of adoption (CAC42, July 2019).
Fortified / Liqueur wine	0.15	Whole commodity	The ML applies to wine made from grapes harvested after the date of adoption (CAC42, July 2019).

MERCURY

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

Toxicological guidance value: At the 72rd meeting (2010), JECFA established a PTWI for inorganic mercury of 4 µg/kg bw. The previous PTWI of 5 µg/kg bw for total mercury, established at the sixteenth meeting, was withdrawn. The new PTWI for inorganic mercury was considered applicable to dietary exposure to total mercury from foods other than fish and shellfish. For dietary exposure to mercury from these foods the previously established PTWI for methyl mercury should be applied.

Contaminant definition: Mercury, Total

Synonyms: Hg

Related code of practice: *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals* (CXC 49-2001)

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

METHYLMERCURY IN CERTAIN FISH SPECIES

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

Commodity / Product Name	Maximum Level (ML) (mg/kg)	Portion of the Commodity/Product to which the ML Applies	Notes/Remarks
Tuna	1.2	Whole commodity fresh or frozen (in general after removing the digestive tract)	Countries or importers may decide to use their own screening when applying the ML for methylmercury in fish by analyzing total mercury in fish. If the total mercury concentration is below or equal to the ML for methylmercury, no further testing is required, and the sample is determined to be compliant with the ML. If the total mercury concentration is above the ML for methylmercury, follow-up testing shall be conducted to determine if the methylmercury concentration is above the ML. The ML also applies to fresh or frozen fish intended for further processing. Countries should consider developing nationally relevant consumer advice for women of childbearing age and young children to supplement the ML.
Alfonsino	1.5		
Marlin	1.7		
Shark	1.6		

TIN

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

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

RADIONUCLIDES

TABLE 1

Commodity/Product Name	Guideline Level (GL) (Bq/kg)	Representative radionuclides	Portion of the Commodity/Product to which the GL applies	Notes/Remarks
Infant foods	1	Pu-238, Pu-239, Pu-240, Am-241		The GL applies to foods intended for consumption by infants.
Infant foods	100	Sr-90, Ru-106, I-129, I-131, U-235		The GL applies to foods intended for consumption by infants.
Infant foods	1 000	S-35 (*), Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192		The GL applies to foods intended for consumption by infants.
Infant foods	1 000	H-3(**), C-14, Tc-99		The GL applies to foods intended for consumption by infants.
Foods other than infant foods	10	Pu-238, Pu-239, Pu-240, Am-241		
Foods other than infant foods	100	Sr-90, Ru-106, I-129, I-131, U-235		
Foods other than infant foods	1 000	S-35 (*), Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192		
Foods other than infant foods	10 000	H-3(**), C-14, Tc-99		

(*) 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.

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

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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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] (CXG 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. 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. 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.

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.

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 (CXG 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.

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:

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

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. 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 $1.3\ 10^{-5}$ mSv/Bq 0.1 = 0.7 mSv;

For infants: E = 1 000 Bq/kg 200 kg $2.1\ 10^{-5}$ 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.

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 value: Provisional Acceptance (1984, the use of food-contact materials from which acrylonitrile may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable)

Contaminant definition: acrylonitrile (monomer)

Synonyms: 2-Propenenitrile; vinyl cyanide (VCN); cyanoethylene; abbreviations, AN, CAN.

Related code of practice: *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals* (CXC 49-2001)

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

CHLOROPROPANOLS

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

Toxicological guidance value: PMTDI 0.002 mg/kg bw (2001, for 3-chloro-1,2-propanediol); maintained in 2006. Establishment of tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorogenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA).

BMDL 10 cancer, 3.3 mg/kg bw/day (for 1,3-dichloro-2-propanol); MOE, 65 000 (general population), 2 400 (high level intake, including young children).

Contaminant definition: 3-MCPD

Synonyms: Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD, also referred to as 3-monochloro-1,2-propanediol) and 1,3-dichloro-2-propanol (1,3-DCP).

Related code of practice: *Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the production of Acid-Hydrolyzed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs* (CXC 64–2008).

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

HYDROCYANIC ACID

Reference to JECFA: 39 (1992), 74 (2011)

Toxicological guidance value: ARfD 0.09 mg/kg bw as cyanide (2011, this cyanide-equivalent ARfD applies only to foods containing cyanogenic glycosides as the main source of cyanide)
PMTDI 0.02 mg/kg bw as cyanide (2011)

Contaminant definition: See explanatory notes in the column “Notes/Remarks”

Synonyms: HCN

Related code of practice: *Code of Practice for the Reduction of Hydrocyanic Acid (HCN) in Cassava and Cassava products* (CXC 73-2013)

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

MELAMINE

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

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Food (other than infant formulae) and feed	2.5		The ML applies to food other than infant formula. The ML applies to levels of melamine resulting from its non-intentional and unavoidable presence in feed and food. The ML does not apply to feed and food for which it can be proven that the level of melamine higher than 2.5 mg/kg is the consequence of: • Authorised use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine. • Migration from food contact materials taking account of any nationally authorized migration limit. The ML does not apply to melamine that could be present in the following feed ingredients / additives: guanidine acetic acid (GAA), urea and biuret, as a result of normal production processes.
Powdered infant formula	1		
Liquid infant formula	0.15		The ML applies to liquid infant formula as consumed.

VINYL CHLORIDE MONOMER

Reference to JECFA: 28 (1984)

Toxicological guidance value: Provisional Acceptance (1984, the use of food-contact materials from which vinyl chloride may migrate is provisionally accepted, on condition that the amount of the substance migrating into food is reduced to the lowest level technologically achievable.

Contaminant definition: Vinylchloride monomer

Synonyms: Monochloroethene, chloroethylene; abbreviation VC or VCM

Related code of practice: *Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals* (CXC 49-2001)

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