# CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS

# IN FOOD AND FEED

**CODEX STAN 193-1995**

## 1.      PREAMBLE

### 1.1   SCOPE

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

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

### 1.2   DEFINITION OF TERMS

### 1.2.1   General

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

### 1.2.2   Contaminant

Codex Alimentarius defines a contaminant as follows:

"Any substance not intentionally added to food, 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 and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Codex Committee on Contaminants in Foods (CCCF) has the objective to protect public health.

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

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

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

5)   Residues of processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA)[1] .

### 1.2.3   Natural toxins included in this standard

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

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

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

Adopted 1995; Revised 1997, 2006, 2008, 2009; Amended 2009, 2010

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

## RADIONUCLIDES

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

\*      When intended for use as such.
\*\*      This represents the value for organically bound sulphur.
\*\*\*      This represents the value for organically bound tritium.

**Scope**: The Guideline Levels apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency[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.

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

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

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

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

Annex 1

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

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

Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the Guideline Levels were issued by the Codex Alimentarius Commission in 1989[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.

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

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

[4]    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 ($^{90}$Sr, $^{131}$I, $^{137}$Cs, $^{134}$Cs, $^{239}$Pu and $^{241}$Am) during one year after the nuclear accident.

[5]    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.

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

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

[8]    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.

**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.

**Annex 2**

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

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

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

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

where:

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

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

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

$IPF$ is the import/production factor[9] (dimensionless).

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

It should be noted that for $^{239}$Pu as well as for a number of other radionuclides the dose estimate is conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life (ICRP, 2005[10]). For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for $^3$H, $^{14}$C, $^{35}$S, iodine and caesium isotopes.

As an example, dose assessment for $^{137}$Cs in foods is presented below for the first year after the area contamination with this nuclide.

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

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[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.

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

**TABLE 2**

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

| Radionuclide | Guideline Level (Bq/kg) | | Effective dose (mSv) | |
| --- | --- | --- | --- | --- |
| | Infant foods | Other foods | 1st year after major contamination | |
| | | | Infants | Adults |
| $^{238}Pu$ | 1 | 10 | 0.08 | 0.1 |
| $^{239}Pu$ | | | 0.08 | 0.1 |
| $^{240}Pu$ | | | 0.08 | 0.1 |
| $^{241}Am$ | | | 0.07 | 0.1 |
| $^{90}Sr$ | 100 | 100 | 0.5 | 0.2 |
| $^{106}Ru$ | | | 0.2 | 0.04 |
| $^{129}I$ | | | 0.4 | 0.6 |
| $^{131}I$ | | | 0.4 | 0.1 |
| $^{235}U$ | | | 0.7 | 0.3 |
| $^{35}S$* | 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)