CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS

CODEX STAN 193-1995 (Rev.1-1997) [1]

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 Volume 1, are applicable to the GSC 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

Volume 1 of the 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 CCPR. Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the General Standard for Contaminants 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 CCRVDF.

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[1] The Preamble to the Codex General Standard for Contaminants and Toxins in Foods was adopted by the 21st Session of the Codex Alimentarius Commission in July 1995. Annexes I-III, the introduction to Annex IV and Annex V were adopted by the Commission at its 22nd Session, 1997. Annex IV-A and Annex IV-B concerning the Annotated List of Contaminants and Toxins have still to be developed.

4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the 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 CCFAC 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 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. [2]

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.

[2] 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.

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 Codex General Standard for Contaminants in Food 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.

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.

I.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 Codex General Standard for Contaminants in Food: (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 IN FOOD

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.

1.4.2 Procedure for preliminary discussion about contaminants in the CCFAC

Suggestions for new contaminants or new contaminant/commodity combinations to be discussed in the CCFAC and to be included in the GSC 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 CCFAC.

When a delegation wishes that the Committee 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 CCFAC 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 CCFAC. In the absence of recommendations by JECFA, decisions may be taken by CCFAC when sufficient information from other sources is available to the Committee and the matter is considered urgent.

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

1.5 FORMAT OF THE STANDARD FOR CONTAMINANTS IN FOODS

The General Standard for Contaminants in Foods 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 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.

The listing of the Codex Standards for the different contaminants may be according to a numbering system for contaminants (see Annex IV). The Codex standards are summarized in a list of contents, and an alphabetical listing of the contaminants shall be added for easy reference.

For each session of the CCFAC, 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 V.

1.6 REVIEW AND REVISION OF THE STANDARD

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 CCFAC.

The criteria mentioned here are elaborated in more detail than in section I.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 CCFAC. 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.

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 CCFAC 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.

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

- 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. 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 CCFAC 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 CCFAC

Case	Criterion				CCFAC 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, CCFAC 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 CCFAC statement
6.	+	+	+	-	Development of MLs by CCFAC
7.	+	+	+	+	Development of MLs by CCFAC, with priority (in urgent cases, if necessary, temporary MLs)

ANNEX III

FORMAT OF THE STANDARD

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 Annex IV.
- ***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 the contaminant in foods:*** this list shall be composed of the following elements, in columns:
  - Classification number of food commodity or food category
  - Name of food commodity/category
  - Numerical value of maximum level
  - Suffix accompanying a ML to specify the application of the ML
  - Step in Codex procedure (only in CCFAC working documents)
  - References to documents, including references to source-directed measures or a code of practice, if appropriate
  - References to standard criteria for methods of analysis and sampling
  - Notes/remarks

When appropriate, instead of a maximum level a (note referring to a) statement regarding the contaminant in the mentioned food (category) may be inserted.

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 CCFAC working documents)
  - References, remarks and notes (shorter than in Schedule I).
- ***Reference to a Code of practice*** *for the food, if appropriate*

ANNEX IV

ANNOTATED LIST OF CONTAMINANTS AND TOXINS

Introduction

In this Annex an annotated list is presented of the contaminants and toxins that are or have been dealt with in the CCFAC. It does not only encompass the contaminants and toxins for which Codex standards exist or are being developed, but also those for which further information is sought or about which a Codex decision has been taken.

The annotated list has the purpose of providing an overview of the situation regarding Codex decisions about this subject and to give guidance about further actions required. Therefore also relevant information and references are added to the list. The information shall comprise at least the current situation regarding the criteria that are important for the decision procedure of the CCFAC.

It is thus an active list, which needs to be regularly updated. In order to provide a structure for it and to facilitate the filing and retrieval of data, a number is assigned to the contaminants and toxins in the list.

The situation regarding contaminants and toxins is very complex and many substances are or have been the subject of scientific research and discussion regarding their occurrence in foods and their significance for human and animal health. On a national level, there are many activities, sometimes implying legal measures which may affect international trade in foods and feeds. It is obviously important for the CCFAC to take note of the developments in this field and to consider the necessity of actions. In order to obtain an overview of the situation, the CCFAC shall develop and maintain a working document in which more comprehensive information regarding contaminants and toxins in foods is presented in summary form. The document shall consist of an annotated comprehensive list of contaminants and toxins (Annex IV-A), and a collection of summarized textual information to the substances on the list, with references (Annex IV-B). Annex IV-A shall be structured according to a substance categorization system, by which code numbers can be assigned to the substances on the list, to allow logical and easy filing and presentation of data. This more comprehensive list shall be the basis for the code numbers which are used in Annex IV.

ANNEX V

FOOD CATEGORIZATION SYSTEM

Introduction

The food categorization system of the Codex General Standard for Contaminants and Toxins in Foods 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 GSC 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 V-A. Annex V-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 GSC

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.

Reference is made to Vol. 2 of the Codex Alimentarius, section 2 (1993), in which this system is described, and to CX/PR 92/6 (in which a different kind of group numbering was introduced).

Annex V-A is the other part of the food categorization system for the GSC. It is developed and maintained by the CCFAC, 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 V-A

COMPLEMENTARY FOOD CATEGORIZATION SYSTEM FOR THE GSC

Introduction

The following additions to the food categorization system described in Annex V-A will serve the need of assigning a food code number to commodities that are not covered by Annex V-A. 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 GSFA for food classification has been utilized as far as it is compatible with the existing Codex classification system described in Annex V-A.

See the annexed list of proposed new food categories. Some explanations are added, and also 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 Annex V-A, may also be mentioned in this Annex.

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)*
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	l0	PP	Other manufactured plant products *(New proposed group; commodity codes to be developed when the need arises)*

Class	Type	Group	Letter code	Product group description
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 meat codes)*
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)*

Class	Type	Group	Letter code	Product group description
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)*
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	FF	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)*

Class	Type	Group	Letter code	Product group description
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)*
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)*