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مواصفة عامة للملوثات والسموم في الأغذية

General Standard for contaminants & toxins in food

ICS: 67.040.00

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally. SFDA sector has adopted the Codex Standard No.(CAC 193). This standard has been approved as national standard by SFDA board of directors in its meeting No (17) Held on (16/09/1439 AH) , (31 /05 /2018 G).

* The limits of food contaminants in this regulation replaced all the food contaminants limits in the approved GSO food technical regulations and standards – if no limits or contaminants are listed for certain food products in this regulation, the food contaminants limits in food product regulation shall be applied.

GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOODS

1 SCOPE

This Standard contains the main principles and procedures which are used and recommended by the Standardization Organization (GSO) in dealing with contaminants and toxins in foods, and lists the maximum levels of contaminants and natural toxicants in foods which are recommended by the (GSO) to be applied to commodities moving in international trade.

2 DEFINITION OF TERMS

2.1 General

The definitions for the purpose of the Standardization Organization (GSO), as mentioned in the Procedural Manual, are applicable to the General Standard for Contaminants and Toxins in Foods of (GSO) 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.

2.2 Contaminant

Standardization Organization (GSO) 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 Standardization Organization (GSO) 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 Standardization Organization (GSO) definition that are within the terms of reference of the General Standard on Pesticide Residues. Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the General Standard for Contaminants and Toxins in Foods.

3) Residues of veterinary drugs, as defined by the (GSO) definition, that are within the terms of reference of the Standardization Organization (GSO).

4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Standardization Organization (GSO).

5) Residues of processing aids that are within the terms of reference of the Standardization Organization (GSO)[1].

6) Naturally occurring toxicants such as are produced as toxic metabolites of certain microfungi that are not intentionally added to food (mycotoxins).

2.3 Maximum level and related terms

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

A GSO ***guideline level*** (***GL)*** is the maximum level of a substance in a food or feed commodity which is recommended by the GSO 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].

3. GENERAL PRINCIPLES REGARDING CONTAMINANTS IN FOODS

3.1 General

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

Contaminant levels in foods shall be as low as reasonably achievable. The following actions may serve to prevent or to reduce contamination of foods and feeds[3]:

- 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 General Standard 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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[2]For the contaminants methylmercury, radionuclides, acrylonitrile and vinylchloride monomer a GSO guideline level (GL) has been established. A GSO guideline level (GL) is the maximum level of a substance in a food or feed commodity which is recommended by the GSO to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. Because the GSO has decided that the preferred format of a GSO standard in food or feed is a maximum level, the present existing or proposed guideline levels shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by General Standard, if appropriate.

[3] In addition, reference is made to the Code of Practice for source Directed measures to reduce contamination of food with chemicals and the Code of Practice on Good Animal Feeding .

3.2 Principles for establishing maximum levels in foods and feeds

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

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

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

3.3 Specific criteria

The following criteria should (not preventing the use of other relevant criteria) be considered when developing recommendations and making decisions in connection with the GSO General Standard for Contaminants and Toxins in Food and Feed: (Further details about these criteria are given in Annex I).

Toxicological information

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

Analytical data

- validated qualitative and quantitative data on representative samples;
- 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.

4 GSO PROCEDURE FOR ESTABLISHING STANDARDS FOR CONTAMINANTS AND TOXINS IN FOODS

4.1 General

The Procedure for the elaboration of GSO 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 GSO Standards for Contaminants and Toxins in Foods.

4.2 Procedure for preliminary discussion about contaminants and Toxins in Foods

Suggestions for new contaminants or new contaminant/commodity combinations to be discussed in GSO Standards for Contaminants and Toxins in Foods and to be included in the General Standard 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 GSO Standards for Contaminants and Toxins in Foods.

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

6 REVIEW AND REVISION OF THE GENERAL 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 General Standard 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 General Standard.

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 General Standard regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological database, shall be the main basis for decisions. In urgent cases, it may be possible to rely on less developed evaluations from General Standard 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 especially vulnerable population groups or animals.

Analytical data

Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representatively 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.

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

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

Fair trade considerations

Existing, expected or potential problems in international trade: In order to assess the urgency of a problem to be discussed by General Standard 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

Risk assessment and risk management are conducted in compliance with the Working Principles for Risk Analysis for food safety by governments.

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. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in the GSO Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups should be consulted.

- 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 GSO 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 judgment 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 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 GSO 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 toxicological reference value.

In case a contaminant is transported from feed to food of animal origin, the intake of a contaminant by the different food producing animal species and the resulting levels in the food of animal origin must be evaluated.

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 GSO MRLs.

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).

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 GSO 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 GSO General Standard Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups. Statements from Governments about the non-acceptance of (proposed) GSO MLs should refer to specified intake calculations and risk management conclusions which support this position.

ANNEX IV

FOOD CATEGORIZATION SYSTEM

Introduction

The food categorization system of the GSO 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 General Standard uses the system which is developed in the framework of the GSO 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 GSO.

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 GSO

The first part contains the categorization system as developed and maintained by the GSO. 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 General Standard. It is developed and maintained by the GSO, 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 GSO MLs for contaminants.

ANNEX IV-A

COMPLEMENTARY FOOD CATEGORIZATION SYSTEM FOR GSO

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 GSO 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 GSO 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	Product group description
				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	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	l0	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	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. *(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	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	Savory snacks (potato, cereal or starch base) *(New proposed group; commodity codes to be developed when the necessity arises)*
F	05	03	NS	Savory 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	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 *(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)*

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

INDEX OF CONTAMINANTS

Table 1.2 Maximum levels of Heavy Metals in foodstuff

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
Edible fats and oils	0.1		0.1	0.001			Whole commodity	
Fat spreads and blended spreads	0.1		0.1					
Natural mineral waters	0.01	0.003	0.01					
Rice, husked	0.35						Whole commodity	
Rice, polished	0.2	0.4					Whole commodity	Calculated as total As in mg/l.
Salt, food grade	0.5	0.5	2	0.1				Cereals excluding bran, germ, wheat and rice
Brassica vegetables		0.05	0.1				Head cabbages and kohlrabi: whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads	The ML does not apply to Brassica leafy vegetables

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
							(immature inflorescence only). Brussels sprouts: "buttons" only.	
Bulb vegetables		0.05	0.1				Bulb/dry onions and garlic: whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached	
Fruiting vegetables		0.05	0.05				Whole commodity after removal of stems. Sweet corn and fresh corn: kernels plus cob without husk	The ML does not apply to tomatoes and edible fungi
Leafy vegetables		0.2	0.3				Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves	The ML also applies to Brassica leafy vegetables.
Legume vegetables		0.1	0.1				Whole commodity as consumed. The succulent forms may be consumed as whole pods or as the shelled product.	

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
Pulses		0.1	0.2				Whole commodity	The ML does not apply to soya bean (dry).
Root and tuber vegetables		0.1	0.1				Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). Potato: peeled potato.	The ML does not apply to celeriac.
Stalk and stem vegetables		0.1						Whole commodity as marketed after removal of obviously decomposed or withered leaves. Rhubarb: leaf stems only. Globe artichoke: flower head only. Celery and asparagus: remove adhering soil.
Cereal grains		0.1	0.2				Whole commodity	The ML does not apply to buckwheat,

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
								cañihua, quinoa, wheat and rice
Wheat		0.2					Whole commodity	The ML applies to common wheat, durum wheat, spelt and emmer.
Marine bivalve molluscs		2					Whole commodity after removal of shell.	The ML applies to clams, cockles and mussels but not to oysters and scallops.
Cephalopods		2					Whole commodity after removal of shell.	The ML applies to cuttlefishes, octopuses and squids without viscera.
Berries and other small fruits			0.1				Whole commodity after removal of caps and stems.	The ML does not apply to cranberry, currant and elderberry.
Cranberry			0.2				Whole commodity after removal of caps and stems.	
Currants			0.2				Fruit with stem	

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

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
Canned fruits			0.1			250	The ML applies to the product as consumed.	
Jams (fruit preserves) and jellies			1					
Mango chutney			1			250		
Canned vegetables			0.1			250	The ML applies to the product as consumed.	The ML does not apply to canned brassica vegetables.
Preserved tomatoes			1					In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.
Table olives			0.4					

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
Pickled cucumbers (cucumber pickles)			0.1					
Processed tomato concentrates			1.5					In order to consider the concentration of the product, the determination of the maximum levels for contaminants shall take into account the natural total soluble solids, the reference value being 4.5 for fresh fruit.
Canned chestnuts and canned chestnuts puree			1			250		
Fruit juices			0.03				Whole commodity (not concentrated) or commodity reconstituted to the original juice concentration, ready to	The ML does not apply to juices exclusively from berries and other small fruit.

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
							drink. The ML applies also to nectars, ready to drink	
Canned chestnuts and canned chestnuts puree			1					
Meat of cattle and sheep			0.1				Whole commodity (without bones)	Also applies to the fat from meat
Meat and fat of poultry			0.1				Whole commodity (without bones)	
Cattle, Edible offal of			0.5				Whole commodity.	
Poultry, Edible offal of			0.5				Whole commodity.	
Milk			0.02				Whole commodity.	Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
								consumption as liquid milk or for further processing. A concentration factor applies to partially or wholly dehydrated milks
Infant formula, formula for special medical purposes intended for infants and follow-up formula			0.01				Whole commodity.	
Fish			0.3		0.5		Whole commodity (in general after removing the digestive tract)	The GL does not apply to predatory fish. The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.

Commodity / Product	ARSENIC	CADMIUM	LEAD	MERCURY	METHYLMERCURY	TIN	Portion of the Commodity /Product to which the ML applies	Notes/Remarks
	Level mg/kg (ppm)							
Predatory fish					1		Whole commodity (in general after removing the digestive tract)	Predatory fish such as shark, swordfish, tuna, pike and others. The guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.
Canned beverages						150		
Canned foods (other than beverages)						250		
Cooked cured chopped meat						50		
Corned beef						50		
Luncheon meat						50		

Table 1.3 Guidelins for Radionuclides in food

RADIONUCLIDES

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

(*) This represents the value for organically bound sulphur.

(**) This represents the value for organically bound tritium.

Scope: The Guideline Levels apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency[1]. These guideline levels apply to food after reconstitution or as prepared for consumption, i.e., not to dried or concentrated foods, and are based on an intervention exemption level of 1 mSv in a year.

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

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

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

2 Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Office, OECD Nuclear Energy Agency, Pan American HealthOrganization, World Health Organization (1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA,Vienna

3 For example, if 134Cs and 137Cs are contaminants in food, the guideline level of 1 000 Bq/kg refers to the summed activity of both these radionuclides

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

Multiple radionuclides in foods: The guideline levels have been developed with the understanding that there is no need to add contributions from radionuclides in different groups. Each group should be treated independently. However, the activity concentrations of each radionuclide within the same group should be added together[3].

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٢ Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Office, OECD Nuclear Energy Agency, Pan American Health Organization, World Health Organization (1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA, Vienna.

٣ For example, if ^{134}Cs and ^{137}Cs are contaminants in food, the guideline level of 1000 Bq/kg refers to the summed activity of both these radionuclides.

Annex 1

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

The proposed draft revised Guideline Levels for Radionuclides in Foods and specifically the values presented in Table 1 above are based on the following general radiological considerations and experience of application of the existing international and national standards for control of radionuclides in food.

Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the Guideline Levels were issued by the Codex Alimentarius Commission in 1989[4] (CAC/GL 5-1989).

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

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

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

Naturally occurring radionuclides: Radionuclides of natural origin are ubiquitous and as a consequence are present in all foodstuffs to varying degrees. Radiation doses from the consumption of foodstuffs typically range from a few tens to a few hundreds of microsieverts in a year. In essence, the doses from these radionuclides when naturally present in the diet are unamenable to control; the resources that would be required to affect exposures would be out of proportion to the benefits achieved for health. These radionuclides are excluded from consideration in this document as they are not associated with emergencies.

One-year exposure assessment: It is conservatively assumed that during the first year after major environmental radioactive contamination caused by a nuclear or radiological emergency it might be difficult to readily replace foods imported from contaminated regions with foods imported from unaffected areas. According to FAO statistical data the mean fraction of major foodstuff quantities imported by all the countries worldwide is 0.1. The values in Table 1 as regards foods consumed by infants and the general population have been derived to ensure that if a country continues to import major foods from areas contaminated with radionuclides, the mean annual internal dose of its inhabitants will not exceed around 1 mSv (see Annex 2). This conclusion might not apply for some radionuclides if the fraction of contaminated food is found to be higher than 0.1, as might be the case for infants who have a diet essentially based on milk with little variety.

Long-term exposure assessment: Beyond one year after the emergency the fraction of contaminated food placed on the market will generally decrease as a result of national restrictions (withdrawal from the market), changes to other produce, agricultural countermeasures and decay.

Experience has shown that in the long term the fraction of imported contaminated food will decrease by a factor of a hundred or more. Specific food categories, e.g. wild forest products, may show persistent or even increasing levels of contamination. Other categories of food may gradually be exempted from controls. Nevertheless, it must be anticipated that it may take many years before levels of individual exposure as a result of contaminated food could be qualified as negligible.

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

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

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

4 K. Smith and A. Jones (2003) Generalised Habit Data for Radiological Assessments. NRPB Report W41.

5 International Commission on Radiological Protection (1999). Principles for the Protection of the Public in Situations of Prolonged Exposure. ICRP Publication 82, Annals of the ICRP.

Annex 2

ASSESSMENT OF HUMAN INTERNAL EXPOSURE WHEN THE GUIDELINE LEVELS ARE APPLIED

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

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

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

where:

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

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

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

IPF is the import/production factor1 (dimensionless)

Assessment results presented in Table 2 both for infants and adults demonstrate that for all the twenty radionuclides doses from consumption of imported foods during the 1st year after major radioactive contamination do not exceed 1 mSv. It should be noted that the doses were calculated on the basis of a value for the IPF equal to 0.1 and that this assumption may not always apply, in particular to infants who have a diet essentially based on milk with little variety

It should be noted that for 239Pu as well as for a number of other radionuclides the dose estimate is

conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life. For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for 3H, 14C, 35S, iodine and caesium isotopes.

As an example, dose assessment for 137Cs in foods is presented below for the first year after the area

contamination with this nuclide.

For adults: E = 1 000 Bq/kg 550 kg 1.3 10^{-5} mSv/Bq 0.1 = 0.7 mSv;

For infants: E = 1 000 Bq/kg 200 kg 2.1 10^{-5} mSv/Bq 0.1 = 0.4 mSv

[9] The import/production factor (***IPF***) is defined as the ratio of the amount of foodstuffs imported per year from areas contaminated with radionuclides to the total amount produced and imported annually in the region or country under consideration.

[10] International Commission on Radiological Protection (2005) Doses to Infants from Radionuclides Ingested in Mothers Milk. To be published.

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

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

* This represents the value for organically bound Sulphur

** This represents the value for organically bound tritium

See for "Scientific Justification for the Guideline Levels" (Annex 1) and the "Assessment of Human Internal Exposure when the Guideline Levels are Applied" (Annex 2)

ACRYLONITRILE

Reference to JECFA: 28 (1984)

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

Contaminant definition: acrylonitrile (monomer)

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

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

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

CHLOROPROPANOLS

Reference to JECFA:	41 (1993; for 1,3-dichloro-2-propanol only), 57 (2001), 67 (2006)
Toxicological guidance value:	PMTDI 0.002 mg/kg bw (2001, for 3-chloro-1,2-propanediol); maintained in 2006. Establishment of tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorogenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA). BMDL 10 cancer, 3.3 mg/kg bw/day (for 1,3-dichloro-2-propanol); MOE, 65 000 (general population), 2 400 (high level intake, including young children).
Contaminant definition:	3-MCPD
Synonyms:	Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD, also referred to as 3-monochloro-1,2-propanediol) and 1,3-dichloro-2-propanol (1,3-DCP).
Related code of practice:	Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the production of AcidHydrolyzed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64–2008).

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

HYDROCYANIC ACID

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

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

PMTDI 0.02 mg/kg bw as cyanide (2011)

Contaminant definition: See explanatory notes in the column "Notes/Remarks.

Synonyms: HCN

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

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the ML applies	Notes/Remarks
Gari	2	Whole commodity	The ML is expressed as free hydrocyanic acid. Relevant standards include GSO 2351
Cassava flour	10		The ML is expressed as free hydrocyanic acid. Relevant standards include GSO CODEX STAN 176

MELAMINE

Reference to JECFA:	FAO/WHO Expert Meeting (2008)
Toxicological guidance value:	TDI 0.2 mg/kg bw (2008))
Contaminant definition:	Melamine
Synonyms:	Monochloroethene, chloroethylene; abbreviation VC or VCM
Related code of practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49- 2001)

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

VINYL CHLORIDE MONOMER

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

Commodity/Product Name	Maximum Level (ML) mg/kg	Portion of the Commodity/Product to which the GL applies	Notes/Remarks
Food	0.01	Whole commodity	The GL in food packaging material is 1.0 mg/kg.

Reference

- GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED CODEX STAN 193-1995