

**CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS**

## CODEX STAN 193-1995

**1. PREAMBLE****1.1 SCOPE**

This Standard contains the main principles and procedures which are used and recommended by the Codex Alimentarius in dealing with contaminants and toxins in foods and feeds, and lists the maximum levels of contaminants and natural toxicants in foods and feeds which are recommended by the CAC to be applied to commodities moving in international trade.

**1.2 DEFINITION OF TERMS****1.2.1 General**

The definitions for the purpose of the Codex Alimentarius, as mentioned in the Procedural Manual, are applicable to the General Standard for Contaminants and Toxins in Foods (GSCTF) 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, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

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

- 1) Contaminants having only food quality significance, but no public health significance, in the food(s).
- 2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR). Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the GSCTF if not dealt with by the CCPR.
- 3) Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
- 4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).
- 5) Processing aids (that by definition are intentionally added to foods).

**1.2.3 Natural toxins included in this standard**

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

Microbial 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.

Inherent natural toxicants that are implicit constituents of foods 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 the Codex Committee on Contaminants in Foods (CCCF) and will be dealt with on a case by case basis.

#### 1.2.4 Maximum level and related terms

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 (CAC) to be legally permitted in that commodity.

A *Codex guideline level (GL)* is the maximum level of a substance in a food or feed commodity which is recommended by the CAC 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.<sup>1</sup>

### 1.3 GENERAL PRINCIPLES REGARDING CONTAMINANTS IN FOODS

#### 1.3.1 General

Foods and feeds can become contaminated by various causes and processes. Contamination generally has a negative impact on the quality of the food or feed and may imply a risk to human or animal health.

Contaminant levels in foods shall be as low as reasonably achievable. The following actions may serve to prevent or to reduce contamination of foods and feeds:

- preventing food contamination at the source, e.g. by reducing environmental pollution.
- applying appropriate technology in food production, handling, storage, processing and packaging.
- applying measures aimed at decontamination of contaminated food or feed and measures to prevent contaminated food or feed 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 foods and feeds 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 foods that are contaminated, it is necessary that a risk assessment is made. When health concerns can be substantiated, a risk management policy must be applied, based on a thorough evaluation of the situation. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish maximum levels or other measures governing the contamination of foods. In special cases, it may also have to be considered to give dietary recommendations, when other measures are not sufficiently adequate to exclude the possibility of hazards to health.

National measures regarding food contamination should avoid the creation of unnecessary barriers to international trade in food or feed commodities. The purpose of the GCCTF is to provide guidance about the possible approach of the contamination problem and to promote international harmonization through recommendations which may help to avoid the creation of trade barriers.

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

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<sup>1</sup> Because the CAC 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.

### **1.3.2 Principles for establishing maximum levels in foods and feeds**

Maximum levels shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They shall be set in such a way that the consumer is adequately protected. At the same time the technological possibilities to comply with maximum levels shall be taken into account. The principles of Good Manufacturing Practice, Good Veterinary Practice and Good Agricultural Practice shall be used. Maximum levels shall be based on sound scientific principles leading to levels which are acceptable worldwide, so that international trade in these foods is facilitated. Maximum levels shall be clearly defined with respect to status and intended use.

### **1.3.3 Specific criteria**

The following criteria shall (not preventing the use of other relevant criteria) be considered when developing recommendations and making decisions in connection with the GSCTF: (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;
- information about acute and long term toxicity and other relevant toxicity;
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable.

#### **Analytical data**

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

#### **Intake data**

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

#### **Fair trade considerations**

- existing or potential problems in international trade;
- commodities concerned moving in international trade;
- information about national regulations, in particular on the data and considerations on which these regulations are based.

#### **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**

- risk assessment;
- risk management options and considerations;
- consideration of possible maximum levels in foods based on the criteria mentioned above;

- consideration of alternative solutions.

## **1.4 CODEX PROCEDURE FOR ESTABLISHING STANDARDS FOR CONTAMINANTS AND TOXINS IN FOODS**

### **1.4.1 General**

The Procedure for the elaboration of Codex Standards, as contained in the Procedural Manual, is applicable. Further details are mentioned here regarding the procedure to be followed and the criteria for decision making, in order to clarify and to facilitate the process of the elaboration of Codex Standards for Contaminants and Toxins in Foods.

### **1.4.2 Procedure for preliminary discussion about contaminants in the CCCF**

Suggestions for new contaminants or new contaminant/commodity combinations to be discussed in CCCF and to be included in the GSCTF may be raised by delegates or by the secretariat. An initial discussion may be held based on oral contributions, but preferably on the basis of a note containing relevant and adequate information. For a satisfactory preliminary review the following information is essential:

- 1) Identification of the contaminant and concise information about the background of the problem.
- 2) Indications about the availability of toxicological information and analytical and intake data, including references.
- 3) Indications about (potential) health problems.
- 4) Indications about existing and expected barriers to international trade.
- 5) Information about technological possibilities and economic aspects related to the management of the contaminant problem in food.
- 6) Preferably a proposal for action by the CCCF.

When a delegation wishes that the CCCF shall consider a request for action concerning a specific contaminant this delegation shall, as far as possible, supply information as stated above to serve as the basis for a preliminary review and request the Secretariat to include the matter on the agenda of the next meeting of the Committee.

### **1.4.3 Procedure for risk management decisions in the CCCF regarding contaminants**

An evaluation by JECFA of the toxicological and of other aspects of a contaminant and subsequent recommendations regarding the acceptable intake and regarding maximum levels in foods shall be the main basis for decisions to be discussed by the CCCF. In the absence of recommendations by JECFA, decisions may be taken by CCCF when sufficient information from other sources is available to the Committee and the matter is considered urgent.

The CCCF procedure for risk management decisions is further described in Annex II.

## **1.5 FORMAT OF THE GSCTF**

The GSCTF contains two types of presentation for the Standards: Schedule I in which the standards are listed per contaminant in the various food categories, and Schedule II (to be developed at a later stage) in which the contaminant standards are presented per food (category).

The format of the presentation is according to the provisions described in the Procedural Manual, in so far they are applicable. In order to obtain maximal clarity, explanatory notes shall be added where appropriate. The format contains all elements necessary for full understanding of the meaning, background, application and scope of the standards and contains references to the relevant documents and discussion reports on which the standard is based.

A full description of the format is given in Annex III.

For each session of the CCCF, a working document shall be prepared in which the complete list of Codex Standards for contaminants in foods (both proposed and agreed) is presented in the form of Schedule I.

The list of Codex contaminant standards for individual foods or food categories shall be presented according to an agreed food categorization system. See Annex IV.

#### **1.6 REVIEW AND REVISION OF THE GSCTF**

The contaminant provisions for this Standard shall be reviewed on a regular basis and revised as necessary in the light of revisions of toxicological advice by JECFA or of changed risk management views, residue management possibilities, scientific knowledge or other important relevant developments.

Specific attention shall be given to the review of existing Maximum Levels and Guideline Levels and to their possible conversion to Maximum Levels.

**ANNEX I**

**CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOODS**

**Introduction**

In this Annex criteria are mentioned regarding information which is considered necessary for evaluating contaminant problems in foods and for the establishment of maximum levels. It is therefore important that these criteria are taken into account when information is supplied to JECFA and/or to the CCCF.

The criteria mentioned here are elaborated in more detail than in section 1.3.3. of the Preamble. Only those aspects are mentioned that need further clarification, so criteria or aspects that are not mentioned 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 JECFA regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological data base, shall be the main basis for decisions by CCCF. 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 foods, indications are desirable about the following aspects:

- identification of the toxic substance(s);
- metabolism in humans and animals, as appropriate;
- toxicokinetics and toxicodynamics;
- 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 specially 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 representativity 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 residue regulation.

*Appropriate sampling procedures* should be applied. Special attention to this aspect is necessary in the case of contaminants that may be unequally 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 average consumers and for high consumers.

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.

## Annex I

**Food consumption data for average, most exposed 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 scale of foodstuffs, so that for every contaminant the most exposed consumer groups may be identified. 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). 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.

**Fair trade considerations**

**Existing, expected or potential problems in international trade:** In order to assess the urgency of a problem to be discussed by CCCF it is important to have information about the magnitude of existing or expected problems, both regarding the amount and the source of the food or feed that is at stake and the concerned parties and economic aspects involved. Potential problems should also be indicated.

**Foods concerned moving in international trade:** The main exporting and importing countries for commodities which are involved in the issue should be identified and it is essential that information is available about contaminant concentrations in the commodities originating from the main exporting countries.

**Information about national regulations:** It is desirable that details are made available by countries (especially the main exporting and importing countries) about their national regulations regarding the contaminant in question, in particular on the data and the considerations on which these regulations are based. For a good evaluation of the problem it is essential that not only the data base is clear, but also the risk assessment and risk management policy which is used for making decisions regarding maximum levels in foods.

**Technological considerations**

Information about the source of the contaminant and the way in which the food is contaminated, possibly including information, if it is 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 quality. Where possible **Source-related measures** should be proposed. **Good Manufacturing Practice (GMP)** and/or **Good Agricultural Practice (GAP)** should also be formulated to control a contamination problem. When this is possible, maximum levels may be based on GMP or GAP considerations and may thus be established at a level as low as reasonably achievable. Considerations regarding the technological possibilities to control a contamination problem, e.g. by cleaning, should also be taken into account when a primary risk assessment model (theoretical maximum daily intake) shows possible intakes exceeding the toxicological maximum intake recommendation. 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 limits can be based on a thorough evaluation of both the public health arguments and the possibilities and problems to comply with the proposed standard.

**Risk assessment and risk management considerations**

A tiered approach, involving risk assessment and risk management procedures, is recommended for developing a consistent policy regarding public health risks related to contaminants in foods.

**Risk assessment** is defined as the scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps: **hazard identification, hazard characterization, exposure assessment and risk characterization**. (The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties).

## Annex I

The first steps are *hazard identification* and *hazard characterization*. *Hazard identification* is the identification of known or potential health effects in humans, produced by a contaminant which may be present in a particular food or group of foods. *Hazard characterization* is the qualitative and, if possible, quantitative evaluation of the nature of the adverse effects associated with the food contaminant, including a dose/response assessment and, when possible, the establishment of a safety standard (ADI, TDI or comparable toxicological recommendation) for the intake of the contaminant. The *exposure assessment* is the qualitative and, when possible, quantitative evaluation of the likely intake of the contaminant via food, as well as exposure from other sources if relevant. In the *risk characterization* step, the hazard identification, hazard characterization and exposure assessment are combined into an estimation of the severity and occurrence of known or potential health effects likely to occur in a given population, including attendant uncertainties.

Potential public health risks can be considered to exist when there is evidence that the contaminant intake of (groups of) consumers may exceed (on a long term basis for long term recommendations) the toxicological recommendation about the maximum acceptable or tolerable intake level. More specific estimation and description of the risks will be necessary to deal adequately with cases when intakes exceeding the toxicological standard occur in practice and cannot easily be reduced. This also applies when it has not been possible to establish a safe dose level of the contaminant.

**Risk management** is defined as the process of weighing policy alternatives in the light of the risk assessment and, if required, to select and implement appropriate control options, including the establishment and enforcement of maximum levels of contaminants in foods. It is based on adequate risk assessment and on information about policy options and strategies to deal with contamination problems and involves **risk communication**.

**Risk communication** is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers and other interested parties. Responsible risk management is based on consistent application of an appropriate policy regarding the protection of public health, but also involves taking into account other relevant criteria, such as the available analytical data, the technological possibilities to control the contamination of products, economic factors and fair trade criteria.

In short, the risk assessment shall establish how many consumers possibly exceed the toxicological standard, and for how long time and how much, and what this implies as real health risks. Risk management involves, in a consistent way, deciding what is acceptable in this respect and what is not, to what extent other factors can be taken into account, and decisions and actions to achieve sufficient public health protection and control of the contamination.

Risk management decisions may lead to maximum levels for foods. In the process leading to such a decision, the consequences, costs and benefits should be presented and evaluated in relation to other policy options.

**Establishment of maximum levels for contaminants**

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

- MLs shall 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 shall be set only for those foods that are 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 the CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups should be consulted (see para. 11 of the “CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods” in the Codex Alimentarius Commission Procedural Manual).

## Annex I

- MLs shall be set as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. Where possible, MLs shall 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. 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 appreciable economic aspects are at stake.
- Proposals for MLs in products shall be based on data from at least 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 shall 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 shall apply to representative samples per lot. If necessary, appropriate methods of sampling shall be specified.
- MLs should not be lower than a level which can be analyzed with methods of analysis that can be readily applied in normal product control laboratories, unless public health considerations necessitate a lower detection limit which can only be controlled by means of a more elaborate method of analysis. In all cases, however, 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 shall 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. Preferably the product shall be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might disturb the preparation of the sample and the analysis. The product definitions used by the CCPR and contained in the Classification of foods and feeds 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 will 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).

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- 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 can likewise be calculated from the composition of the food. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance here. 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, maximum levels should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient foods by using appropriate factors. When these factors are sufficiently known, they should be added to the data base about the contaminant and mentioned in connection to the maximum level in a product.
- MLs shall 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 for contaminants**

It will be evident that in the case of contaminants, it is more difficult to control food 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 contaminant MLs, it is therefore important that assessments of the acceptability of those MLs 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 maximally acceptable intake from the toxicological point of view.

For pesticide residues, Guidelines (WHO, 1989, revised 1995) have been prepared for predicting the dietary intake, involving a two-tiered approach with increasingly realistic predictions of intake. In the crude estimate phase, hypothetical global and cultural diets are used to calculate the theoretical maximum daily intake (TMDI) (based on proposed or existing MRLs). The best estimate involves the national dietary pattern and corrections for residue losses during transport, storage, food preparation, for known residue level in foods as consumed, etc. It is recommended to be cautious in 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. The procedure is used to assess the acceptability of proposed MRLs and to promote international acceptance of Codex MRLs.

For contaminants and natural toxins in food, essentially the same procedure is used. 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. Calculated data should where possible always be compared with measured intake data. Proposals for Codex MLs should be accompanied by intake calculations and risk assessment conclusions regarding their acceptability and use. The intake calculations should follow the methodology described in the CCFAC Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups (see paras 5-8 and 12-14 of the CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods in the Codex Alimentarius Commission 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**

**PROCEDURE FOR RISK MANAGEMENT DECISIONS**

**Introduction**

The recommended procedure for risk management decisions in the CCCF is presented here as a simple decision scheme based on the main criteria, mentioned in the Preamble, I.4.2. Criterion (1), basic information about the contaminant (problem) is not further mentioned, because it is considered a prerequisite, without which no sensible discussion can take place, hazard identification and characterization. Criterion (5), technological and economic aspects, is an essential tool for making recommendations about the risk management of the contaminant problem and for developing MLs, and when this information is not adequate, further data shall be requested. Bearing this in mind, it need not be further mentioned in the decision scheme, which is shown below. Decisions can be based on the availability of information (- or + or ?) on the following criteria:

- (2a) Tox toxicological information;
- (3) PHP potential health problems;,
- (2b) A/In analytical and intake data;,
- (4) TP international trade problems.

The question mark ? is used in the column PHP, to indicate that only toxicological information is sufficiently available, or only intake data, so that there is no sufficient basis to decide whether there are potential health problems. Obviously, in practice there will be many situations which are not so clear cut as it is presented in the scheme. Information may be considered sufficient by some, and inadequate by others. Decisions will have to be taken on a case by case basis, considering the criteria mentioned in Annex I. Further quantification of the criteria for the necessary data base for making decisions may become inevitable when serious problems are encountered in practice regarding this aspect.

**Risk management decision scheme for CCCF**

Case	Criterion				CCCF Action
	(2a) Tox	(2b) A/In	(3) PHP	(4) TP	
1.	-	+	?	-	Request Tox data/evaluation by JECFA
2.	-	+	?	+	Request Tox data/evaluation by JECFA, national risk assessment. In urgent cases, CCCF statement
3.	+	-	?	-	Request analytical/intake data
4.	+	+	-	-	No further action
5.	+	+	-	+	Request national risk assessment. After evaluation (in urgent cases, after a preliminary assessment) a CCCF statement
6.	+	+	+	-	Development of MLs by CCCF
7.	+	+	+	+	Development of MLs by CCCF, with priority (in urgent cases, if necessary, temporary MLs)

(-) insufficient information

(+) sufficient information

(?) only toxicological information is sufficiently available, or only intake data, so that there is no sufficient basis to decide whether there are potential health problems.

**ANNEX III**

**FORMAT OF THE GSCTF**

**Introduction**

The format for Schedule I shall contain the following elements:

- ***Name of the contaminant:*** symbols, synonyms, abbreviations, scientific descriptions and identification codes that are commonly used shall be mentioned, too.
- ***Codex number of the contaminant:*** number according to the list described in Schedule I.
- ***Reference to JECFA meetings*** (in which the contaminant was discussed).
- ***ADI, TDI, PTWI or similar toxicological intake recommendation:*** when the situation is complex a short statement and further references may be necessary here.
- ***Residue definition:*** definition of the contaminant as it shall be analyzed and to which the maximum level applies.
- ***List of Codex standards for contaminants in that food commodity/category:*** This list shall be composed of the following elements, in columns:
  - Name of the contaminant;
  - Numerical value of maximum level;
  - Step in Codex procedure (only in CCCF working documents);
  - References, remarks and notes.
- ***Reference to a Code of practice for the food,*** if appropriate.
- ***Name of food commodity/category;***
- ***Classification number of food commodity or food category;***

The format of Schedule II shall contain the following elements:

- ***Name of food commodity/category;***
- ***Classification number of food commodity or food category;***
- ***List of Codex standards for contaminants in that food commodity/category:*** This list shall be composed of the following elements, in columns:
  - Name of the contaminant;
  - Numerical value of maximum level;
  - Step in Codex procedure (only in CCCF working documents);
  - References, remarks and notes (shorter than in Schedule I).
- ***Reference to a Code of practice for the food,*** if appropriate.

## **ANNEX IV**

### **FOOD CATEGORIZATION SYSTEM (GSCTF)**

#### **Introduction**

The food categorization system of the GSCTF is constructed to perform the following functions:

It has a logical structure which enables a clear and systematic presentation of the (proposed) MLs. It contains (references to) product definitions and definitions of the part of the product which is analyzed and to which the ML refers. It contains codes for the food categories and the individual foods, so that data can be stored and retrieved in a convenient way.

To achieve as much harmonization as possible, an existing agreed categorization system is used.

The GSCTF uses the system which is developed in the framework of the CCPR as it is also suitable for contaminants. It is adopted for characterizing the various food and feed groups and the individual commodities. This system is especially elaborated regarding primary agricultural commodities, but needs further extension regarding processed products. Where necessary, new (sub)group codes or commodity codes are therefore introduced. These are described in Annex IV-A. Annex IV-A will also contain product descriptions as far as they are different from those contained in the existing system described by the CCPR.

Where appropriate and possible, the descriptive texts accompanying the food categories do or should also contain indications about the concentration or dilution factor in the processed commodities mentioned, in relation to the primary product(s) involved. In that way a first estimate can be made of the possible carry-over of contaminants from primary products to the various processed products. It has to be borne in mind however that the specific distribution of a contaminant in the primary product and the behaviour during processing is a complicating factor here. Further advice may be necessary in those cases. See also the general indications in Annex I and possible specific information mentioned in relation to the contaminant.

#### **Description of the food categorization system of the GSCTF**

The first part contains the categorization system as developed and maintained by the CCPR. It consists of 5 classes, covering primary food commodities of plant, resp. animal origin, primary feed commodities and processed commodities of plant, resp. animal origin. The classes are subdivided in 19 types and 93 groups, which are identified by code numbers and letters.

Annex IV-A is the other part of the food categorization system for the GSCTF. It is developed and maintained by the CCCF, and is complementary to the system described in the first part. It is mainly directed to processed, derived and multi-ingredient foods and encompasses all those types and groups and commodity descriptions that are necessary to assign food categorization codes to existing or planned Codex MLs for contaminants.

**ANNEX IV-A**

**COMPLEMENTARY FOOD CATEGORIZATION SYSTEM FOR THE GSCTF**

**Introduction**

The additions to the food categorization system described in this Annex will serve the need of assigning a food code number to commodities that are not covered by this Annex. The commodities involved are mainly processed, derived and multi-ingredient foods.

The system has been designed as a comprehensive list (on a general level), in order to be able to accommodate possible future needs.

In this phase no individual product definitions and codes are given. It seems sufficient to go no further than a type or group level in judging the acceptability of the system. The classification can be developed in further detail as the need arises.

The system used in the Codex General Standard for Food Additives (GSFA) for food classification has been utilized as far as it is compatible with the existing Codex classification system described in this Annex.

See the following list of proposed new food categories. Some explanations (as shown in the list) and some existing related food categories, for a better insight in the proposed system.

Commodity descriptions can often be derived from existing Codex Standards.

Information regarding concentration and dilution factors, in relation to contaminant carry-over from primary products, will be added where appropriate and available.

Definitions for the part of the product that shall be analyzed and to which the ML of a contaminant will apply, that are different from existing definitions in this Annex, will also be added.

Class	Type	Group	Letter code	Product group description
<b>D</b>				<b>PROCESSED FOODS OF PLANT ORIGIN</b> <i>(existing)</i>
<b>D</b>	<b>01</b>			<b>Secondary commodities of plant origin</b> <i>(5 existing groups)</i>
D	01	06	TF	Treated fruit products (peeled, cut, frozen etc.) <i>(New proposed group; commodity codes can be derived from existing fruit codes)</i>
D	01	07	TV	Treated vegetable products (cleaned, cut, frozen etc.) <i>(New proposed group; commodity codes can be derived from existing vegetable codes)</i>
<b>D</b>	<b>02</b>			<b>Derived products of plant origin</b> <i>(7 existing groups)</i>
D	02	08	JV	Vegetable juices and purees <i>(New proposed group; commodity codes can be derived from the existing vegetable codes)</i>
D	02	09	SH	Sugars, syrups and honey <i>(New proposed group; commodity codes to be developed)</i>
<b>D</b>	<b>03</b>			<b>Manufactured foods of plant origin (multi-ingredient)</b> <i>(1 existing group)</i>
D	03	01	CP	Manufactured multi-ingredient cereal products (e.g. bread and other cooked cereal products) <i>(existing group)</i>

Class	Type	Group	Letter code	Product group description
D	03	02	CB	Beverages derived from cereals (e.g. beer) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
D	03	03	NF	Fruit nectars <i>(New proposed group; commodity codes can be derived from the existing fruit codes)</i>
D	03	04	FF	Fermented fruit beverages (wine, cider) <i>(New proposed group; commodity codes can be derived from the existing fruit concerned)</i>
D	03	05	DA	Distilled alcoholic beverages <i>(New proposed group; commodity codes to be developed when the need arises)</i>
D	03	06	FJ	Fruit jams, jellies, marmalades etc. <i>(New proposed group; commodity codes to be derived from the existing fruit codes)</i>
D	03	07	SF	Fruit chutneys and comparable preparations <i>(New proposed group; commodity codes to be derived from the existing fruit codes)</i>
D	03	08	SV	Vegetable chutneys and comparable preparations <i>(New proposed group; commodity codes to be derived from the existing vegetable codes)</i>
D	03	09	PS	Preparations from nuts, oil seeds and other seeds <i>(New proposed group; commodity codes to be derived from the existing product codes)</i>
D	03	10	PP	Other manufactured plant products <i>(New proposed group; commodity codes to be developed when the need arises)</i>
<b>E</b>				<b>PROCESSED FOODS OF ANIMAL ORIGIN</b> <i>(existing class)</i>
<b>E</b>	<b>01</b>			<b>Secondary commodities of animal origin</b> <i>(2 existing groups)</i>
E	01	03	MS	Secondary meat products (e.g. cooked meat) <i>(New proposed group; commodity codes to be derived from the existing meat codes)</i>
E	01	04	ES	Secondary egg products (e.g. egg powder) <i>(New proposed group; commodity codes to be derived from the existing egg codes)</i>
E	01	05	WS	Secondary fishery products (e.g., smoked fish) <i>(New proposed group; commodity codes to be derived from the existing fish codes)</i>
<b>E</b>	<b>02</b>			<b>Derived animal products of animal origin</b> <i>(4 existing groups)</i>
E	02	05	MC	Derived meat products (e.g. meat extract) <i>(New proposed group; commodity codes to be derived from existing meat codes)</i>
E	02	06	ED	Derived egg products (e.g. egg white, yolk) <i>(New proposed group; commodity codes to be derived from existing egg codes)</i>

Class	Type	Group	Letter code	Product group description
E	02	07	WD	Derived fishery products <i>(New proposed group; commodity codes to be derived from the existing fish codes)</i>
<b>E</b>	<b>03</b>			<b>Manufactured food (single ingredient), animal origin</b> <i>(1 existing group)</i>
E	03	01	LI	Manufactured milk products (single ingredient) <i>(existing group)</i>
E	03	02	MT	Manufactured meat products (e.g. cured meat) <i>(New proposed group; commodity codes to be derived from existing meat codes)</i>
E	03	03	EM	Manufactured egg products (e.g. egg white powder) <i>(New proposed group; commodity codes to be derived from existing egg codes)</i>
E	03	04	WP	Manufactured fishery products <i>(New proposed group; commodity codes to be derived from existing fish codes)</i>
<b>E</b>	<b>04</b>			<b>Manufactured food (multi-ingredient) of animal origin</b> <i>(1 existing group)</i>
E	04	01	LM	Manufactured milk products (multi-ingredient) <i>(existing group)</i>
E	04	02	MP	Manufactured meat products (multi-ingredient) (e.g. sausage) <i>(New proposed group; commodity codes to be developed in relation to commodity description)</i>
E	04	03	EP	Manufactured egg products (multi-ingredient) <i>(New proposed groups; commodity codes to be developed in relation to commodity description)</i>
E	04	04	WI	Manufactured fishery products (multi-ingredient) <i>(New proposed group; commodity codes to be derived from existing fish codes)</i>
<b>F</b>				<b>MULTI-INGREDIENT MANUFACTURED FOODS</b> <i>(New proposed class)</i>
<b>F</b>	<b>01</b>			<b>Beverages (multi-ingredient)</b> <i>(New proposed type)</i>
F	01	01	BS	Beverages (soft drinks and comparable preparations) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	01	02	BA	Alcoholic multi-ingredient beverages <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
<b>F</b>	<b>02</b>			<b>Sauces, salad dressings, soups, bouillons etc.</b> <i>(New proposed type)</i>
F	02	01	SP	Seasonings and condiments <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	02	PV	Vinegars (multi-ingredient) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>

Class	Type	Group	Letter code	Product group description
F	02	03	PM	Mustards <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	04	BS	Soups and broths <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	05	ME	Sauces and comparable products <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	02	06	BC	Salads and sandwich spreads <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
<b>F</b>	<b>03</b>			<b>Chocolate &amp; other confectionery</b> <i>(New proposed type)</i>
F	03	01	CC	Chocolate products <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	03	02	CS	Sugar confectionery, including nut based and comparable multi-ingredient confectionery <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	03	03	CG	Chewing gum <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
<b>F</b>	<b>04</b>			<b>Margarines &amp; other multi-ingredient fatty foods</b> <i>(New proposed type)</i>
F	04	01	HF	Margarines > 80 % fat <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	04	02	LF	Margarines < 80 % fat <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	04	03	OF	Other products based on fat emulsions <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
<b>F</b>	<b>05</b>			<b>Multi-ingredient bakery wares</b> <i>(New proposed type)</i>
F	05	01	BF	Fine bakery wares <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	05	02	BS	Savoury snacks (potato, cereal or starch base) <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	05	03	NS	Savoury coated nuts, other nut snacks, nut mixtures <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
<b>F</b>	<b>06</b>			<b>Multi-ingredient foods for special dietary uses</b> <i>(New proposed type)</i>

Class	Type	Group	Letter code	Product group description
F	06	01	ID	Infant and follow-on formulae <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	02	CD	Weaning foods <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	03	HD	Dietetic foods intended for special medical purposes <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	04	TD	Dietetic formulae for slimming purposes and weight reduction <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	05	SD	Supplementary foods for dietetic uses <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
F	06	06	AD	Food supplements <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>
<b>G</b>				<b>OTHER EDIBLE PRODUCTS</b> <i>(New proposed class)</i>
<b>G</b>	<b>01</b>			<b>Water, minerals and organic compounds</b> <i>(New proposed type)</i>
G	01	01	DW	Drinking water, mineral water, table waters <i>(New proposed group, commodity codes to be developed when the necessity arises)</i>
G	01	02	SW	Salt, salt substitutes, mineral preparations <i>(New proposed group; commodity codes to be developed when the necessity arises)</i>

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

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**EXPLANATORY NOTES**

Reference to JECFA:	References to JECFA meeting in which the contaminant was evaluated and the year of that meeting
Toxicological guidance value:	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed in milligrammes (mg) per kg body weight (bw). The year of recommendations and additional explanation are included.
Residue definition:	Definition of the contaminant in the form of which the ML applies or which may or should be analyzed in commodities.
Synonyms:	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity code:	The code for food commodities is according to the food and feed categorization system as contained in Annex IV-A of the GSCTF or the Codex Classification of foods and feeds. The food/feed categorization system also specifies the part of Commodity which should be analysed and to which the ML applies, unless a specific commodity definition is provided as an annex to the ML. For those maximum levels contained in Codex commodity standards, the relevant standard numbers are referred, if the code numbers are not readily available for these commodities.
Suffix:	A note accompanying an ML or GL, used to specify the application or the future revision of the ML, e.g., specific residue definitions can be mentioned by abbreviations here. See also "Qualification of MLs" below.
Type:	Indicates whether the value is Codex maximum level (ML) or Codex guideline level (GL). See also the definitions of these terms in the preamble of the GSCTF.

**Qualification of MLs**

C:	In canned products only
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**Definitions of some toxicological terms**

PMTDI:	<i>(Provisional Maximum Tolerable Daily Intake)</i> 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:	<i>(Provisional Tolerable Weekly Intake)</i> 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:	<i>(Provisional Tolerable Monthly Intake)</i> An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods

**AFLATOXINS, TOTAL**

Reference to JECFA:	31 (1987), 46 (1996), 49 (1997), 68 (2007)
Toxicological guidance:	Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible.)
Residue definition:	Aflatoxins total (B1 +B2 + G1 + G2)
Synonyms:	Abbreviations, AFB, AFG, with numbers, to designate specific compounds
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004) Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005) Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CAC/RCP 45-1997) Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (CAC/RCP 65-2008)

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
SO 0697	Peanut	15		ML		The ML applies to peanuts intended for further processing. For sampling plan, see Annex 1 below.
TN 0660	Almonds	15		ML		The ML applies to almonds intended for further processing. For sampling plan, see Annex 2 below.
TN 0666	Hazelnuts	15		ML		The ML applies to hazelnuts intended for further processing. For sampling plan, see Annex 2 below.
TN 0675	Pistachios	15		ML		The ML applies to pistachios intended for further processing. For sampling plan, see Annex 2 below.
TN 0660	Almonds	10		ML		The ML applies to almonds "ready-to-eat". For sampling plan, see Annex 2.
TN 0666	Hazelnuts	10		ML		The ML applies to hazelnuts "ready-to-eat". For sampling plan, see Annex 2.
TN 0675	Pistachios	10		ML		The ML applies to pistachios "ready-to-eat". For sampling plan, see Annex 2.

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

**Annex 1**

**SAMPLING PLAN FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING**

**INTRODUCTION**

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

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

**A. Definitions**

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

**B. Sampling**

Material to be Sampled

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

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

Table 1: Subdivision of Large Lots into Sublots for Sampling

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

Number of Incremental Samples for Lots of Less than 15 Tonnes

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

Table 2: Number of Incremental Samples to be Taken Depending on the Weight of the Lot

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

Incremental Sample Selection

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

7. Since there is no way to know if the contaminated peanut kernels are uniformly dispersed through out 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 through 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 :  $S = (D \times LT) / (T \times V)$ . 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 :  $SF = (S \times V) / (D \times MR)$ .

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,

$$T = (5.08 \text{ cm} \times 30,000 \text{ kg}) / (20 \text{ kg} \times 30 \text{ cm/sec}) = 254 \text{ sec}$$

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

Weight of the Incremental Sample

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

Packaging and transmission of samples

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

Sealing and labelling of samples

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

**C. Sample Preparation**

Precautions

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

Homogenisation – Grinding

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

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

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

Test portion

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

**D. Analytical Methods**

Background

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

*Performance Criteria for Methods of Analysis*

Table 3: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	-
Recovery-Aflatoxins Total	1 - 15 µg/kg	70 to 110 %	
	> 15 µg/kg	80 to 110 %	
Precision RSD <sub>R</sub>	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD <sub>T</sub> may be calculated as 0.66 times Precision RSD <sub>R</sub> 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<sub>R</sub> 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 = 100g/100g, 0.001 = 1,000 mg/kg)

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

**Annex 2**

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

**DEFINITION**

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

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

**Sampling plan** - is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum level.

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

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

**Laboratory sample** – the smallest quantity of tree nuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.

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

**Ready-to-eat treenuts** – nuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins.

**Treenuts destined for further processing** – nuts, which are intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by color sorting, and sorting by specific gravity and color (damage). There is some evidence that roasting reduces aflatoxins in pistachios but for other nuts the evidence is still to be supplied.

**Operating Characteristic (OC) Curve** – a plot of the probability of a accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

**SAMPLING PLAN DESIGN CONSIDERATIONS**

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

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<sup>2</sup> Whitaker, T., Dickens, J., Monroe, R., and Wiser, E. 1972. Comparison of the negative binomial distribution of aflatoxin in shelled peanuts to the negative binomial distribution. J. American Oil Chemists' Society, 49:590-593.

5. In Annex I, the analytical variance reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data<sup>3</sup>. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for the three treenuts. The within laboratory analytical uncertainty for each treenut can be found at the website <http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html>.
6. The issue of correcting the analytical test result for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestions for the range of acceptable recovery rates.

#### **AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS**

7. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the proposed maximum level and the aflatoxin test procedure are given below in this section.
8. The maximum levels for total aflatoxins in treenuts (almonds, hazelnuts, and pistachios) “ready-to-eat” and “destined for further processing” are 10 and 15 ng/g, respectively.
9. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the proposed aflatoxin sampling plans use a 20 kg aggregate sample for all three treenuts.
10. The two sampling plans (RTE and DFP) have been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of treenuts traded in the export market.

##### Treenuts destined for further processing

Maximum level – 15 ng/g total aflatoxins

Number of laboratory samples – 1

Laboratory sample size - 20 kg

Almonds – shelled nuts

Hazelnuts – shelled nuts

Pistachios – inshell nuts (equivalent to about 10kg shelled nuts that is calculated on the basis of the actual edible portion in the sample)

Sample preparation – dry grind with vertical cutter mixer type mill and a 50 g test portion

Analytical method – performance based (see Table 2)

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

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

##### Ready-to-eat treenuts

Maximum level – 10 ng/g total aflatoxins

Number of laboratory samples – 2

Laboratory sample size - 10 kg

Almonds – shelled nuts

Hazelnuts – shelled nuts

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

Sample preparation – dry grind with vertical cutter mixer type mill and a 50 g test portion

Analytical method – performance based (see Table 2)

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

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<sup>3</sup> Thompson, M. 2000. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. J. Royal Society of Chemistry, 125:385-386.

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

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

## SAMPLE SELECTION

### Material to be sampled

- Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a subplot should not exceed 25 tonnes. The minimum lot weight should be 500 kg.
- Taking into account that the weight of the lot is not always an exact multiple of 25 tonne sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 25%.
- 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.
- In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

### Incremental Sample Selection

- 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.
- 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

- The number and size of the laboratory sample(s) will not vary with lot (subplot) size. However, the number and size of the incremental samples will vary with lot (subplot) size.
- The number of incremental samples to be taken from a lot (subplot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes below 25 tonnes. The number of incremental samples varies from a minimum of 10 and to a maximum of 100.

**Table 1. Number and size of incremental samples composited for an aggregate sample of 20 kg<sup>a</sup> as a function of lot (or subplot) weight.**

Lot or Sublot Weight <sup>b</sup> (T in Tonnes)	Minimum Number of Incremental Samples	Minimum Incremental Sample Size <sup>c</sup> (g)	Minimum Aggregate Sample Size (kg)
T<1	10	2000	20
1≤T<5	25	800	20
5≤T<10	50	400	20
10≤T<15	75	267	20
15≤T	100	200	20

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

b/ 1 Tonne = 1000 kg

c/ Minimum incremental sample size = laboratory sample size (20 kg)/minimum number of incremental samples,

i.e. for  $0.5 < T < 1$  tonne,  $2000 \text{ g} = 20000/10$

#### Weight of the Incremental Sample

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

#### Static Lots

21. A static lot can be defined as a large mass of treenuts contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the nuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or subplot 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:

$$\text{Equation 1: } SF = (LT \times IS) / (AS \times IP).$$

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:

$$\text{Equation 2: } S = (D \times LT) / (T \times V),$$

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).

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.

$$\text{Equation 3: } SF = (S \times V) / (D \times MR).$$

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,

$$T = (5.0 \text{ cm} \times 20,000 \text{ kg}) / (20 \text{ kg} \times 30 \text{ cm/sec}) = 250 \text{ sec.}$$

31. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2400 sec) and only 9.6 cuts (9 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (2,083.3 kg) passes through the sampler between the time the cup cuts through the stream.

#### Packaging and Transportation of Samples

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

#### Sealing and Labelling of Samples

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

### **SAMPLE PREPARATION**

#### Precautions

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

#### Homogenization - Grinding

35. As the distribution of aflatoxin is extremely non-homogeneous, laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.
36. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation (Annex I) approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.
37. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction<sup>4</sup>. 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<sup>5</sup>.

#### Test portion

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

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<sup>4</sup> Ozay, G., Seyhan, F., Yilmaz, A., Whitaker, T., Slate, A., and Giesbrecht, F. 2006. Sampling hazelnuts for aflatoxin: Uncertainty associated with sampling, sample preparation, and analysis. *J. Association Official Analytical Chemists, Int.*, 89:1004-1011.

<sup>5</sup> Spanjer, M., Scholten, J., Kastrup, S., Jorissen, U., Schatzki, T., Toyofuku, N. 2006. Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?, *Food Additives and Contaminants*, 23:73-83.

## ANALYTICAL METHODS

### Background

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

### Performance Criteria for Methods of Analysis

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

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

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

n/a = not applicable

43. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values are calculated from equations 4 and 5 developed by Thompson<sup>2</sup> and Horwitz and Albert<sup>6</sup>, respectively.

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

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

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 =  $0.66RSD_R$
- $c$  = the aflatoxin concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)
- $C$  = aflatoxin concentration or mass of aflatoxin to mass of treenuts (i.e. ng/g)

<sup>6</sup> Horwitz, W. and Albert, R. 2006. The Horwitz ratio (HorRat): A useful index of method performance with respect to precision. J. Association of Official Analytical Chemists, Int., 89:1095-1109.

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 I**

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

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

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

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

**Table 1. Variances<sup>a</sup> associated with the aflatoxin test procedure for each treenut.**

Test Procedure	Almonds	Hazelnuts	Pistachios
Sampling <sup>b,c</sup>	$S_s^2 = (7,730/ns)5.759C^{1.561}$	$S_s^2 = (10,000/ns)4.291C^{1.609}$	$S_s^2 = 8,000/ns)7.913C^{1.475}$
Sample Prep <sup>d</sup>	$S_{sp}^2 = (100/nss)0.170C^{1.646}$	$S_{sp}^2 = (50/nss)0.021C^{1.545}$	$S_{sp}^2 = (25/nss)2.334C^{1.522}$
Analytical <sup>e</sup>	$S_a^2 = (1/na)0.0484C^{2.0}$	$S_a^2 = (1/na)0.0484C^{2.0}$	$S_a^2 = (1/na)0.0484C^{2.0}$
Total variance	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$	$S_s^2 + S_{sp}^2 + S_a^2$

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

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

c/ Shelled nut count/kg for almonds, hazelnuts, and pistachios is 773, 1000, and 1600, respectively.

d/ Sample preparation for almonds, hazelnuts, and pistachios reflect Hobart, Robot Coupe, and Marjaan Khatman type mills, respectively. Laboratory samples were dry ground into a paste for each treenut.

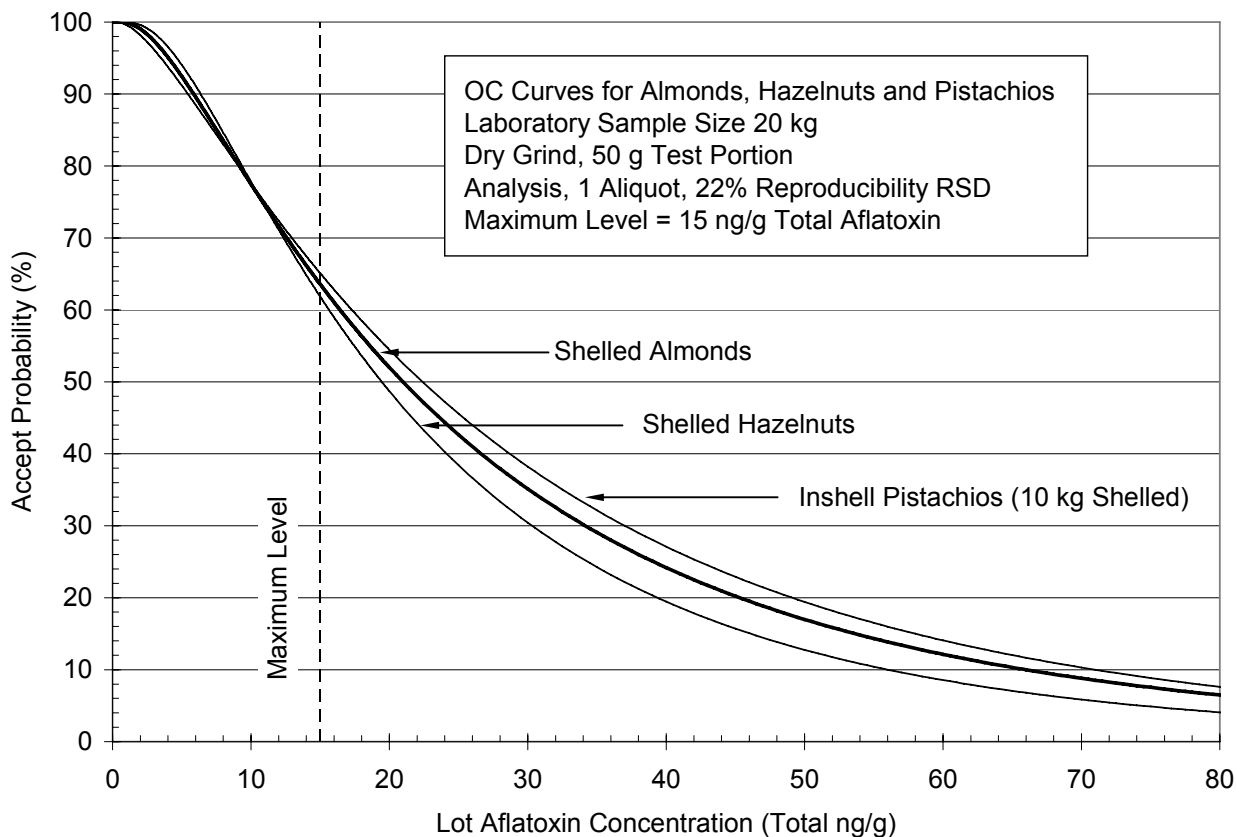
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson<sup>2</sup> (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories.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

Annex II

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

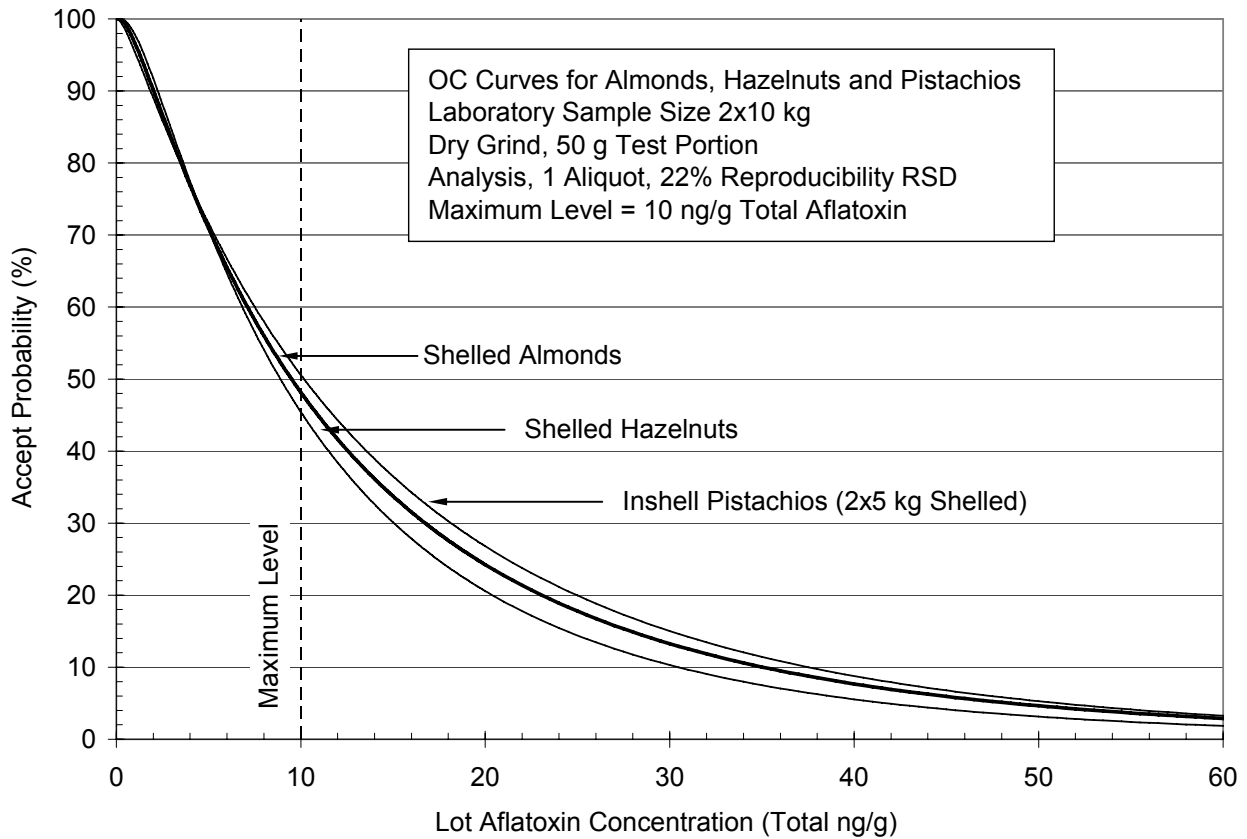
*Treenuts Destined for Further Processing*

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



Ready-to-Eats Treenuts

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



**AFLATOXIN M1**

Reference to JECFA: 56 (2001)  
 Toxicological guidance: Cancer potency estimates at specified residue levels (2001, Using worst-case assumptions, the additional risks for liver cancer predicted with use of proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small. The potency of aflatoxin M1 appears to be so low in HBsAg- individuals that a carcinogenic effect of M1 intake in those who consume large quantities of milk and milk products in comparison with non-consumers of these products would be impossible to demonstrate. Hepatitis B virus carriers might benefit from a reduction in the aflatoxin concentration in their diet, and the reduction might also offer some protection in hepatitis C virus carriers.)  
 Residue definition: Aflatoxin M1  
 Synonyms: AFM1

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
ML 0106	Milk	0.5		ML		

**OCHRATOXIN A**

Reference to JECFA: 37 (1990), 44 (1995), 56 (2001), 68 (2007)  
 Toxicological guidance: PTWI 0.0001 mg/kg bw (2001)  
 Residue definition: Ochratoxin A  
 Synonyms: (The term ‘ochratoxins’ includes a number of related mycotoxins (A, B, C and their esters and metabolites), the most important one being ochratoxin A)  
 Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisin and Tricothecenes (CAC/RCP 51-2003)  
 Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (CAC/RCP 63-2007)

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
GC 0654	Raw Wheat	5		ML		
GC 0640	Barley	5		ML		
GC 0650	Rye	5		ML		

**PATULIN**

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

Commodity/Product Code	Product Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
JF 0226	Apple juice	50		ML		The ML also covers apple juice as ingredient in other beverages.

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

**ARSENIC**

Reference to JECFA: 5 (1960), 10 (1967), 27 (1983), 33 (1988)  
 Toxicological guidance: PTWI 0.015 mg/kg bw (1988, For inorganic arsenic)  
 Residue definition: Arsenic: total (As-tot) when not otherwise mentioned; inorganic arsenic (As-in); or other specification  
 Synonyms: As  
 Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Edible fats and oils	0.1		ML	CS 19-1981	Edible fats and oils not covered by individual standards
	Margarine	0.1		ML	CS 32-1981	
	Minarine	0.1		ML	CS 135-1981	
	Named animal fats	0.1		ML	CS 211-1999	Lard, rendered pork fat, premier jus and edible tallow.
OR 0305	Olive oil, refined	0.1		ML	CS 33-1981	
OC 0305	Olive oil, virgin	0.1		ML	CS 33-1981	
OR 5330	Olive, residue oil	0.1		ML	CS 33-1981	Olive pomace oil
OC 0172	Vegetable oils, Crude	0.1		ML	CS 210-1999	Named vegetable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.
OR 0172	Vegetable oils, Edible	0.1		ML	CS 210-1999	Named vegetable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Natural mineral waters	0.01		ML	CS 108-1981	Expressed in total As mg/l
	Salt, food grade	0.5		ML	CS 150-1985	

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

#### CADMIUM

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

Toxicological guidance: PTWI 0.007 mg/kg bw (1988 (maintained in 2000 & 2003), The 64th JECFA concluded that the effect of different MLs on overall intake of cadmium would be very small. At the proposed Codex MLs, mean intake of cadmium would be reduced by approximately 1% of the PTWI. The imposition of MLs one level lower would result in potential reductions in intake of cadmium of no more than 6% (wheat grain, potatoes) of the PTWI. At the proposed Codex MLs, no more than 9% of a commodity would be violative (oysters). MLs one level below those proposed would result in approximately 25% of molluscs, potatoes, and other vegetables being violative.)

Residue definition: Cadmium, total

Synonyms: Cd

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

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
VB 0040	Brassica vegetables	0.05		ML		
VA 0035	Bulb vegetables	0.05		ML		
VC 0045	Fruiting vegetables, cucurbits	0.05		ML		
VO 0050	Fruiting vegetables, other than cucurbits	0.05		ML		Excluding tomatoes and edible fungi.
VL 0053	Leafy vegetables	0.2		ML		

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
VP 0060	Legume vegetables	0.1		ML		
VR 0589	Potato	0.1		ML		Peeled
VD 0070	Pulses	0.1		ML		Excluding soya bean (dry)
VR 0075	Root and tuber vegetables	0.1		ML		Excluding potato and celeriac
VS 0078	Stalk and stem vegetables	0.1		ML		
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.1		ML		Excluding wheat and rice; and bran and germ
CM 0649	Rice, polished	0.4		ML		
GC 0654	Wheat	0.2		ML		
IM 0151	Marine bivalve molluscs	2		ML		Excluding oysters and scallops
IM 0152	Cephalopods	2		ML		Without viscera
	Natural mineral waters	0.003		ML	CS 108-1981	Expressed in mg/l
	Salt, food grade	0.5		ML	CS 150-1985	

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

#### LEAD

Reference to JECFA:	10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999)
Toxicological guidance:	PTWI 0.025 mg/kg bw (1987 for infants and young children, extended to all age groups in 1993, maintained 1999)
Residue definition:	Lead, total
Synonyms:	Pb
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CAC/RCP 56-2004) Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
FT 0026	Assorted (sub)tropical fruits, edible peel	0.1		ML		
FI 0030	Assorted (sub)tropical fruits, inedible peel	0.1		ML		
FB 0018	Berries and other small fruits	0.2		ML		
FC 0001	Citrus fruits	0.1		ML		

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
FP 0009	Pome fruits	0.1		ML		
FS 0012	Stone fruits	0.1		ML		
VB 0040	Brassica vegetables	0.3		ML		Excluding kale
VA 0035	Bulb vegetables	0.1		ML		
VC 0045	Fruiting vegetables, Cucurbits	0.1		ML		
VO 0050	Fruiting vegetables, other than Cucurbits	0.1		ML		Excluding mushrooms
VL 0053	Leafy vegetables	0.3		ML		Including Brassica leafy vegetables but excluding spinach.
VP 0060	Legume vegetables	0.2		ML		
VD 0070	Pulses	0.2		ML		
VR 0075	Root and tuber vegetables	0.1		ML		Including peeled potatoes
	Canned fruit cocktail	1		ML	CS 78-1981	
	Canned grapefruit	1		ML	CS 15-1981	
	Canned mandarin oranges	1		ML	CS 68-1981	
	Canned mangoes	1		ML	CS 159-1987	
	Canned pineapple	1		ML	CS 42-1981	
	Canned raspberries	1		ML	CS 60-1981	
	Canned strawberries	1		ML	CS 62-1981	
	Canned tropical fruit salad	1		ML	CS 99-1981	
	Jams (fruit preserves) and jellies	1		ML	CS 79-1981	
	Mango chutney	1		ML	CS 160-1987	
	Table olives	1		ML	CS 66-1981	
	Canned asparagus	1		ML	CS 56-1981	
	Canned carrots	1		ML	CS 116-1981	
	Canned green beans and canned wax beans	1		ML	CS 16-1981	
	Canned green peas	1		ML	CS 58-1981	
	Canned mature processed peas	1		ML	CS 81-1981	
	Canned mushrooms	1		ML	CS 55-1981	
	Canned palmito	1		ML	CS 144-1985	
	Canned sweet corn	1		ML	CS 18-1981	
	Canned tomatoes	1		ML	CS 13-1981	
	Pickled cucumbers (cucumber pickles)	1		ML	CS 115-1981	
	Processed tomato concentrates	1.5		ML	CS 57-1981	
JF 0175	Fruit juices	0.05		ML		Including nectars; Ready to drink
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.2		ML		

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Canned chestnuts and canned chestnuts puree	1		ML	CS 145-1985	
MM 0097	Meat of cattle, pigs and sheep	0.1		ML		Also applies to the fat from meat
PM 0110	Poultry meat	0.1		ML		
MO 0812	Cattle, Edible offal of	0.5		ML		
MO 0818	Pig, Edible offal of	0.5		ML		
PO 0111	Poultry, Edible offal of	0.5		ML		
	Edible fats and oils	0.1		ML	CS 19-1981	Edible fats and oils not covered by individual standards
	Fish	0.3		ML		
	Margarine	0.1		ML	CS 32-1981	
	Minarine	0.1		ML	CS 135-1981	
	Named animal fats	0.1		ML	CS 211-1999	Lard, rendered pork fat, premier jus and edible tallow.
OR 0305	Olive oil, refined	0.1		ML	CS 33-1981	
OC 0305	Olive oil, virgin	0.1		ML	CS 33-1981	
OR 5330	Olive, residue oil	0.1		ML	CS 33-1981	Olive pomace oil
PF 0111	Poultry fats	0.1		ML		
OC 0172	Vegetable oils, Crude	0.1		ML	CS 210-1999	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, saflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.
OR 0172	Vegetable oils, Edible	0.1		ML	CS 210-1999	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, saflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.
ML 0106	Milks	0.02		ML		A concentration factor applies to partially or wholly dehydrated milks.
LS	Secondary milk products	0.02		ML		As consumed
	Natural mineral waters	0.01		ML	CS 108-1981	Expressed in mg/l
	Infant formula	0.02		ML		Ready to use
	Salt, food grade	2		ML	CS 150-1985	
	Wine	0.2		ML		

**MERCURY**

Reference to JECFA:	10 (1966), 14 (1970), 16 (1972), 22 (1978)
Toxicological guidance:	PTWI 0.005 mg/kg bw (1978)
Residue definition:	Mercury, Total
Synonyms:	Hg
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Natural mineral waters	0.001		ML	CS 108-1981	Expressed in mg/l
	Salt, food grade	0.1		ML	CS 150-1985	

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

**METHYLMERCURY**

Reference to JECFA:	22 (1978), 33 (1988), 53 (1999), 61 (2003)
Toxicological guidance:	PTWI 0.0016 mg/kg bw (2003)
Residue definition:	Methylmercury
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Fish	0.5		GL		Except predatory fish The Guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade. Predatory fish such as shark (WS 0131), swordfish, tuna (WS 0132), pike (WF 0865) and others. The Guideline level for methylmercury in fresh or processed fish and fish products moving in international trade.
	Predatory fish	1		GL		

Lots should be considered as being in compliance with the guideline levels if the level of methylmercury in the analytical sample, derived from the composite bulk sample, does not exceed the above levels. Where these Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction and what recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women. Methylmercury is the most toxic form of mercury and is formed in aquatic environments. Methylmercury therefore is found mainly in aquatic organisms. It can accumulate in the food chain; the levels in large predatory fish species are therefore higher than in other species and fish is the predominant source of human exposure to methylmercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products.

**TIN**

Reference to JECFA: 10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26(1982), 33(1988), 55 (2000), 64 (2005)

Toxicological guidance: PTWI 14 mg/kg bw (1988, Expressed as Sn; includes tin from food additive uses; maintained in 2000.)

Residue definition: Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification

Synonyms: Sn

Related Code of Practice: Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods (CAC/RCP 60-2005)  
Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Canned foods (other than beverages)	250	C	ML		
	Canned beverages	150	C	ML		
	Canned fruit cocktail	250	C	ML	CS 78-1981	
	Canned grapefruit	250	C	ML	CS 15-1981	
	Canned mandarin oranges	250	C	ML	CS 68-1981	
	Canned mangoes	250	C	ML	CS 159-1987	
	Canned pineapple	250	C	ML	CS 42-1981	
	Canned raspberries	250	C	ML	CS 60-1981	
	Canned strawberries	200	C	ML	CS 62-1981	
	Canned tropical fruit salad	250	C	ML	CS 99-1981	
	Jams (fruit preserves) and jellies	250	C	ML	CS 79-1981	
	Mango chutney	250	C	ML	CS 160-1987	
	Table olives	250	C	ML	CS 66-1981	
	Canned asparagus	250	C	ML	CS 56-1981	
	Canned carrots	250	C	ML	CS 116-1981	
	Canned green and wax beans	250	C	ML	CS 16-1981	
	Canned green peas	250	C	ML	CS 58-1981	
	Canned mature processed peas	250	C	ML	CS 81-1981	
	Canned mushrooms	250	C	ML	CS 55-1981	
	Canned palmito	250	C	ML	CS 144-1985	
	Canned sweet corn	250	C	ML	CS 18-1981	
	Canned tomatoes	250	C	ML	CS 13-1981	
	Pickled cucumber	250	C	ML	CS 115-1981	
	Processed tomato concentrates	250	C	ML	CS 57-1981	
	Canned chestnuts and chestnut purée	250	C	ML	CS 145-1985	
	Cooked cured chopped meat	200	C	ML	CS 98-1981	For products in tinplate containers
	Cooked cured chopped meat	50		ML	CS 98-1981	For products in other containers
	Cooked cured ham	50		ML	CS 96-1981	For products in other containers

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Cooked cured ham	200	C	ML	CS 96-1981	For products in tinfoil containers
	Cooked cured pork shoulder	50		ML	CS 97-1981	For products in other containers
	Cooked cured pork shoulder	200	C	ML	CS 97-1981	For products in tinfoil containers
	Corned beef	50		ML	CS 88-1981	For products in other containers
	Corned beef	200	C	ML	CS 88-1981	For products in tinfoil containers
	Luncheon meat	200	C	ML	CS 89-1981	For products in tinfoil containers
	Luncheon meat	50		ML	CS 89-1981	For products in other containers

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

#### RADIONUCLIDES

Commodity Code	Product Name	Representative radionuclides	Dose per unit intake factor in Sv/Bq	Level in Bq/kg	Type	Reference	Notes/Remarks for Codex Alimentarius
	Infant foods*	<sup>238</sup> Pu, <sup>239</sup> Pu, <sup>240</sup> Pu, <sup>241</sup> Am		1	GL		
	Infant foods *	<sup>90</sup> Sr, <sup>106</sup> Ru, <sup>129</sup> I, <sup>131</sup> I, <sup>235</sup> U		100	GL		
	Infant foods *	<sup>35</sup> S**, <sup>60</sup> Co, <sup>89</sup> Sr, <sup>103</sup> Ru, <sup>134</sup> Cs, <sup>137</sup> Cs, <sup>144</sup> Ce, <sup>192</sup> Ir		1000	GL		
	Infant foods *	<sup>3</sup> H***, <sup>14</sup> C, <sup>99</sup> Tc		1000	GL		
	Foods other than infant foods	<sup>238</sup> Pu, <sup>239</sup> Pu, <sup>240</sup> Pu, <sup>241</sup> Am		10	GL		
	Foods other than infant foods	<sup>90</sup> Sr, <sup>106</sup> Ru, <sup>129</sup> I, <sup>131</sup> I, <sup>235</sup> U		100	GL		
	Foods other than infant foods	<sup>35</sup> S**, <sup>60</sup> Co, <sup>89</sup> Sr, <sup>103</sup> Ru, <sup>134</sup> Cs, <sup>137</sup> Cs, <sup>144</sup> Ce, <sup>192</sup> Ir		1000	GL		
	Foods other than infant foods	<sup>3</sup> H***, <sup>14</sup> C, <sup>99</sup> Tc		10000	GL		

\* When intended for use as such.

\*\* 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<sup>1</sup>. These guideline levels apply to food after reconstitution or as prepared for consumption, i.e., not to dried or concentrated foods, and are based on an intervention exemption level of 1 mSv in a year.

**Application:** As far as generic radiological protection of food consumers is concerned, when radionuclide levels in food do not exceed the corresponding Guideline Levels, the food should be considered as safe for human consumption. When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. National governments may wish to adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply, e.g., in the case of wide-spread radioactive contamination. For foods that are consumed in small quantities, such as spices, that represent a small percentage of total diet and hence a small addition to the total dose, the Guideline Levels may be increased by a factor of 10.

**Radionuclides:** The Guideline Levels do not include all radionuclides. Radionuclides included are those important for uptake into the food chain; are usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods, and; could be accidentally released into the environment from typical installations or might be employed in malevolent actions. Radionuclides of natural origin are generally excluded from consideration in this document.

In the Table, the radionuclides are grouped according to the guideline levels rounded logarithmically by orders of magnitude. Guideline levels are defined for two separate categories “infant foods” and “other foods”. This is because, for a number of radionuclides, the sensitivity of infants could pose a problem. The guideline levels have been checked against age-dependent ingestion dose coefficients defined as committed effective doses per unit intake for each radionuclide, which are taken from the "International Basic Safety Standards" (IAEA, 1996)<sup>2</sup>.

**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<sup>3</sup>.

## Annex 1

### SCIENTIFIC JUSTIFICATION FOR PROPOSED DRAFT REVISED GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY

The proposed draft revised 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<sup>4</sup> (CAC/GL 5-1989).

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

<sup>2</sup> 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.

<sup>3</sup> For example, if <sup>134</sup>Cs and <sup>137</sup>Cs are contaminants in food, the guideline level of 1000 Bq/kg refers to the summed activity of both these radionuclides.

**Infants and adults:** The levels of human exposure resulting from consumption of foods containing radionuclides listed in Table 1 at the suggested guideline levels have been assessed both for infants and adults and checked for compliance with the appropriate dose criterion.

In order to assess public exposure and the associated health risks from intake of radionuclides in food, estimates of food consumption rates and ingestion dose coefficients are needed. According to Ref. (WHO, 1988) it is assumed that 550 kg of food is consumed by an adult in a year. The value of infant food and milk consumption during first year of life used for infant dose calculation equal to 200 kg is based on contemporary human habit assessments (F. Luykx, 1990<sup>5</sup>; US DoH, 1998<sup>6</sup>; NRPB, 2003<sup>7</sup>). The most conservative values of the radionuclide-specific and age-specific ingestion dose coefficients, i.e. relevant to the chemical forms of radionuclides which are most absorbed from the gastro-intestinal tract and retained in body tissues, are taken from the (IAEA, 1996).

**Radiological criterion:** The appropriate radiological criterion, which has been used for comparison with the dose assessment data below, is a generic intervention exemption level of around 1 mSv for individual annual dose from radionuclides in major commodities, e.g. food, recommended by the International Commission on Radiological Protection as safe for members of the public (ICRP, 1999)<sup>8</sup>.

**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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<sup>4</sup> The Codex Alimentarius Commission at its 18th Session (Geneva 1989) adopted Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989) applicable for six radionuclides (<sup>90</sup>Sr, <sup>131</sup>I, <sup>137</sup>Cs, <sup>134</sup>Cs, <sup>239</sup>Pu and <sup>241</sup>Am) during one year after the nuclear accident.

<sup>5</sup> F. Luykx (1990) Response of the European Communities to environmental contamination following the Chernobyl accident. In: Environmental Contamination Following a Major Nuclear Accident, IAEA, Vienna, v.2, 269-287.

<sup>6</sup> US DoHHS (1998) Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. Food and Drug Administration, Rockville.

<sup>7</sup> K. Smith and A. Jones (2003) Generalised Habit Data for Radiological Assessments. NRPB Report W41.

<sup>8</sup> International Commission on Radiological Protection (1999). Principles for the Protection of the Public in Situations of Prolonged Exposure. ICRP Publication 82, Annals of the ICRP.

### ASSESSMENT OF HUMAN INTERNAL EXPOSURE WHEN THE GUIDELINE LEVELS ARE APPLIED

For the purpose of assessment of the mean public exposure level in a country caused by the import of food products from foreign areas with residual radioactivity, in implementing the present guideline levels the following data should be used: annual food consumption rates for infants and adults, radionuclide- and age-dependent ingestion dose coefficients and the import/production factors. When assessing the mean internal dose in infants and adults it is suggested that due to monitoring and inspection the radionuclide concentration in imported foods does not exceed the present guideline levels. Using cautious assessment approach it is considered that all the foodstuffs imported from foreign areas with residual radioactivity are contaminated with radionuclides at the present guideline levels.

Then, the mean internal dose of the public,  $E$  (mSv), due to annual consumption of imported foods containing radionuclides can be estimated using the following formula:

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

where:

$GL(A)$  is the Guideline Level (Bq/kg)

$M(A)$  is the age-dependent mass of food consumed per year (kg)

$e_{ing}(A)$  is the age-dependent ingestion dose coefficient (mSv/Bq)

$IPF$  is the import/production factor<sup>9</sup> (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 1<sup>st</sup> 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 <sup>239</sup>Pu as well as for a number of other radionuclides the dose estimate is conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life (ICRP, 2005<sup>10</sup>). For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for <sup>3</sup>H, <sup>14</sup>C, <sup>35</sup>S, iodine and caesium isotopes.

As an example, dose assessment for <sup>137</sup>Cs in foods is presented below for the first year after the area contamination with this nuclide.

For adults:  $E = 1000 \text{ Bq/kg} \cdot 550 \text{ kg} \cdot 1.3 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.7 \text{ mSv}$ ;

For infants:  $E = 1000 \text{ Bq/kg} \cdot 200 \text{ kg} \cdot 2.1 \cdot 10^{-5} \text{ mSv/Bq} \cdot 0.1 = 0.4 \text{ mSv}$

<sup>9</sup> 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.

<sup>10</sup> International Commission on Radiological Protection (2005) Doses to Infants from Radionuclides Ingested in Mothers Milk. To be published.

**TABLE 2**

**ASSESSMENT OF EFFECTIVE DOSE FOR INFANTS AND ADULTS FROM INGESTION OF IMPORTED FOODS IN A YEAR**

Radionuclide	Guideline Level (Bq/kg)		Effective dose (mSv)	
	Infant foods	Other foods	1 <sup>st</sup> year after major contamination	
			Infants	Adults
<sup>238</sup> Pu	<b>1</b>	<b>10</b>	<b>0.08</b>	<b>0.1</b>
<sup>239</sup> Pu			<b>0.08</b>	<b>0.1</b>
<sup>240</sup> Pu			<b>0.08</b>	<b>0.1</b>
<sup>241</sup> Am			<b>0.07</b>	<b>0.1</b>
<sup>90</sup> Sr	<b>100</b>	100	<b>0.5</b>	<b>0.2</b>
<sup>106</sup> Ru			<b>0.2</b>	<b>0.04</b>
<sup>129</sup> I			<b>0.4</b>	<b>0.6</b>
<sup>131</sup> I			<b>0.4</b>	<b>0.1</b>
<sup>235</sup> U			<b>0.7</b>	<b>0.3</b>
<sup>35</sup> S*	<b>1000</b>	<b>1000</b>	<b>0.2</b>	<b>0.04</b>
<sup>60</sup> Co			<b>1</b>	<b>0.2</b>
<sup>89</sup> Sr			<b>0.7</b>	<b>0.1</b>
<sup>103</sup> Ru			<b>0.1</b>	<b>0.04</b>
<sup>134</sup> Cs			<b>0.5</b>	<b>1</b>
<sup>137</sup> Cs			<b>0.4</b>	<b>0.7</b>
<sup>144</sup> Ce			<b>1</b>	<b>0.3</b>
<sup>192</sup> Ir			<b>0.3</b>	<b>0.08</b>
<sup>3</sup> H**	<b>1000</b>	<b>10000</b>	<b>0.002</b>	<b>0.02</b>
<sup>14</sup> C			<b>0.03</b>	<b>0.3</b>
<sup>99</sup> Tc			<b>0.2</b>	<b>0.4</b>

\* This represents the value for organically bound sulphur.

\*\* This represents the value for organically bound tritium.

See for “Scientific justification for the Guideline Levels” (Annex 1) and the “Assessment of human internal exposure when the Guideline Levels are applied” (Annex 2).

**ACRYLONITRILE**

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

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Food	0.02		GL		

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as packaging material for o.a. foods. Acrylonitrile is not known to occur as a natural product. Acrylonitrile is classified by IARC as possibly carcinogenic to humans (Group 2B). Polymers derived from acrylonitrile may still contain small amounts of free monomer.

**CHLOROPROPANOLS**

Reference to JECFA:	41 (1993; for 1,3-dichloro-2-propanol only), 57 (2001), 67 (2006)
Toxicological guidance:	PMTDI 0.002 mg/kg bw (2001, for 3-chloro-1,2-propanediol); maintained in 2006. Establishment of tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorigenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA). BMDL 10 cancer, 3.3 mg/kg bw/day (for 1,3-dichloro-2-propanol); MOE, 65000 (general population), 2400 (high level intake, including young children)
Residue definition:	3-MCPD
Synonyms:	Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD, also referred to as 3-monochloro-1,2-propanediol) and 1,3-dichloro-2-propanol (1,3-DCP)
Related Code of Practice:	Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the production of Acid-Hydrolyzed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64 – 2008)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Liquid condiments containing acid-hydrolyzed vegetable proteins (excluding naturally fermented soy sauce)	0.4		ML		

**DIOXINS**

Reference to JECFA: 57 (2001)  
 Toxicological guidance: PTMI 70 pg TEQ/kg bw (2001, Including coplanar PCBs)  
 Synonyms: Polychlorinated dibenzo-dioxins and -furans  
 Related Code of Practice: Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006); Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
						NO ML

**VINYL CHLORIDE MONOMER**

Reference to JECFA: 28 (1984)  
 Toxicological guidance: Provisional Acceptance (1984, the use of food-contact materials from which vinyl chloride may migrate is provisionally accepted, on condition that the amount of the substance migrating into food is reduced to the lowest level technologically)  
 Residue definition: Vinylchloride monomer  
 Synonyms: Monochloroethene, chloroethylene; abbreviation VC or VCM  
 Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
	Food	0.01		GL		The GL in food packaging material is 1.0 mg/kg.

Vinylchloride monomer is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods. Vinyl chloride is not known to occur as a natural product. Residues of VCM may be still present in the polymer. Vinyl chloride is considered by IARC to be a human carcinogen (as has been shown in occupational exposure situations).

**SCHEDULE II – MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOODS**

**(to be developed after finalisation of the Food Category System)**