CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS

CODEX STAN 193-1995, Rev.3-2007

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. [1]

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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[1] 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.

- 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).

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

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

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

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

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

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

INDEX OF CONTAMINANTS

EXPLANATORY NOTES

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

Definitions of some toxicological terms

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

AFLATOXINS, TOTAL

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

Commodity/Product Code	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 below.

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

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.