codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 12 **CX/FAC 06/38/18**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

The Hague, the Netherlands, 24 – 28 April 2006

WORKING DOCUMENT FOR INFORMATION AND USE IN DISCUSSIONS ON THE GSCTF

(Prepared by Japan and the Netherlands)

Background

1. The 37th Session of the Committee endorsed the recommendations of the *ad hoc* Working Group on Contaminants and Toxins:

- to append Schedule I to the GSCTF with the approved modifications regarding the correspondence between commodity codes and descriptions regarding and deletion of all references to commodity standards;
- to request the 28th Session of the Commission to revoke the existing individual Codex standards for Maximum/Guideline Levels for contaminants and toxins
- to append Schedule II to the GSCTF as an empty annex awaiting the finalization of the food categorization system; and
- to integrate the Annotated List of Contaminants and Toxins in Foods (Part 1 and Part 2) into a separate document "Working document for information and use in discussions on the GSCTF".

2. The Delegations of Japan and the Netherlands agreed to revise the document, using a suitable database, for presentation at the next session of the Committee (ALINORM 05/28/12, paras 123-125).

3. The 28th Commission noted that Codex Maximum/Guideline Levels for Contaminants and Toxins were incorporated in Schedule I of the GSCTF, which had not been officially forwarded for adoption by the Commission. Therefore, the Commission agreed to postpone the revocation of individual Codex MLs/GLs as proposed by the CCFAC to its next session, pending submission by CCFAC of Schedule I of the GSCTF to the Commission (ALINROM 05/28/41, para. 90).

4. The Working Document for Information and Use in Discussions on the GSCTF was prepared on the basis of the Annotated List of Contaminants and Toxins in Foods published for the 37th CCFAC held in 2005. The Working Document shares the same format as the Annotated List and incorporates all the corrections and modifications proposed in the comment papers for the 37th Session and by the JECFA Secretariat. It also incorporates all the decisions made at the 37th CCFAC and the 28th Codex Alimentarius Commission.

Working Document for Information and Use in Discussions on the GSCTF

A Working Document for Information and Use in Discussions on the GSCTF presents contaminants and toxins that are or have been dealt with in the CCFAC. It does not only encompass the contaminants and toxins for which Codex standards exist or are being developed, but also those for which further information is sought or about which a Codex decision has been taken.

The Working Document has the purpose of providing an overview of the situation regarding Codex decisions about this subject and guidance about further actions required. Therefore also relevant information and references are added to the List.

The list of maximum levels / guideline levels is thus active, which needs regular update. In order to provide a structure for it and to facilitate the filing and retrieval of data, a number is assigned to contaminants and toxins in the list.

The situation regarding contaminants and toxins is very complex and many substances are or have been the subject of scientific research and discussion regarding their occurrence in foods and their significance for human and animal health. On a national level, there are many activities, sometimes implying legal measures which may affect international trade in foods and feeds. It is obviously important for the CCFAC to take note of the developments in this field and to consider the necessity of actions. In order to obtain an overview of the situation, the CCFAC shall develop and maintain a working document in which more comprehensive information regarding contaminants and toxins in foods is presented in a summary form.

The Working Document has two parts: *Part 1* containing maximum and guideline levels developed by CCFAC and contaminant provisions included in commodity standards; and *Part 2* containing maximum levels developed for copper, iron and zinc which are regarded as quality factors as opposed to safety factors. Part 1 contains also those levels still at various Steps of the Codex elaboration procedure for the facilitation of consideration of proposed maximum levels by the CCFAC.

INDEX OF CONTAMINANTS IN ALPHABETICAL ORDER

EXPLANATORY NOTES

Reference to JECFA:	References to JECFA meeting in which the contaminant was evaluated and the year of that meeting
Toxicological guidance value:	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed in milligrammes (mg) per kg body weight (bw). The year of recommendations and additional explanation are included.
Residue definition:	Definition of the contaminant in the form of which the ML applies or which may or should be analyzed in commodities.
Synonyms:	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity code:	The code for food commodities are according to the food categorization system as contained in Annex IV of the GSCTF or the Codex Classification of Foods and Animal Feeds as contained in Volume 2 of the Codex Alimentarius. The food/feed categorization system also specifies the part of commodity which should be analyzed and to which the ML applies, unless a specific commodity definition is provided as an annex to the ML. For those maximum levels contained in Codex commodity standards, the relevant standard numbers are referred, if the code numbers are not readily available for these commodities.
Suffix:	A note accompanying an ML or GL, used to specify the application or the future revision of the ML, e.g., specific residue definitions can be mentioned by abbreviations here. See also “Qualification of MLs” below.
Type:	Indicates whether the value is Codex maximum level (ML) or Codex guideline level (GL). See also the definitions of these terms in the preamble of the GSCTF.
Step:	Step of the Codex Elaboration Procedure at which each maximum level is (at the time of the publication of this paper). See the Codex Procedural Manual. The term “Adopted” is used for an adopted MLs and Codex Standards.

Qualification of MLs

C:	In canned products only

Definitions of some toxicological terms

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

1.03 Arsenic

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Edible fats and oils	0.1		ML	Adopted	CS 19-1981, Rev.2-1999	FO	Edible fats and oils not covered by individual standards	1)
	Fat spreads and blended spreads	0.1		ML	7		FO 03, 05		
	Margarine	0.1		ML	Adopted	CS 32-1981, Rev.1-1989	FO		2)
	Minarine	0.1		ML	Adopted	CS 135-1981, Rev.1-1989	FO		2)
	Named animal fats	0.1		ML	Adopted	CS 211-1999	FO	Lard, rendered pork fat, premier jus and edible tallow.	1)
OR 0305	Olive oil, refined	0.1		ML	Adopted	CS 33-1981, Rev.2-2003	FO		
OC 0305	Olive oil, virgin	0.1		ML	Adopted	CS 33-1981, Rev.2-2003	FO		
OR 5330	Olive, residue oil	0.1		ML	Adopted	CS 33-1981, Rev.2-2003	FO	Olive pomace oil	
OC 0172	Vegetable oils, Crude	0.1		ML	Adopted	CS 210-1999, Rev.1-2001	FO	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	
OR 0172	Vegetable oils, Edible	0.1		ML	Adopted	CS 210-1999, Rev.1-2001	FO	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	1)
	Natural mineral waters	0.01		ML	Adopted	CS 108-1981, Rev.1-1997	NMW-01	Expressed in total As mg/l	Changed from 0.05 mg/l in 2001.
	Salt, food grade	0.5		ML	Adopted	CS 150-1985, Rev.1-1997	NFSDU-96		

Arsenic is a metalloid element which is normally occurring in mineral bound form in the earth's crust and which can become more easily available by natural sources such as volcanic activity and weathering of minerals, and by anthropogenic activity causing emissions in the environment, such as ore smelting, burning of coal and specific uses, such as arsenic-based wood preservatives, pesticides or veterinary or human medicinal drugs. As a result of naturally occurring metabolic processes in the biosphere arsenic occurs as a large number of organic or inorganic chemical forms in food (species). Especially in the marine environment arsenic is often found in high concentrations of organic forms, up to 50 mg/kg of arsenic on a wet weight basis in some seafood including seaweed, fish, shellfish and crustaceans. In fresh water and in the terrestrial environments arsenic is normally found in much lower levels (typically 0-20 ug/kg) in crop plants and in livestock. Higher levels may be found in rice, mushrooms and sometimes in poultry which is fed fish meal containing arsenic. Levels of arsenic in drinking water are of concern in many countries; levels exceeding 200 mg/l have been reported, which can adversely affect the health of consumers. The most toxic forms of arsenic are the inorganic arsenic (III) and (V) compounds; the inorganic arsenic trioxide is well known as a rat poison, which was also sometimes used for homicide. Methylated forms of arsenic have a low acute toxicity; arsenobetaine which is the principal arsenic form in fish and crustaceans is considered non-toxic. In shellfish, molluscs and seaweed dimethylarsinylriboside derivatives occur ("arsenosugars"), the possible toxicity of which is not known in detail. Only a few percent of the total arsenic in fish is present in inorganic form, which is the only form about which a PTWI has been developed by JECFA. The human epidemiological data used for this risk assessment is based on exposure to inorganic arsenic in drinking water. IARC has classified inorganic arsenic as a human carcinogen, and the estimated lifetime risk for arsenic-induced skin cancer which may be caused by drinking water at or in excess of the WHO guideline for arsenic in drinking water is estimated at 6x 10-4.

The analysis of total arsenic in food has up to date suffered from difficulties with respect to accuracy and precision. Furthermore, speciated data for arsenic are strongly needed because of the large differences in toxicity to humans of the various forms of arsenic.

The intake of total arsenic in the human diet is usually dominated by organic arsenic derived from seafood. The available data about the possible human exposure to inorganic arsenic (often using the assumption that non-seafood commodities contain only inorganic arsenic) suggest that the PTWI will normally not be exceeded, unless there is a large contribution from drinking water. Further research is needed about the fate of organic arsenicals and the possibility that they might be converted to more toxic inorganic forms of arsenic, whether by processing or by metabolism in animals or humans.

1) The revised Standards for oils and fats contain the following wording for the mentioned contaminant MLs: "The products covered by the provisions of this Standard shall comply with MLs being established by the CAC but in the meantime the following limits will apply." CS for Edible Fats and Oils Not Covered by Individual Standards contains the same contaminant provision as the other recent Standards for oils and fats (only applying to Pb and As).

2) The Standards for margarine and minarine (CS 32-1981 and CS 135-1981) contain MLs for Fe, Cu, Pb and As, but the CCFO is working on a draft Standard for fat spreads and blended spreads, which will contain the same text as in the more recently revised Standards for oils and fats and which will only apply to Pb and As.

A position document CX/FAC 99/22 on arsenic was last discussed in the 31st CCFAC (1999) (see ALINORM 99/12A, para. 137). The document noted that several countries have established MLs for arsenic in food commodities and some of these were stringent regarding sea foods, so trade problems might occur. The present range of Codex MLs for arsenic in some commodities do not cover all national MLs. The document concluded however that in general there are no indications that specific Codex MLs for arsenic in food commodities would be necessary. Also, at present there is no sufficient basis to decide about the establishment of Codex MLs for arsenic, due to the uncertainties mentioned about the levels of naturally occurring arsenic species in foods, about their toxicity and about the availability of suitable analytical methods. It was acknowledged that at present especially the ML for arsenic in drinking water and in mineral water is relevant. The CCFAC asked Denmark to finalize the position paper and agreed that the finalized position paper would form the basis for future work until such time as routine methodology became available to determine toxic arsenic compounds in food.

1.06 Cadmium

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

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

Residue definition: Cadmium, total

Synonyms: Cd

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
VB 0040	Brassica vegetables	0.05		ML	Adopted	CS 248-2005	FAC		
VA 0035	Bulb vegetables	0.05		ML	Adopted	CS 248-2005	FAC		
VC 0045	Fruiting vegetables, cucurbits	0.05		ML	Adopted	CS 248-2005	FAC		
VO 0050	Fruiting vegetables, other than cucurbits	0.05		ML	Adopted	CS 248-2005	FAC	Excluding tomatoes and edible fungi.	
VL 0053	Leafy vegetables	0.2		ML	Adopted	CS 248-2005	FAC		
VP 0060	Legume vegetables	0.1		ML	Adopted	CAC/GL 39-2001	FAC		
VR 0589	Potato	0.1		ML	Adopted	CS 248-2005	FAC	Peeled	
VD 0070	Pulses	0.1		ML	Adopted	CAC/GL 39-2001	FAC	Excluding soya bean (dry)	
VR 0075	Root and tuber vegetables	0.1		ML	Adopted	CS 248-2005	FAC	Excluding potato and celeriac	
VS 0078	Stalk and stem vegetables	0.1		ML	Adopted	CS 248-2005	FAC		
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.1		ML	Adopted	CAC/GL 39-2001		Excluding wheat and rice; and bran and germ	
CM 1205	Rice, polished	0.4		ML	6		FAC 02, 03, 04, 05		1)
GC 0654	Wheat	0.2		ML	Adopted	CS 248-2005	FAC		
IM 0152	Cephalopods	1		ML	6		FAC 02, 03, 04, 05	Without viscera	2)
IM 0151	Marine bivalve molluscs	1		ML	6		FAC 02, 03, 04, 05	Excluding oysters and scallops	2)
	Natural mineral waters	0.003		ML	Adopted	CS 108-1981, Rev.1-1997	NMW-01	Expressed in mg/l	
	Salt, food grade	0.5		ML	Adopted	CS 150-1985, Rev.1-1999	NFSDU 96		

List of Maximum Level for Contaminants and Toxins in Foods: Part 1

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

Data from experimental animals and humans show that pulmonary absorption is higher than gastrointestinal absorption. The gastrointestinal absorption of cadmium is influenced by the type of diet and nutritional status. Cadmium absorbed from the lungs or the gastrointestinal tract mainly accumulates in the liver and kidneys. Although cadmium accumulates in the placenta, transfer to the fetus is low. Excretion is normally slow, and the biological half-time is very long (decades). The binding of intracellular cadmium to metallothionein in tissues protects against the toxicity of cadmium. Excretion occurs mainly via urine. (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992). The kidney is considered the critical target organ for the general population as well as for occupationally exposed populations. The accumulation of cadmium in the kidney leads to renal dysfunction. Chronic obstructive airway disease is associated with long-term high-level occupational exposure by inhalation. (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992). The IARC classified cadmium and cadmium compounds in group 1, carcinogenic to humans (1993).

The commodities that contribute significantly to total intake of cadmium include: rice, wheat, potatoes, stem/root vegetables, leafy vegetables, other vegetables, and molluscs.

At the 61th JECFA it was estimated that the total intake of cadmium ranged from 2.8 to 4.2 μg/kg bw per week. This was calculated from available data on concentrations and food consumption taken from the GEMS/Food regional diets and corresponds to approximately 40-60% of the current PTWI of 7 μg/kg bw/week.

At its 36th Session, the Codex Committee on Food Additives and Contaminants requested to analyse the impact of introducing maximum levels for cadmium in commodities.

At the 64th JECFA intakes of cadmium were recalculated taking into account the proposed Codex maximum levels (MLs) for the different commodities, that is 0.4 mg/kg (rice), 0.2 mg/kg (wheat), 0.1 mg/kg (potatoes), 0.1 mg/kg (stem/root vegetables), 0.2 mg/kg (leafy vegetables), 0.05 mg/kg (other vegetables), 3 mg/kg (oysters), 1 mg/kg (other mollusks) and one level lower and one level higher than the proposed MLs. The impact of each ML (per commodity) on intake of cadmium was evaluated.

The 64th JECFA concluded that the impact of introducing MLs on overall intake of cadmium would be very small. At the proposed Codex MLs, mean intake of cadmium would be reduced by approximately 1% of the PTWI. The imposition of MLs one level lower would result in potential reductions in intake of cadmium of no more than 6% (wheat grain, potatoes) of the PTWI.

At the proposed Codex MLs, no more than 9% of oysters would be violative. MLs one level below those proposed would result in approximately 25% of molluscs, potatoes, and other vegetables being violative. The committee noted that in its previous assessment the total intake of cadmium was only 40-60% of the PTWI of 7 μg/kg bw per week; therefore, a reduction of 1-6% due to the use of the proposed MLs is of no significance in terms of risk to human health.

A position document (CX/FAC 95/19) on cadmium was followed by a discussion document (last version CX/FAC 99/21) in which MLs for cadmium were proposed. Since then the proposed MLs have been discussed in the CCFAC and progress is mentioned in the CCFAC Reports. The 36th CCFAC decided to discontinue the work on developing MLs for cadmium in fruits, meat of cattle, pigs, sheep and poultry; hourse meat; herbs, fresh; fungi (edible); celeriac; soya beans (dry); and peanuts as no levels were necessary because these foods were no major contributors to cadmium intake (ALINORM 04/27/12, para. 176).

The 64th JECFA concluded that the effect of different MLs on the overall intake of cadmium would be very small. At the proposed MLs, the main intake of cadmium would be reduced by approximately 1% of the PTWI. The imposition of ML one level lower would result in potential reductions in intake of cadmium of no more than 6% of the PTWI (wheat grain, potatoes). At the proposed MLs, no more than 9% of a commodity would be violative (oysters). MLs one level below those proposed would result in approximately 25% of molluscs, potatoes, and other vegetables being violative.

1) The 35th CCFAC kept the proposed draft ML for rice, polished at Step 3 for a further round of comments (ALINORM 03/12A, para. 165). The 36th CCFAC advanced to the proposed draft ML to Step 5 for adoption by the CAC (ALINORM 04/27/12, paras 175-182). The 27th CAC returned the proposed draft ML to Step 3 (ALINORM 04/27/41, para. 68). The 37th CCFAC advanced the proposed draft ML to Step 5 (ALINORM 05/28/12, para. 175). The 28th CAC adopted the proposed draft ML at Step 5 and advanced it to Step 6 (ALINORM 05/28/41).

2) The 35th CCFAC kept the proposed draft ML for molluscs at Step 3 for a further round of comments (ALINORM 03/12A, para. 165). The 36th CCFAC returned the proposed draft ML for mollusks (including cephalopods) to Step 3 (ALINORM 04/27/12, paras 175-182). The 37th CCFAC advanced the proposed draft MLs Step 5 (ALINORM 05/28/12, para. 175). The 28th CAC adopted the proposed draft ML at Step 5 and advanced it to Step 6 (ALINORM 05/28/41)

1.11 Lead

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
FT 0026	Assorted (sub)tropical fruits, edible peel	0.1		ML	Adopted	CS 230-2001	FAC		
FI 0030	Assorted (sub)tropical fruits, inedible peel	0.1		ML	Adopted	CS 230-2001	FAC		
FB 0018	Berries and other small fruits	0.2		ML	Adopted	CS 230-2001	FAC		
FC 0001	Citrus fruits	0.1		ML	Adopted	CS 230-2001	FAC		
FP 0009	Pome fruits	0.1		ML	Adopted	CS 230-2001	FAC		
FS 0012	Stone fruits	0.1		ML	Adopted	CS 230-2001	FAC		
VB 0040	Brassica vegetables	0.3		ML	Adopted	CS 230-2001	FAC	Excluding kale	
VA 0035	Bulb vegetables	0.1		ML	Adopted	CS 230-2001	FAC		
VC 0045	Fruiting vegetables, Cucurbits	0.1		ML	Adopted	CS 230-2001	FAC		
VO 0050	Fruiting vegetables, other than Cucurbits	0.1		ML	Adopted	CS 230-2001	FAC	Excluding mushrooms	
VL 0053	Leafy vegetables	0.3		ML	Adopted	CS 230-2001	FAC	Including Brassica leafy vegetables but excluding spinach.	
VP 0060	Legume vegetables	0.2		ML	Adopted	CS 230-2001	FAC		
VD 0070	Pulses	0.2		ML	Adopted	CS 230-2001	FAC		
VR 0075	Root and tuber vegetables	0.1		ML	Adopted	CS 230-2001	FAC	Including peeled potatoes	
	Canned fruit cocktail	1		ML	Adopted	CS 78-1981	PFV		
	Canned grapefruit	1		ML	Adopted	CS 15-1981	PFV		
	Canned mandarin oranges	1		ML	Adopted	CS 68-1981	PFV		
	Canned mangoes	1		ML	Adopted	CS 159-1987	PFV		
	Canned pineapple	1		ML	Adopted	CS 42-1981	PFV		
	Canned raspberries	1		ML	Adopted	CS 60-1981	PFV		
	Canned strawberries	1		ML	Adopted	CS 62-1981	PFV		
	Canned tropical fruit salad	1		ML	Adopted	CS 99-1981	PFV		
	Jams (fruit preserves) and jellies	1		ML	Adopted	CS 79-1981	PFV		
	Mango chutney	1		ML	Adopted	CS 160-1987	PFV		

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Table olives	1		ML	Adopted	CS 66-1981, Rev.1-1987	PFV		
	Canned asparagus	1		ML	Adopted	CS 56-1981	PFV		
	Canned carrots	1		ML	Adopted	CS 116-1981	PFV		
	Canned green beans and canned wax beans	1		ML	Adopted	CS 16-1981	PFV		
	Canned green peas	1		ML	Adopted	CS 58-1981	PFV		
	Canned mature processed peas	1		ML	Adopted	CS 81-1981	PFV		
	Canned mushrooms	1		ML	Adopted	CS 55-1981	PFV		
	Canned palmito	1		ML	Adopted	CS 144-1985	PFV		
	Canned sweet corn	1		ML	Adopted	CS 18-1981	PFV		
	Canned tomatoes	1		ML	Adopted	CS 13-1981	PFV		
	Pickled cucumbers (cucumber pickles)	1		ML	Adopted	CS 115-1981	PFV		
	Processed tomato concentrates	1.5		ML	Adopted	CS 57-1981	PFV		
JF 0175	Fruit juices	0.05		ML	Adopted		FAC	Including nectars; Ready to drink	Although this ML was adopted by the 2001 CAC (ALINORM 01/41, para. 132), it is not mentioned in CS 230-2001.
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.2		ML	Adopted	CS 230-2001	FAC		
	Canned chestnuts and canned chestnuts puree	1		ML	Adopted	CS 145-1985	PFV		
MM 0097	Meat of cattle, pigs and sheep	0.1		ML	Adopted	CS 230-2001	FAC 00	Also applies to the fat from meat	
PM 0110	Poultry meat	0.1		ML	Adopted	CS 230-2001	FAC		
MO 0812	Cattle, Edible offal of	0.5		ML	Adopted	CS 230-2001	FAC		Appendix XI of ALINORM 01/12 includes "Edible offal of cattle, pig and poultry" and MO 0097 which is the code for Edible offal of cattle, pig and sheep.
MO 0818	Pig, Edible offal of	0.5		ML	Adopted	CS 230-2001	FAC		Appendix XI of ALINORM 01/12 includes "Edible offal of cattle, pig and poultry" and MO 0097 which is the code for Edible offal of cattle, pig and sheep.

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
PO 0111	Poultry, Edible offal of	0.5		ML	Adopted	CS 230-2001	FAC		Appendix XI of ALINORM 01/12 includes "Edible offal of cattle, pig and poultry" but it does not mention "PO 0111" in the table.
	Fish	0.2		ML	7		FAC 02, 03, 04, 05	Fish muscle	2)
	Edible fats and oils	0.1		ML	Adopted	CS 19-1981, Rev.2-1999	FO	Edible fats and oils not covered by individual standards	3)
	Fat spreads and blended spreads	0.1		ML	7		FO 03, 05		
	Margarine	0.1		ML	Adopted	CS 32-1981, Rev.1-1989	FO 03		The Standards for margarine and minarine (CS 32-1981 and CS 135-1981) contain MLs for Fe, Cu, Pb and As, but the CCFO is working on a draft Standard for fat spreads and blended spreads, which will contain the same text as in the more recently revised Standards for oils and fats and which will only apply to Pb and As.
	Minarine	0.1		ML	Adopted	CS 135-1981, Rev.1-1989	FO 03		The Standards for margarine and minarine (CS 32-1981 and CS 135-1981) contain MLs for Fe, Cu, Pb and As, but the CCFO is working on a draft Standard for fat spreads and blended spreads, which will contain the same text as in the more recently revised Standards for oils and fats and which will only apply to Pb and As.
	Named animal fats	0.1		ML	Adopted	CS 211-1999	FO	Lard, rendered pork fat, premier jus and edible tallow.	1)
OR 0305	Olive oil, refined	0.1		ML	Adopted	CS 33-1981, Rev.2-2003	FO		
OC 0305	Olive oil, virgin	0.1		ML	Adopted	CS 33-1981, Rev.2-2003	FO		
OR 5330	Olive, residue oil	0.1		ML	Adopted	CS 33-1981, Rev.2-2003	FO	Olive pomace oil	
PF 0111	Poultry fats	0.1		ML	Adopted	CS 230-2001	FAC		
OC 0172	Vegetable oils, Crude	0.1		ML	Adopted	CS 230-2001, CS 210-1999, Rev.1-2001	FO, FAC	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, saflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.	

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
OR 0172	Vegetable oils, Edible	0.1		ML	Adopted	CS 230-2001, CS 210-1999, Rev.1-2001	FO, FAC	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, saflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.	
ML 0106	Milks	0.02		ML	Adopted	CS 230-2001, Rev.1-2003	FAC	A concentration factor applies to partially or wholly dehydrated milks.	The previous footnote “For dairy products, an appropriate concentration factor should apply”, was changed to “a concentration factor applies to partially or wholly dehydrated milk” by the 35th CCFAC. 1)
LS	Secondary milk products	0.02		ML	Adopted	CS 230-2001	FAC 00-03	As consumed	
	Natural mineral waters	0.01		ML	Adopted	CS 108-1981, Rev.1-1997	NMW	Expressed in mg/l	
	Infant formula	0.02		ML	Adopted	CS 230-2001	FAC	Ready to use	CCNFSDU is revising at Step 6 the Codex Standard for Infant formula which includes an ML for lead at the same level.
	Salt, food grade	2		ML	Adopted	CS 150-1985, Rev.1-1997	NFSDU		
	Wine	0.2		ML	Adopted	CS 230-2001	FAC		The OIV requested special consideration to be given to levels of lead in wines that had been stored for long periods of time (ALINORM 01/41).

1) The 2001 CAC requested reevaluation of the lead MLs in milk and milk fat (ALINORM 01/41, para. 121); see also ALINORM 03/12 para. 135-137. The 35th CCFAC discussed the issue of the necessity of an ML for milk, as milk was not a major contributor to the intake of lead. However, in view of opinions that milk is a major contributor to the exposure of infants and young children, the ML for milk was maintained. The Committee decided to inform the CAC that the current level for lead in milk fat (0.1 mg/kg) should be revoked (no documentation of such a decision is found in the CAC 2003 report however).

2) The 34th and the 35th CCFAC discussed various options for establishing ML(s) for lead in fish. Also analytical problems and economic aspects were highlighted. The 35th CCFAC decided to return the draft ML at Step 6 and to request a statistical analysis of the data available and of the comments submitted, using different levels of concern (e.g. 0.2, 0.4 and 0.5 mg/kg) in order to have a basis for decisions on whether or not to adopt a tiered approach. The need for more data (in GEMS Food format) and relevant information was stressed (ALINORM 03/12A, paras 137-142). The 36th CCFAC agreed to retain the draft ML at Step 7 and to review the level at its next Session in the light of the result of the assessment of the 53rd JECFA, the list of the main internationally traded fish to be elaborated by Denmark, and comments received (ALINORM 04/27/12, paras. 161-165). Recalling that this item had been discussed for many years and various approached had been attempted without making appreciable progress, the 37th CCFAC decided not to develop a list of fish and to consider setting a maximum level for lead in a range between 0.2-0.5 mg/kg for all fish taking into account the results of the 53rd JECFA, the WHO data on lead contamination in fish, and other relevant information such as those provided at the 36th CCFAC. It agreed to retain the draft ML of 0.2 mg/kg at Step 7 and to decide the level at the next session baased on the information contained in a discussion paper (ALINORM 05/28/12, paras154-157).

3) The revised Standards for oils and fats contain the following wording for the mentioned contaminant MLs: "The products covered by the provisions of this Standard shall comply with MLs being established by the CAC but in the meantime the following limits will apply." CS for Edible Fats and Oils Not Covered by Individual Standards contains the same contaminant provisions as the other

recent Standards for oils and fats (only applying to Pb and As).

1.13.1 Mercury

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Natural mineral waters	0.001		ML	Adopted	CS 108-1981, Rev.1-1997	NMW	Expressed in mg/l	
	Salt, food grade	0.1		ML	Adopted	CS 150-1985, Rev.1-1997	FAC		

Mercury is a naturally occurring metallic element which can be present in foodstuffs by natural causes; elevated levels can also occur due to e.g. environmental contamination by industrial or other uses of mercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products. No CCFAC position document is available about mercury.

The draft Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (ALINORM 01/12A, Appendix XIII) was adopted by the 24th CAC (2001), with an amendment to paragraph 3 of the introduction (ALINORM 01/41, paras 130-131).

1.13.2 Methylmercury

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Fish	0.5		GL	Adopted	CAC/GL 7-1991	CCFAC	Except predatory fish The Guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade. 1)	
	Predatory fish	1		GL	Adopted	CAC/GL 7-1991	CCFFP	Predatory fish such as shark (WS 0131), swordfish, tuna (WS 0132), pike (WF 0865) and others. The Guideline level for methylmercury in fresh or processed fish and fish products moving in international trade. 1)	The GLs for methylmercury in fish The GLs for methylmercury in fish were adopted by the CAC-19 in 1991 (ALINORM 91/40, para. 202), on the understanding that the levels would be kept under review by the CCFAC as well as the CCFFP, especially as to the identification of predatory species of fish to which the higher GL applies. 1)

Methylmercury is the most toxic form of mercury and is formed in aquatic environments. Methylmercury therefore is found mainly in aquatic organisms. It can accumulate in the food chain; the levels in large predatory fish species are therefore higher than in other species and fish is the predominant source of human exposure to methylmercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products. The 53rd JECFA calculated the human exposure to methylmercury in regional diets to range from 0.3-1.5 ug/kg bw/week. Nationally reported dietary exposures are in the range 0.1 –2.0 ug/kg bw/week.

The 1992 CCFAC informed the CAC and the CCFFP that the recommended GLs for mercury in fish referred to total mercury rather than methylmercury. The 20th CAC (1993) decided to maintain the GLs for methylmercury in fish as previously adopted, while recommending that the establishment of corresponding GLs for total mercury in fish be considered by the CCFAC at its next meeting. The 26th CCFAC (1994) noted that analysis of total mercury was generally adequate to ensure that GLs for methylmercury were not exceeded and decided that the establishment of GLs for total mercury in fish was not necessary. The 29th CCFAC noted that the 43rd CXEXEC had recommended that the CCFAC initiate a new risk analysis on mmthylmercury. It was decided to defer any decision on the question of GLs based on methylmercury or total mercury until JECFA had performed the risk assessment. The 53rd JECFA (1999) maintained the existing PTWI for methylmercury and recommended that methylmercury be re-evaluated in 2002 when a new information on the cohort in one of the studies could be assessed and possibly other new relevant data could be available. The 53rd JECFA also recommended that the nutritional benefits of fish consumption are weighed against the possibility of harm when limits on methylmercury concentrations in fish or on fish consumption are being considered. The 32nd CCFAC(2000) took note of these recommendations.

The 37th CCFAC agreed that the revision of the GLs requires more comprehensive consideration by CCFAC in order to take into account all factors related to the consumption of fishi, in particular, risks and benefits and that, in the meantime, the existing GLs can be retained with the understanding that enforcement can be performed by determination of total mercury as a screening method (for facilitating control/monitoring). Methylmercury needs only be determined for verification purposes (ALINORM 05/28/12, para. 202)

1) Lots should be considered as being in compliance with the guideline levels if the level of methylmercury in the analytical sample, derived from the composite bulk sample, does not exceed the above levels. Where these Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction and what

recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women.

1.16 Tin

Reference to JECFA: 10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26(1982), 33(1988), 55 (2000), 64 (2005)
Toxicological guidance: PTWI 14 mg/kg bw (1988, Expressed as Sn; includes tin from food additive uses; maintained in 2000.)
Residue definition: Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification
Synonyms: Sn
Related Codes of Practice: Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods (CAC/RCP 60-2005)
Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Canned fruit cocktail	250	C	ML	Adopted	CS 78-1981	PFV		
	Canned grapefruit	250	C	ML	Adopted	CS 15-1981	PFV		
	Canned mandarin oranges	250	C	ML	Adopted	CS 68-1981	PFV		
	Canned mangoes	250	C	ML	Adopted	CS 159-1987	PFV		
	Canned pineapple	250	C	ML	Adopted	CS 42-1981	PFV		
	Canned raspberries	250	C	ML	Adopted	CS 60-1981	PFV		
	Canned strawberries	200	C	ML	Adopted	CS 62-1981	PFV		
	Canned tropical fruit salad	250	C	ML	Adopted	CS 99-1981	PFV		
	Jams (fruit preserves) and jellies	250	C	ML	Adopted	CS 79-1981	PFV		
	Mango chutney	250	C	ML	Adopted	CS 160-1987	PFV		
	Table olives	250	C	ML	Adopted	CS 66-1981, Rev.1-1987	PFV		
	Canned asparagus	250	C	ML	Adopted	CS 56-1981	PFV		
	Canned carrots	250	C	ML	Adopted	CS 116-1981	PFV		
	Canned green and wax beans	250	C	ML	Adopted	CS 16-1981	PFV		
	Canned green peas	250	C	ML	Adopted	CS 58-1981	PFV		
	Canned mature processed peas	250	C	ML	Adopted	CS 81-1981	PFV		
	Canned mushrooms	250	C	ML	Adopted	CS 55-1981	PFV		
	Canned palmito	250	C	ML	Adopted	CS 144-1985	PFV		
	Canned sweet corn	250	C	ML	Adopted	CS 18-1981	PFV		
	Canned tomatoes	250	C	ML	Adopted	CS 13-1981	PFV		
	Pickled cucumber	250	C	ML	Adopted	CS 115-1981	PFV		
	Processed tomato concentrates	250	C	ML	Adopted	CS 57-1981	PFV		
	Canned beverages	150	C	ML	4		FAC 99-05		Changed from 200 mg/kg in 2005. 2)
	Canned chestnuts and	250	C	ML	Adopted	CS 145-1985	PFV		

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	chestnut purée								
	Cooked cured chopped meat	200	C	ML	Adopted	CS 98-1981, Rev.1-1991	PMPP	For products in tinplate containers	
	Cooked cured chopped meat	50		ML	Adopted	CS 98-1981, Rev.1-1991	PMPP	For products in other containers	
	Cooked cured ham	50		ML	Adopted	CS 96-1981, Rev.1-1991	PMPP	For products in other containers	
	Cooked cured ham	200	C	ML	Adopted	CS 96-1981, Rev.1-1991	PMPP	For products in tinplate containers	
	Cooked cured pork shoulder	50		ML	Adopted	CS 97-1981, Rev.1-1991	PMPP	For products in other containers	
	Cooked cured pork shoulder	200	C	ML	Adopted	CS 97-1981, Rev.1-1991	PMPP	For products in tinplate containers	
	Corned beef	50		ML	Adopted	CS 88-1981, Rev.1-1991	PMPP	For products in other containers	
	Corned beef	200	C	ML	Adopted	CS 88-1981, Rev.1-1991	PMPP	For products in tinplate containers	
	Luncheon meat	200	C	ML	Adopted	CS 89-1981	PMPP	For products in tinplate containers	
	Luncheon meat	50		ML	Adopted	CS 89-1981	PMPP	For products in other containers	
	Canned foods other than beverages	250	C	ML	4		FAC 99-04		2)

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).

In previous JECFA meetings it was noted that inorganic tin compounds generally have low systemic toxicity in aminals, because of limited absorption from the gastrointestinal tract, low accumulation in tissues, and rapid passage through the gastrointestinal tract. Insoluble tin compounds are less toxic than soluble tin salts.

The 33th JECFA established a PTWI for inorganic tin of 14 mg/kg bw.

At the 55th JECFA, it was concluded that the acute toxicity of inorganic tin in animals and humans results from irritation of the mucosa of the gastrointestinal tract, which may lead to vomiting, diarrhea, anorexia, depression, ataxia, and muscular weakness. There was insufficient data available to establish an ARfD for inorganic tin. The committee did not consider studies on organic tin compounds, since it had concluded at the 22th JECFA, that these compounds differ considerably from inorganic tin compounds with respect to toxicity and should be considered separately.

At its 35th and 36th session, the CCFAC, requested to evaluate inorganic tin and to determine an ARfD, since new data would have become available. When possible, population sensitivity should be taken in consideration.

The 64th JECFA concluded that the data available indicated that it is inappropriate to establish an ARfD for inorganic tin, because the occurrence of irritation of the gastrointestinal tract after ingestion of a food containing tin depends on the concentration and nature of tin in the product, rather than on the dose ingested on a body-weight basis. No information was available regarding subpopulations such as children or people with gastrointestinal disorders. The committee reiterated its opinion, expressed at the 33th and 55th JECFA, that the available data indicated that inorganic tin at concentrations of >150 mg/kg in canned beverages or >250 mg/kg in canned foods may produce acute manifestations of gastric irritation in certain individuals. Therefore, ingestion of reasonably-sized portions containing inorganic tin at concentrations equal to the proposed standard for canned beverages (200 mg/kg) may lead to adverse reactions. The committee reiterated its advice that consumers should not store food and beverages in open tinplated cans.

Concentrations as low as 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may produce acute manifestations of gastric irritation in certain individuals.

The 64th JECFA concluded that the data available indicated that it is inappropriate to establish and ARfD for inorganic tin, since hether or not irritation of the gastrointestinal tract occurs after ingestion of a food containing tin depends on the concentration and nature of tin in the product, rather than on the dose ingested on a body-weight basis.

2) The 55th JECFA (2000) maintained the existing PTWI and reiterated that limited human data available indicate that concentrations of 150 mg/kg tin in canned beverages and 250 mg/kg in other canned foods may produce acute manifestations of gastric irritation in certain individuals. This is considered to be a reversible effect however, which may occur in a limited number of sensitive subject only. Following the discussions in the 34th CCFAC (2002) and in the 35th CCFAC (2003)(ALINORM 03/12, para. 146 and ALINORM 03/12A, para. 160), the proposed MLs were repeatedly returned to step 3. The 35th CCFAC changed the terminology of the commodities to which the proposed draft MLs apply, which previously was “liquid canned foods resp. solid foods”, to “canned beverages” and “canned foods other than beverages”. The Committee decided to ask JECFA to evaluate current tin levels in canned foods and to determine an acute reference dose; it was noted that new data would become available

The acute toxicity was assessed at the 55th JECFA but data were insufficient for establishing an acute reference dose. The 55th JECFA reiterated that tin concentrations as low as 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may produce acute manifestations of gastric irritation in certain individuals.

After discussions concerning appropriate MLs the 37th CCFAC agreed to circulate the proposed ML for comments at Step 3 and further consideration at the 38th session.

A discussion paper on tin (last version CX/FAC 03/29) is a revision of the position paper first discussed in CCFAC 1997 and contains all relevant information and references. The 35th CCFAC decide to discontinue its future consideration. The 35th CCFAC agreed that a Code of Practice for the Prevention and Reduction of Tin should be elaborated, for consideration at its next session.

3.01.5 Vinyl chloride monomer

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Food	0.01		GL	Adopted	CAC/GL 6-1991	FAC 86-91	The GL in food packaging material is 1.0 mg/kg.	

Vinylchloride monomer is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods. Vinyl chloride is not known to occur as a natural product. Residues of VCM may be still present in the polymer. Vinyl chloride is considered by IARC to be a human carcinogen (as has been shown in occupational exposure situations). Migration of possibly harmful substances from food contact materials has been discussed in the CCFA/CCFAC in the period 1986-1991.

Guideline levels for vinyl chloride monomer and acrylonitrile in food and packaging material were adopted by the CAC at its 19th session (1991) on the understanding that the AOAC and the ISO would develop appropriate sampling plans and methods of analysis.

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3.03 Polybrominated diphenyl ethers

Reference to JECFA: 64 (2005)
Toxicological guidance: (Intake estimates: mean approximately 4 ng/kg bw/day
Based on limited toxicity data, The 64th JECFA concluded that there appeared to be a large MOE for a non-genotoxic compound which, despite the inadequacy of the data on toxicity and intake, gave reassurance that intakes of PBDEs are not likely to be a significant health concern.)
Synonyms: PBDEs
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Polybrominated diphenyl ethers (PBDEs) are anthropogenic chemicals that are added to a wide variety of consumer/commercial products (e.g. plastics, polyurethane foam, textiles) in order to improve their fire resistance. Theoretically, 209 distinct PBDE isomers are possible, however, each commercial mixture usually only contains a limited number of congeners from each homologue group. PDBEs have been produced primarily as three main commercial products (mixtures): pentabromodiphenyl oxide or ether (PentaBDE), octabromodiphenyl oxide or ether (OctaBDE) and decabromodiphenyl oxide or ether (DecaBDE). Some variability in composition is known to exist between products from different manufacturers. The worldwide demand for PBDEs in 2001 was estimated to be almost 70 000 tonnes, with DecaBDE accounting for almost 80% of the total market.

Absorption of PBDEs is directly related to the extent of bromination of the parent diphenyl ether; as a general rule, greater substitution of bromine leads to a decrease in bioavailability. The metabolism of PBDEs consists of hydroxylation and methoxylation reactions and, in the case of congeners with a higher degree of bromination, oxidative debromination. Faecal excretion appears to be the dominant route of elimination, however, species differences exist. Limited data are available regarding the half-lives, however, preliminary values ranged from 30 to 90 days for the tetra- to hexa-substituted congeners. Moreover, limited pharmacokinetic data are available for humans, however, based on the observed increase in concentrations of PBDEs in tissue in time, PDBEs are absorbed and bioaccumulate.

The acute toxicity of mixtures of PBDEs is low in rodents, however, increased mortality, neurobehavioural effects, changes in gross pathology, induction of enzymes, changes in levels of hormones have been observed. In short-term studies the main effects of mixtures of PBDEs were seen in the liver (enlargement, 'round bodies', vacuolization, necrosis), kidney (hyaline degenerative cytoplasmic changes) and thyroid (hyperplasia). Embryo and fetus may be more sensitive to PBDEs than maternal animals; exposure to OctaBDE mixtures caused an increase in the incidence of developmental abnormalities. The results of the majority of tests for genotoxicity indicated that PBDE mixtures and single congeners are not genotoxic. The only long-term study was conducted with the DecaBDE mixture in mice and rat, however, evidence for the carcinogenicity of DecaBDE is limited. No information is available on the carcinogenic potential of other PBDE mixtures. Available studies in humans are not adequate to evaluate whether exposure to PBDEs is associated with adverse health effects. Some toxicity data may be confounded by the presence of traces of impurities that are Ah-receptor agonists (e.g. dioxin).

In 1994, WHO published an Environmental Health Criteria document on PBDEs. Recent analysis of samples from environment and from human collected over the last 3-4 decades demonstrated significant increases in concentrations of PBDEs. At its 35th session the CCFAC requested to evaluate the potential risks associated with the presence of PBDEs in food.

The 64th JECFA noted that the available data on PBDEs were not adequate to allocate a PTWI or PMTDI, because:

-PBDEs represent a complex group of related chemicals and the pattern of PDBE congeners in food is not clearly defined by a single commercial mixture;

-Data are inadequate to establish a common mechanism of action that would allow a single congener to be used as a surrogate for total exposure or, alternatively, as the basis for establishing toxic equivalence factors;

-There is no systematic database on toxicity including long-term studies on the main congeners present in diet, using standardized testing protocols that could be used to define a NOEL for individual PBDEs of importance;

-Several of the reported effects are biological outcomes for which the toxicological significance remains unclear;

-Studies with purified PBDE congeners in vitro have shown a lack of Ah receptor activation, however, many of the adverse effects reported are similar to those found with dioxin-like contaminants, suggesting that some toxicity data may be confounded by the presence of traces of impurities that are potent Ah receptor agonists.

The 64th JECFA recognized the preliminary nature of the data on concentrations of PBDEs in food and human milk and estimated the dietary intake for the sum of all measured PBDE congeners to be approximately 4 ng/kg bw/day, while intake by breastfeeding infants could be up to 100 ng/kg bw/day. Adverse effects for PBDE congeners would be unlikely to occur at doses of less than approximately 100 μg/kg bw/day.

Based on limited toxicity data, The 64th JECFA concluded that there appeared to be a large MOE for a non-genotoxic compound which, despite the inadequacy of the data on toxicity and intake, gave reassurance that intakes of PBDEs are not likely to be a significant health concern. The committee considered that continuing studies of PBDEs in samples from humans, including human milk, would be useful in assessing the overall exposures to PBDEs in foods and other possible sources

3.04 Polychlorinated biphenyls

Reference to JECFA: 35 (1989)
Toxicological guidance: Not established (, For coplanar PCBs (dioxin-like PCBs), see the toxicological guidance value of 3.08 Dioxins)
Synonyms: Abbreviations, PCBs
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

PCBs are a class of stable chlorinated aromatic hydrocarbons which (mostly prior to the 1970s) have been produced since 1930 and used extensively in a wide range of industrial applications. One of the main uses which still persists is as dielectric and heat exchange fluids. Despite increasing withdrawal of the use and restrictions on the production, large amounts of PCBs continue to be present in the environment, either in use in existing industrial systems, or in waste materials, or dispersed as persistent pollutants. PCBs are mixtures of related chemicals which are formed by the chlorination of biphenyl. Theoretically, 209 congeners are possible; in practice about 130 are likely to occur in commercial products. Also related by-products are formed, such as polychlorinated dibenzofurans (PCDFs), and may be found in technical PCB-mixtures. Some of the trade names for technical PCB-mixtures as they were produced are Aroclor, Clophen, Kanechlor. The different congeners in PCB-mixtures can be designated by their IUPAC number, and different industrial PCB-mixtures can be characterized by their composition in terms of the relative percentages of the congeners.

Degradation of PCBs in the environment depends on the degree of chlorination (higher chlorinated compounds are generally more persistent against photolytic, microbial and animal metabolic degradation) and on the position of the chlorine atoms in the molecule. All congeners are lipophilic and accumulate in the food chain.

PCBs were discussed by the 35th JECFA (1989); it was difficult to come to clear conclusions about the toxicity of PCBs as such because impurities such as dioxins and related compounds (e.g., PCDFs) probably were present in the PCB-mixtures used for the animal studies. The Committee concluded that 0.04 mg/kg bw was the NOEL in monkey studies. However, because of the limitations of the data and the ill-defined nature of the materials used in the study, no tolerable intake for humans could be established. One of the complications is that humans are exposed to biologically filtered mixtures of congeners, which are rather different from the industrial PCB-mixtures that were used for the studies. No toxicological monograph was prepared (see however EHC 140).

PCBs were evaluated by IARC in 1978 and 1987. The conclusion was that PCBs are carcinogenic for laboratory animals and are probably carcinogenic for humans (IARC, 1987). Extensive documentation about PCBs is gathered in EHC 140 (WHO, 1993)

The major foods in which contamination with PCBs can be significant are fish, milk and dairy products, meat and eggs. Because PCBs bioaccumulate, the levels will usually be higher in animals which are higher in the food chain, but local pollution and feed composition may have major influence on the levels in animal products. Humans with a considerable intake of animal fats also may accumulate high levels of PCBs and as a consequence also PCB-levels in breast milk and in human adipose fat may be high. The JECFA, however, considered that the advantages to the infant of breast-feeding outweigh any potential hazards due to the PCB-content of breast milk. The JECFA recommended that PCB-levels in foods are monitored, preferably by quantifying the most important individual congeners. Safety studies should be carried out on the toxicological potential of the PCB-congeners which are predominantly present in foods. It is evident that in relation to the persistent nature of PCBs and ongoing environmental contamination, it is still valid to pay due attention to PCBs. JECFA pointed out that a long-term goal should be the reduction of PCBs in the diet to a minimum.

PCBs are related to other chlorinated hydrocarbons, such as polybrominated biphenyls (PBBs), polychlorinated terphenyls (PCTs), tetrachlorobenzyltoluenes, and polychlorinated dibenzodioxins and dibenzofurans. Coplanar PCBs were integrated included in the toxicological evaluation of dioxins (see the PTMI of 3.08 Dioxins), but it has to be borne in mind that the toxicological effects of PCBs are broader than the dioxin-related effects. The CCFAC discussed PCBs from 1990 to 1994 on the basis of CX/FAC 90/20-Add.1 and further related documents. It was noted that several countries have established MLs for PCBs in food, so that trade issues might arise. Some of these countries have introduced MLs for the sum of some specific PCB-congeners, which is probably the best defined way of analysing and reporting PCBs. The most important congeners for analysis of the general content of PCBs in foods are usually considered to be IUPAC numbers 28, 52, 101, 118, 138, 153 and 180.

The CCFAC also acknowledged that source-directed measures were most important to reduce contamination with PCBs. The Committee agreed in 1992 that it was premature to set (maximum) levels for these contaminants at this stage. The discussions later were focused on dioxins and the dioxin-related PCBs.

The PCB-congeners that most easily adopt a co-planar configuration (the non-ortho substituted PCBs, numbers 77, 126 and 169) are potent Ah receptor agonists. Mono-ortho substituted PCBs are less potent but are included with a TEQ-factor for dioxin-like activity (nos 105, 114, 118, 123, 156, 157, 167, 189). Sometimes also PCB 81 and two di-ortho substituted PCBs (170 and 180) were included in the discussion about the TEF-approach for dioxins because of their ability to induce P4501A1 enzymes and their occurrence and persistence in the environment; they however were not incorporated in the WHO-recommendation about the TEF-approach for dioxin-related compounds (1998). The PCBs with a TEF form usually only a few percent of the total PCBs, but are relevant because of this specific toxicity, which can form an important contribution to the total TEQ for dioxins in a sample of food and in the human diet.

3.08 Dioxins

Reference to JECFA: 57 (2001)
Toxicological guidance: PTMI 70 pg TEQ/kg bw (2001, Including coplanar PCBs)
Synonyms: Polychlorinated dibenzo-dioxins and -furans
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

The term dioxins refers to a group of polychlorinated planar aromatic compounds. The group consists of 75 dibenzo-p-dioxins (PCDD) and 135 dibenzofurans (PCDF). The most studied and toxic dioxins are 17 congeners with a 2,3,7,8-chlorosubstitution pattern, of which 2,3,7,8-tetra-CDD (TCDD) is the most toxic and most studied congener. Dioxins are ubiquitously present as contaminants in the environment and in food, be it in minute amounts. Dioxins are lipophilic compounds which bind to sediment and organic matter in the environment and tend to be absorbed in animal and human fatty tissue. They are extremely resistant towards chemical and biological transformation processes and are consequently persistent in the environment and accumulate in the food chain. Dioxins are formed as unwanted by-products in combustion processes or industrial processes. Most of the dioxins enter the environment by emission to air. The Ah receptor is an important factor in the toxicological effects of dioxins. Activation of this receptor can result in endocrine and paracrine disturbances and alterations in cell functions including growth and differentiation.

Developmental neurobehavioral (cognitive) and reproductive effects and immunotoxic effects belong to the most sensitive endpoints of dioxin toxicology. TCDD is classified by IARC as Group 1 human carcinogen. It has been shown to be carcinogenic in several animal species at multiple sites, but TCDD is not an initiator of carcinogenesis and the tumour promotion in animal studies indicated a non-genotoxic mechanism.

The toxic equivalency concept has been developed for application to dioxins in order to assess the toxicity of a mixture of congeners as it exists in practice. Toxic Equivalency Factors (TEFs) have been established in relation to TCDD and the total toxicity of a mixture can thus be calculated as total toxic equivalents (TEQs). It has been shown that also some PCB-congeners (those with a planar dioxin-like structure) have effects on the Ah receptor and thus they are given TEFs and can be combined with the dioxins for the calculation of total TEQ of a sample.

The situation regarding dioxins has been reviewed in a discussion paper (last version CX/FAC 00/26). The 32nd CCFAC requested an additional position paper in which recent intake assessments and national regulations regarding dioxins are assembled. This was presented to the 33rd CCFAC. A revision of this document was requested, with also data on dioxin levels in food and feedingstuffs and breast-milk; the latest version is CX/FAC 03/32. The 34th CCFAC agreed that it should not draft MLs for dioxins at the time. The 35th CCFAC requested a revision of the position paper, including the insertion of a new section to cover ranges of data on background levels of dioxins and dioxin-like PCBs in food and feed. The 36th CCFAC encouraged Codex members to submit data on dioxins and dioxin-like PCBs in foods, and it agreed to request WHO to report in a detailed way to the Committee on the data submitted within three years time. In view of this, the CCFAC agreed to discontinue the consideration of the position paper (ALINORM 04/27/12, paras 188-189).

A proposed draft Code of Practice for source directed measures to reduce dioxin and dioxin like PCB contamination of foods has been prepared to be discussed by the 35th CCFAC. The 35th CCFAC agreed that a revised draft should be elaborated, taking into account the comments submitted and, in particular, Annex C of the Stockholm Convention on Persistent Organic Pollutants.

The 36th CCFAC returned the proposed draft Code of Practice to Step 2 for revision, circulation and comments at Step 3, and further consideration at the next session of the Committee (ALINORM 04/27/12, para. 185).

3.10 Chloropropanols

Reference to JECFA: 41 (1993; for 1,3-dichloro-2-propanol only) 57 (2001)
Toxicological guidance: PMTDI 0.002 mg/kg bw (2001, For 3-chloro-1,2-propanediol. 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. However, JECFA noted that 1,3-dichloro-2-propanol is associated with high levels of 3-chloro-1,2-propanediol, and regulatory control for the latter would abviate the need for specific controls for
Residue definition: 3-MCPD
Synonyms: Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Liquid condiments containing acid-hydrolyzed vegetable protein (excluding naturally fermented soy sauce)	0.4			3		FAC 05		

Chloropropanols can be formed in foods as a result of specific processing and storage conditions. The main source is acid hydrolysation of vegetable proteins for the production of savoury food ingredients. In this process the use of hydrochloric acid can result in high temperature chlorination of lipids present in the protein starting materials. 3-MCPD has been shown to be a precursor for 1,3-DCP-formation and control of the levels of 3-MCPD is expected to obviate the need for specific control on 1,3-DCP. High levels of chloropropanols (up to 100 mg/kg and more) have especially been found in products like non-traditionally fermented soy sauces and hydrolysed vegetable proteins (HVP).

There is an obvious connection with the conditions of the production method and the levels of chloropropanols in these products are shown to be declining in the last decade since the problem was noticed and measures have been taken to reduce the formation of chloropropanols. These compounds have also been found however in many other foods, including baked goods, bread, cooked/cured meat/fish and malt ingredients. There are (inconclusive) indications that cooking (grilling) could result in some formation of 3-MCPD. Also packaging materials and paper used for processing of food may contain 3-MCPD and could contribute to exposure via food, but this has led to the development of resins with significantly lower levels of 3-MCPD. Further information is required on the levels of chloropropanols in foods and food ingredients, on the dietary exposure to these compounds, on the origin and formation and on production methods which can be utilised to avoid chloropropanol contamination of foodstuffs.

A position papers have been written; the 35th CCFAC agreed that the paper should be revised on the basis of the discussions and of submitted comments and data (ALINORM 03/12A, para. 179).

The setting of MLs for chloropropanols in foodstuffs was asked to be considered at the 35th session of the CCFAC. The CCFAC could not reach a consensus on a ML of 1 mg/kg for acid-HVP soy sauce as proposed, and deferred the elaboration of MLs in different foodstuffs until its next session; the revised position paper should include proposals for the elaboration of MLs for chloropropanols in relevant foods (ALINORM 03/12A, paras 173-179).

The 36th CCFAC agreed to commence work on the establishment of a maximum level for 3-MCPD in acid-HVPs and acid-HVP containing products subject to approval as new work, in addition, the CCFAC agreed that a working group would prepare an updated discussion paper (ALINORM 04/27/12, paras 193-194).

3.12 Polycyclic aromatic hydrocarbons

Reference to JECFA: 64 (2005)
Toxicological guidance: (Intake estimates for benzo[a]pyrene as marker for PAHs: mean 4 ng/kg bw/day; high 10 ng/kg b/day
Margin of exposure (MOE): Cancer (BMDL for benzo[a]pyrene as marker for mixtures of PAHs 100 000 ng/kg bw/day), mean intake 25 000; high intake 10 000.)
Synonyms: PAHs

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Polycyclic aromatic hydrocarbons (PAHs) constitute a large class of organic compounds containing two or more fused aromatic rings. Foods can be contaminated by two major routes: firstly, by environmental PAHs present in air, soil and water; secondly, PAHs can be formed during processing (drying, smoking) or cooking (grilling, roasting, frying) of foods.

Absorption of dietary PAH is determined by size and lipophilicity of the molecule and the lipid content of the food. PAHs are metabolized by oxidation of the aromatic rings, followed by formation of glutathione, glucuronide and sulfate conjugates. Oxidation can generate electrophilic metabolites that bind covalently to nucleic acids and proteins. Some PAH and PAH metabolites bind to the aryl hydrocarbon (Ah) receptor, resulting in upregulation of enzymes involved in PAH metabolism.

The major foods containing higher concentrations of PAHs are meat and fish products, particularly grilled and barbecued products, oils and fats, cereals and dry foods.

At the 37th JECFA the committee evaluated benzo[a]pyrene and recognized that it was one member of a family of PAHs that should be considered as a class. The most significant toxicological effect was carcinogenicity and it was noted that the estimated average daily intake of benzo[a]pyrene by humans was about four orders of magnitude lower than that reported to be without effect on the incidence of tumors in rats. However, the committee was unable to establish a tolerable intake for benzo[a]pyrene, based on the available data.

At its 35th session, the Codex Committee on Food Additives and Contaminants requested to review all relevant information of PAHs in food.

The 64th JECFA evaluated 33 compounds. Some were found to be clearly genotoxic and carcinogenic (benz[a]anthracene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, chrysene, dibenz[a,h]anthracene, dibenzo[a,e]pyrene, dibenzo[a,h]pyrene, dibenzo[a,l]pyrene, dibenzo[a,l]pyrene, indeno[1,2,3-cd]pyrene, 5-methylchrysene), whereas others were not. There is limited or no evidence on the reproductive toxicity of individual PAHs, other than benzo[a]pyrene, which showed impaired fertility in the offspring of female mice. Developmental toxicity after oral administration has been reported for benz[a]anthracene, benzo[a]pyrene, dibenz[a,h]anthracene and naphthalene. A NOEL for reproductive toxicity has not been established. Using parenteral administration, it was shown that PAHs exert immunosuppressive effects, probably via the Ah receptor. The NOEL for immunosuppressive effects of benzo[a]pyrene was 3 mg/kg bw/day. No quality data for humans are available.

To evaluate the combined toxicity of PAHs, the 64th JECFA decided to use a surrogate approach, with benzo[a]pyrene being used as a marker of exposure to, and effect of the 13 genotoxic and carcinogenic PAHs. A BMDL equivalent to 0.1 mg benzo[a]pyrene.kg bw/day was derived for mixtures of PAHs in food. The committee concluded that a representative mean intake of benzo[a]pyrene of 0.004 μg/kg bw/day and high-level intake of 0.01 μg/kg bw/day could be used in the evaluation. Comparison of these mean and high-level intakes with the BMDL indicates MOEs of 25 000 and 10 000, respectively.

Based on these MOEs, the committee concluded that the estimated intakes of PAHs were of low concern for human health. Measures to reduce intake of PAHs could include avoiding contact of foods with flames, and cooking with the heat source above rather than below the food. Efforts should be made to reduce contamination with PAHs during drying and smoking processes by replacing direct smoking (with smoke developed in the smoking chamber, traditionally in smokehouses) with indirect smoking. Washing or peeling fruit and vegetable before consumption would help to remove surface contaminants.

Recommendations by 64th JECFA:

- Future monitoring should include, but not be restricted to, analysis of the 13 PAHs identified as being genotoxic and carcinogenic.

4.05 Acrylamide

Reference to JECFA: 64 (2005)
Toxicological guidance: (Intake estimates: mean 0.001 mg/kg bw/day; high 0.004 mg/kg bw/day
Margin of exposure (MOE): morphological changes in nerves (MOEL 0.2 mg/kg bw/day), mean intake 200, high intake 50; reproductive, developmental and other non-neoplastic effects (NOEL 2 mg/kg bw/day), mean intake 2000, high intake 500; cancer (BMDL 0.3 mg/kg bw/day), mean intake 300, high intake 75.)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Acrylamide is an important industrial chemical used since the mid 1950s as a chemical intermediate in the production of polyacrylamides, which are used as flocculants for clarifying drinking water and other industrial applications. Recently, attention was drawn to the formation of acrylamide at high temperatures during frying, baking or other thermal processing of a variety of foods, typically plant commodities high in carbohydrates and low in protein. In this Maillard reaction, the most important precursor amino acid asparagine reacts with reducing sugars. After its formation acrylamide seems to be stable in a large majority of the affected foods. Acrylamide levels in commodities are highly variable because its formation is dependent on the exact conditions of time and temperature used to heat process the food and the composition of the food. Research on acrylamide formation is ongoing; mitigation could be accomplished by adjustments in existing production procedures.

In experimental animals, acrylamide is rapidly and extensively absorbed following oral administration and widely distributed to the tissues, as well as the fetus. It has also been found in breast milk. The major metabolite is glycidamide, formed by a CYP2E1-mediated oxidation, which is much more reactive with DNA than acrylamide itself. Acrylamide and metabolites are rapidly eliminated via urine.

The neurotoxicity of acrylamide in humans is well-known from occupational and accidental exposures. In addition, experimental studies in animals have shown reproductive, genotoxic and carcinogenic properties.

The nervous system is the principal site of toxic actions of acrylamide, which is expressed by morphological cq. Degenerative changes in nerves (NOEL 0.2 mg/kg/day, based on a study in rats). Reproduction studies showed reduced fertility, adverse effects on sperm-count and -morphology in male rodents, however, no adverse effects have been observed in female rodents (NOEL 2 mg/kg/day). Furthermore, acrylamide was not teratogenic in mice or rats. Acrylamide is genotoxic, however, metabolism to glycidamide appears to be a prerequisite. Acrylamide was evaluated by IARC in 1994 and classified as probably carcinogenic to humans on the basis of a positive cancer bioassay and evidence that acrylamide is efficiently biotransformed to the genotoxic metabolite glycidamide. BMDL for 10% extra risk of tumors was established by the JECFA to be 0.3 mg/kg/day.

A wide range of commodities may be contaminated with acrylamide, such as cereals and cereals-based products, fish and seafood, meat and offals, milk and milkproducts, nuts and oilseeds, pulses, potato and potatoproducts, coffee, sugars and honey, vegetables. Studies conducted in Sweden in 2002 showed the formation of high levels of acrylamide during frying or baking of a variety of food. JECFA was asked by the 36th Session of Codex Committee on Food Additives and Contaminants to evaluate acrylamide.

The 64th JECFA concluded that a dietary intake of 1 μg/kg/day of acrylamide represents the average for the general population and an intake of 4 μg/kg/day represents the high consumers; this includes children. Comparison of these intakes with the NOEL of 0.2 mg/kg bw/day for morphological changes in nerves would provide MOEs of 200 and 50, respectively. Comparison with the NOEL of 2 mg/kg bw/day for reproductive, developmental and other non-neoplastic effects would provide MOEs of 2000 and 500, respectively. For the induction of tumors, the MOE is established to 300 and 75, respectively.

The 64th JECFA concluded that adverse effects on morphological changes in nerves and on reproductive, developmental and other non-neoplastic effects are unlikely at the estimated average intakes, but that morphological changes in nerves cannot be excluded for some individuals with very high intakes. It considered the MOEs (induction of tumors - mean and high intakes) to be low for a compound that is genotoxic and carcinogenic and that they may indicate a human health concern. Therefore, appropriate efforts to reduce acrylamide concentrations in food stuffs should continue.

Recommendations by 64th JECFA:

- Acrylamide be re-evaluated when results of ongoing carcinogenicity and longterm neurotoxicity studies become available.
- Work should be continued on using PBPK modeling to better link human biomarker data with exposure assessments and toxicological effects in experimental animals.
- Appropriate efforts to reduce acrylamide concentrations in food should continue.
- In addition, the Committee noted that it would be useful to have occurrence data on acrylamide in foods as consumed in developing countries. This information will be useful in conducting intake assessments as well as considering mitigation approaches to reduce human exposure.

4.09.1 Acrylonitrile

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

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Food	0.02		GL	Adopted	CAC/GL 6-1991	FAC 86-91		

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as packaging material for o.a. foods. Acrylonitrile is not known to occur as a natural product. Acrylonitrile is classified by IARC as possibly carcinogenic to humans (Group 2B). Polymers derived from acrylonitrile may still contain small amounts of free monomer. Migration of possibly harmful substances from food contact materials has been discussed in the CCFA/CCFAC in the period 1986-1991.

Guideline Levels for Acrylonitrile in Food and Vinyl Chloride Monomer in Food and Food Packaging Materials were adopted by the CAC at its 19th session (1991) with the understanding that the AOAC and the ISO would be requested to elaborate appropriate sampling plans and methods of analysis (ALINORM 91/40, paras 203-204).

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4.11.1 Ethyl carbamate

Reference to JECFA: 64 (2005)
Toxicological guidance: (Intake estimates: from food (=mean) 15 ng/kg bw/day; from food and alcoholic beverages (=high) 80 ng/kg bw/day Margin of Exposure (MOE): cancer (BMDL 0.3 mg/kg bw/day), mean intake 20 000, high intake 3 800.)
Synonyms: Urethane; abbreviation, EC

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Ethyl carbamate (EC) can be formed from various substances derived from food and beverages, including hydrogen cyanide, urea, citrulline and other N-carbamyl compounds. Cyanate is probably the ultimate precursor, reacting with ethanol to form the carbamate ester. Over the past years, major reductions in concentrations of EC have been achieved using two approaches: first, by reducing the concentration of the main precursor substances in the food and beverages; second, by reducing the tendency for these precursor substances to react to form cyanate, e.g. by the exclusion of light from bottled spirits. Also, diethylpyrocarbonate, an inhibitor of fermentation, and azodicarbonamide, a blowing agent for sealing gaskets, can form ethyl carbamate. Diethylpyrocarbonate is revoked by the JECFA at its 17th meeting, azodicarbonamide is not recommended for bottling alcoholic beverages.

Ethyl carbamate is well absorbed from the gastrointestinal tract and is rapidly distributed throughout the body. Elimination is also rapid, with most being excreted as carbon dioxide as studied in mice. CYP2E1 activity is responsible for most of the metabolism of EC to carbon dioxide. EC may also undergo metabolic activation to vinyl carbamate epoxide, which binds covalently to nucleic acids and proteins. Moreover, hydrolysis to ethanol and ammonia may occur.

The acute oral toxicity of EC is low; however, high doses caused anaesthesia in rodents. Effects on lung, liver, kidney, heart, spleen, lymph nodes, thymus, bone marrow and ovaries were seen during chronic exposure to EC, as studied in mice and rats. Reproduction studies showed high rates of embryonic/fetal mortality and malformations. EC is genotoxic and carcinogenic. Single doses, short-term and long-term oral dosing of EC have been shown to induce tumors in all species tested (BMDL 0.3 mg/kg bw/day). IARC classified EC in Group 2B, possibly carcinogenic to humans (1974). No quality data for humans are available.

When EC was discussed in the CCFAC in 1991, a Danish national TDI of 0.2 ug/kg bw was reported. The intake of a person consuming some of the higher contaminated food products was estimated to be more than 50% of this TDI. Therefore measures aimed at reducing the EC formation were seen as necessary. No specific health effects by EC in humans related to dietary exposure are reported however.

Some countries mentioned national GLs for EC. No trade problems are reported however. The 27th CCFAC (1995) decided that no further action was needed at present.

The 64th JECFA evaluated the national estimates of intake submitted to the committee by Denmark, Switzerland, USA (assessments conducted in the early 1990s) and South Korea, Australia, New Zealand (assessments conducted more recently). The committee noted that mitigation measures have been effective in reducing residual concentrations of EC, and that, consequently the older data published in the early 1990s and used to make the initial estimates of intake of EC no longer accurately reflect current intake from alcoholic beverages. The committee estimated the mean intake of ethyl carbamate from food to be approximately 15 ng/kg bw/day, this was based on the relevant foods, including bread, fermented milk products and soy sauce; alcoholic beverages were not included. With the inclusion of alcohol beverages the estimated intake is 80 ng/kg bw/day. High consumption of stone-fruit brandies could lead to higher intakes of EC.

The 64th JECFA concluded that intake of ethyl carbamate from foods excluding alcoholic beverages would be of low concern (MOE: 20 000). However, the MOE from all intakes, food and alcoholic beverages combined (MOE: 3800), is of concern and therefore mitigation measures to reduce concentrations of ethyl carbamate in some alcoholic beverages should be continued.

5.01.1 Aflatoxins, Total

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

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
TN 0660	Almonds	15		ML	6		FAC 05		
TN 0660	Almonds	15		ML	3		FAC 05	Processed	
TN 0666	Hazelnuts	15		ML	6		FAC 05		
TN 0666	Hazelnuts	15		ML	3		FAC 05	Processed	
SO 0697	Peanut	15		ML	Adopted	CS 209-199, Rev.1-2001	FAC	The ML applies to peanuts intended for further processing. For sampling plan, see Annex 2.	1)
TN 0675	Pistachio nut	15		ML	6		FAC 05		
TN 0675	Pistachio nut	15		ML	3		FAC 05	Processed	

Aflatoxins are a group of highly toxic mycotoxins produced by fungi of the genus Aspergillus. The four main aflatoxins found in contaminated plant products are B1, B2, G1 and G2 and are a group of structurally related difuranocoumarin derivatives that usually occur together in varying ratios, AFB1 usually being the most important one. These compounds pose a substantial hazard to human and animal health. IARC (1992) classified aflatoxin B1 in Group 1 (human carcinogen) and AFM in Group 2B (probable human carcinogen). The liver is the primary target organ. A wide range of foods may be contaminated with aflatoxins; they are most commonly found in groundnuts (peanuts), dried fruit, tree nuts (such as almonds, pecans, walnuts, pistachio and brazil nuts), spices, figs, crude vegetable oils, cocoa beans, maize, rice, cottonseed and copra. AFB1 present in animal feed can partly be transferred to milk in the form of the metabolite AFM1 (mostly 1-2%, but higher percentages are found at low contamination levels in high producing animals.) Aflatoxin contamination is responsible for considerable economic losses and efforts are being made to reduce contamination of food and feedingstuffs.

The 23rd CCFAC (1991) decided to discontinue the development of a ML for aflatoxins in foods in general, and to discuss the problems on a commodity basis.

It is acknowledged that for primary plant products the aflatoxin contamination is often not homogeneous and a sampling plan is necessary to assure reasonable application of MLs. A general position paper on aflatoxins in food and feeds (CX/FAC 97/16) was presented to the 1997 CCFAC.

- A discussion Paper on aflatoxins in tree nuts (last published version CX/FAC 03/23) was discussed by the 2003 CCFAC; the CCFAC agreed that it would be revised for

consideration at its next meeting. Additional information is requested on aflatoxin contamination in tree nuts other than almonds, hazelnuts and pistachios. The Committee agreed to the elaboration of MLs for aflatoxins in almonds, hazelnuts and pistachios, based on the ALARA principle and with the understanding that related sampling plans need to be established. This activity was approved by the 2003 CAC as new work. A Code of Practice for the reduction of aflatoxin contamination in tree nuts is being developed (last published version CX/FAC 03/24). This activity was approved by the 2002 CXEXEC as new work. The draft is to be revised for consideration at the next meeting of the CCFAC.

- Corn was included in a Technical Consultation on sampling plans for aflatoxins in commodities. See FAO Food and nutrition Paper 55 (Rome, 1993).

- The 1994 CCFAC decided to discontinue the establishment of GLs for AFB1 in supplementary feedingstuffs for milk-producing animals (previously proposed at the

level of 5 mcg/kg), based on the assumption that the relationship between aflatoxins in milk and feeds is not (completely) clear and that there is not much international trade in (composite) supplementary feedingstuffs. International trade mostly is in the form of individual commodities which can be used as feed components in various quantities, directed to other feed uses than milk producing animals, or to other uses in general, or be decontaminated etc. Therefore, a Code of Practice for the reduction of aflatoxin B1 in raw materials and supplemental feedingstuffs for milk-producing animals was developed and adopted as RCP 045-1997.

1) The 1994 CCCPL decided not to proceed with the proposed GL for processed peanuts and to advance the proposed GL for raw peanuts (intended for further processing), associated with a specific sampling plan because the contamination is ususally very inhomogeneous in a lot. It is assumed that raw peanuts are the major commodity in international trade. The 49th JECFA (1997) evaluated hypothetical standards of 10 and 20 ug/kg AFB in peanuts and concluded that the higher standard would not result in any observable difference in rates of liver cancer. As a result of this evaluation, the 1998 CCFAC (discussing options of 10 and 15 ug/kg as a ML for AF-total in peanuts), decided to propose 15 ug/kg as ML. The resulting CS 209-1999 contains a sampling plan. A discussion paper on the development of a Code of Practice for the reduction of aflatoxin contamination in peanuts (CX/FAC 03/25) was considered by the 2003 CCFAC. The CCFAC forwarded the proposed draft Code of Practice to the 26th CAC for adoption at step 5. The 2003 CAC adopted this proposal, so the draft Code of Practice will be on the agenda of the 2004 CCFAC at step 6.

5.01.2 Aflatoxin M1

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

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
ML 0106	Milk	0.5		ML	Adopted	CS 232-2001	FAC 88-01		

The 24th CCFAC (1993) decided to stop the development of a specific standard for AFM1 in milk destined for use in baby foods.

The CCFAC has discussed 2 options for a standard for AFM1 in milk: 0.05 ug/kg and 0.5 ug/kg. At the request of the 32nd CCFAC (2000), the 56th JECFA (2001) examined exposure to AFM1 and conducted a quantitative risk assessment to compare the consequences of setting the maximum level in milk at 0.05 ug/kg and 0.5 ug/kg. The estimates of the potency of aflatoxin M1 were combined with estimates of intake from the GEMS/Food European regional diet. JECFA noted that the calculation showed that, with worst case assumptions, the projected risks for liver cancer at the proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 ug/kg are very small. As a result, 0.5 ug/kg was forwarded to the 2001 CCFAC which adopted this draft ML, noting that data supporting the lower level, if and when available, could be examined by the CCFAC at a future meeting when necessary.

It is acknowledged that the AFM1 level in milk is related to the AFB1 level in the animal feed. See note under Aflatoxins, total.

5.02.1 Ochratoxin A

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

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
GC 0640	Barley	5		ML	7		FAC 91-04		1)
GC 0650	Rye	5		ML	7		FAC 91-04		1)
GC 0654	Wheat	5		ML	7		FAC 91-04		1)

Ochratoxin A (OTA) is the major compound of a group of chemically related mycotoxins produced by species of the genera Aspergillus and Penicillium. OTA contamination is commonly found in various cereals, some pulses, coffee, cocoa, figs, grapes, wine, nuts and coconut products. It can also be transferred through the feed to animal products and concentrates especially in the kidney, but may also be found in meat and milk. Most OTA is however converted to the less harmful ochratoxin- in the rumen of ruminants.

OTA is a nephrotoxic mycotoxin, which is carcinogenic to rodents and has also teratogenic, immunotoxic and possibly neurotoxic properties. It has been associated with Balkan Endemic Nephropathy.

The situation regarding ochratoxins has been reviewed in a position paper (last version CX/FAC 99/14).

OTA is incorporated with a specific Annex in the Code of Practice for the prevention of mycotoxin contamination in cereals, which was adopted by the 2003 CAC (last published version in Appendix X of ALINORM 03/12A).

1) The draft ML of 5 mcg/kg for OTA was forwarded for adoption at step 8 by the 2002 CCFAC (ALINORM 03/12, para 111-114), on the basis of the assumption that this level was ALARA. The 26th CAC (2003) discussed this proposal (ALINORM 03/41, PARAS 45-47). Many delegations were of the opinion that this proposed ML was too low and, taking account of the evaluation of the 56th JECFA, noted that a ML of 20 mcg/kg could be adequate in terms of public health and safety. The CAC concluded that there was a lack of consensus both regarding the appropriate ML and regarding the reference to derived products and returned the standard to step 6 for further work by the CCFAC.

5.03.1 T-2 and HT-2 toxin

Reference to JECFA: 56 (2001)
Toxicological guidance: PMTDI 0.00006 mg/kg bw (Group PMTDI for T-2 and HT-2 toxins, alone or in combination)
Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes (CAC/RCP 51-2003)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

T-2 and HT-2 toxin are closely related compounds belonging to a group of chemically related mycotoxins called type A trichothecenes (which are epoxy-sesquiterpenoid compounds) and are produced by certain Fusarium species, which are pathogens of several cereal grains. The most important producer is F. sporotrichioides, a saprophyte which only will grow at high water activities. As a consequence, T-2 and HT-2 toxins are not normally found in grain at harvest, but result from water damage when it remains wet for longer periods in the field or after harvest. T-2 and HT-2 toxin undergo rapid metabolism and elimination in livestock species and the transfer from feed to animal products is probably negligible. Maximum levels in feed are not needed to product public health, but are useful for the protection of animal health and productivity. Especially pigs are vulnerable. In animals, decreased feed consumption, diarrhea and vomiting have been observed as acute effects.

T-2 toxin is a potent inhibitor of protein synthesis, both in vivo and in vitro. T-2 toxin is linked to outbreaks of acute poisoning of humans, in which the adverse effects reported include nausea, vomiting, pharyngeal irritation, abdominal pain, diarrhea, bloody stool, dizziness and chills. Co-occurrence of T-2 toxin with other trichothecenes in these cases is likely. T-2 toxin is also associated with food-related poisoning incidents in 1931- 1947 referred to as alimentary toxic aleukia, in the former Soviet Union. The PMTDI is based on a 3-week dietary study with pigs, applying a safety factor of 500 to a LOEL for changes in white and red cell counts. The average intake of T-2 and HT-2 toxin via the human diet was estimated by JECFA as 8 resp. 9 ng/kg bw, which is lower than the group PMTDI. An intake at the level of the PMTDI is not expected to result in effects of T-2 and HT-2 toxin on the immune system and to haematotoxicity, which are considered critical effects after short-term intake. JECFA recommended that toxic equivalency factors relative to DON be developed for the other trichothecenes commonly occurring in cereal grains, if sufficient data become available.

T-2 and HT-2-toxin are incorporated with a specific Annex for trichothecenes in the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, which was adopted by the 2003 CAC (last published version in Appendix X of ALINORM 03/12A).

No further action on T-2 and HT-2 toxin has been recommended by the 2001 CCFAC, probably based on the understanding that the (limited) information available suggested that intakes would not exceed the PMTDI (ALINORM 01/12A, para. 16).

5.03.8 Deoxynivalenol

Reference to JECFA: 56 (2001)
Toxicological guidance: PMTDI 0.001 mg/kg bw (2001,)
Synonyms: Vomitoxin; Abbreviation, DON
Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes (CAC/RCP 51-2003)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Deoxynivalenol (DON) is the major compound of a group of chemically related mycotoxins called type B trichothecenes (which are epoxy-sesquiterpenoid compounds) and is produced by certain Fusarium species, which are pathogens of several cereal grains. Closely related compounds are e.g. nivalenol and several acetyl-DON derivatives. DON is water-soluble and chemically very stable under most normal food processing conditions. DON contamination is commonly found in various cereals and cereal products. It undergoes rapid metabolism and elimination in livestock species and the transfer from feed to animal products is probably negligible. Maximum levels in feed are not needed to product public health, but are useful for the protection of animal health and productivity. Especially pigs are vulnerable.

In animals, decreased feed consumption, diarrhoea and vomiting have been observed as acute effects. JECFA recognized that DON can lead to outbreaks of acute illness in humans. The available data did not permit to set an acute reference dose however. The PMTDI is based on a chronic dietary study with mice, applying a safety factor of 100. An intake at the level of the PMTDI is not expected to result in effects of DON on the immune system, growth or reproduction, which are the most critical effects. JECFA recommended that toxic equivalency factors relative to DON be developed for the other trichothecenes commonly occurring in cereal grains, if sufficient data become available.

The JECFA estimated that the PMTDI for DON could be exceeded in 4 out of 5 GEMS/Food regional diets.

The situation regarding deoxynivalenol has been reviewed in a discussion paper (last version CX/FAC 03/35); the 35th CCFAC discontinued the consideration of this discussion paper and agreed to commence work on the elaboration of MLs for DON (ALINORM 03/12A, paras 180-182).

The CAC in 2003 approved the development of maximum levels for DON as new work.

DON is incorporated with a specific Annex for trichothecenes in the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, which was adopted by the 2003 CAC (last published version in Appendix X of ALINORM 03/12A).

5.04.1 Fumonisins

Reference to JECFA: 56 (2001)
Toxicological guidance: PMTDI 0.002 mg/kg bw (2001,)
Synonyms: (Several related compounds have been described, notably fumonisin B1, B2 and B3 (abbreviation: FB1 etc.))
Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes (CAC/RCP 51-2003)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC

No ML

Fumonisins are a class of recently identified mycotoxins that are produced mainly by certain Fusarium species, especially F. moniliforme which is a pathogen of corn (Zea mays). Fumonisins are a structurally related group of diesters of propane-1, 2, 3-tricarboxylic acid and various 2-amino-12, 16-dimethylpolyhydroxyeicosanes. There are at least 12 fumonisin analogues identified, classified into series A, B, F and P. The B-series, consisting mainly of FB1 and FB2, are believed to be the most abundant and most toxic compounds. A typical ratio between these analogues is B1:B2:B3 as 10:3:1. The worldwide occurrence of fumonisins in corn and corn-based products is well documented; sporadic natural occurrence in sorghum, rice and navy beans has been reported. Fumonisins are heat-stable, so cooking and other heat processes do not substantially reduce their levels in foods. Processing involving treatment of wet milling fractions may however lead to elimination of most fumonisin. The human exposure via food can vary to a large extent, because of the large range of fumonisin contents which have been found in practice. Fumonisins undergo rapid metabolism and elimination in livestock species and the transfer from feed to animal products is probably negligible. Maximum levels in feed are not needed to product public health, but are useful for the protection of animal health and productivity.

In animals, various adverse effects have been observed. The horse appears to be the most sensitive species, and equine leukoencephalomalacia (ELEM) is the most frequently encountered disease. Fumonisins are also associated with liver damage, often also kidney lesions and changes in certain lipid classes, especially sphingolipids, in all animals studied. Carcinogenic effects have been observed in animals exposed to high dietary levels.

Nephrotoxicity, observed in several strains of rat, was considered by JECFA to be the most sensitive toxic effect. On the basis of the NOEL for renal toxicity and a safety factor of 100, the PMTDI was established. National estimates for the mean or median intake were generally much lower than the PMTDI (the highest being 0.2 mcg/kg bw).

A position paper has been prepared for fumonisins (last version CX/PR 00/22). The 2000 CCFAC asked the US to finalise the position paper as a potential basis for future work (ALINORM 01/12 para. 106-109). No ML-proposals have been suggested.

Fumonisins are incorporated with a specific Annex in the Code of Practice for the prevention of mycotoxin contamination in cereals, which was adopted by the 2003 CAC (last published version in Appendix X of ALINORM 03/12A).

5.04.3 Zearalenone

Reference to JECFA: 53 (1999)
Toxicological guidance: PMTDI 0.0005 mg/kg bw (1999, The total intake of zearalenone and its metabolites (including alpha-zearalanol (zeranol)) should not exceed the PMTDI.)
Synonyms: (Zearalenone is the most important of a group of related mycotoxins and relevant metabolites. Abbreviation, ZEN. Its metabolite, alpha-zearalanol (zeranol) is used as vererinary drug.)
Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, Including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes (CAC/RCP 51-2003)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Zearalenone (ZEN) is the most important of a group of resorcyclic acid lactone mycotoxins, produced by several species of Fusarium moulds.

It is found worldwide in a number of cereal crops and also in derived products like beer. It has been implicated in numerous incidents of mycotoxicosis in farm animals, especially pigs. ZEN is rapidly metabolized and excreted in animals; residues of this mycotoxin in animal products are probably not significant from a health point of view. A metabolite of ZEN, alpha-zearalanol (zeranol, abbreviated here as ZAL) is, however, relevant relating to its potential use as a veterinary drug. Also beta-zearalanol (taleranol) has hormonal activity. Besides these substances which can be used as anabolic growth promotors, also alpha- and beta-zearalenol (ZEL) and zearalanone (ZAN) are mentioned as possibly occurring metabolites of or co-occurring substances with ZEN.
The PMTDI for ZEN was set by applying a safety factor of 100 from the lowest NOAEL, related to the estrogenic effect in pigs.

ZAL has an ADI of 0,5 mcg/kg bw (ref. JECFA 26, 27 and 32)

The situation regarding ZEN has been reviewed in a position paper (last version CX/FAC 00/19). Preliminary intake calculations indicate values well below the PMTDI. It is mentioned however that further action seems required to reduce the levels of ZEN in risk products (especially maize containing products) for especially children with a high intake of these products. The 31st CCFAC (1999) agreed that, recognizing that there were no identified trade problems with ZEN, Codex MLs were not necessary for the time being. The standards mentioned here for ZAL in cattle liver and cattle muscle have been established by the CCRVDF because of recognized use of zeranol in cattle; they are relevant for the CCFAC in so far that feed contamination with ZEN can lead to residues of both ZEN and ZAL (and other metabolites) in cattle liver and muscle.

ZEN is incorporated with a specific Annex in the Code of Practice for the prevention of mycotoxin contamination in cereals, which was adopted by the 2003 CAC (last published version in Appendix X of ALINORM 03/12A).

Residues of ZEN and ZAL together in an animal product may be regarded as evidence that the animal feed was contaminated with ZEN. In order to distinguish between contamination of the feed with mycotoxins of the ZEN group or use of ZAL as veterinary drug, it may be necessary to determine the relative proportions of the different residues, e.g. as ZEN + - and -ZEL against ZAL. A ratio of 5 or more probably indicates only contamination by mycotoxins.

Maximum residue limits have been recommended by Codex for zeranol in cattle muscle and liver.

5.06.1 Patulin

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

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
JF 0226	Apple juice	50		ML	Adopted	CS 235-2003	FAC	The ML also covers apple juice as ingredient in other beverages.	

Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera Aspergillus, Penicillium and Byssochlamys. The major sources of patulin contamination are apples with brown rot and blue mould. Because patulin does not spread much from spoilt tissue, the main human exposure can be expected from processed products, like apple juice and apple sauce, in which the contamination is not visible. Because fermentation destroys patulin, it is not normally present in cider and perry, unless unfermented apple juice has been added after fermentation. Patulin may also be a contaminant of soft fruits, some vegetables, barley, wheat and corn.

The PMTDI was set by applying a safety factor of 100 from the lowest NOAEL of 43 mcg/kg bw/day in rats. Potential health problems related to patulin are connected to cytotoxic, immunotoxic, neurotoxic, gastrointestinal and other effects observed in animals. Patulin is mostly eliminated within a few days after ingestion.

8 Radionuclides

Commodity/Product Code	Name	Representative radionuclides	Dose per unit intake factor in Sv/Bq	Level in Bq/kg	Type	Reference	Notes/Remarks for Codex Alimentarius
	Foods destined for general consumption	^{241}Am, ^{239}Pu	10^{-6}	10	GL	CAC/GL 5-1989	
	Foods destined for general consumption	^{90}Sr	10^{-7}	100	GL	CAC/GL 5-1989	
	Foods destined for general consumption	^{131}I, ^{134}Cs, ^{137}Cs	10^{-8}	1000	GL	CAC/GL 5-1989	
ML 0106	Milks	^{241}Am, ^{239}Pu	10^{-6}	1	GL	CAC/GL 5-1989	
ML 0106	Milks	^{131}I, ^{90}Sr	10^{-7}	100	GL	CAC/GL 5-1989	
ML 0106	Milks	^{134}Cs, ^{137}Cs	10^{-8}	1000	GL	CAC/GL 5-1989	
	Infant foods	^{241}Am, ^{239}Pu	10^{-6}	1	GL	CAC/GL 5-1989	
	Infant foods	^{131}I, ^{90}Sr	10^{-7}	100	GL	CAC/GL 5-1989	
	Infant foods	^{134}Cs, ^{137}Cs	10^{-8}	1000	GL	CAC/GL 5-1989	

These levels are designed to be applied only to radionuclides contaminating food moving in international trade following an accident and not to naturally occurring radionuclides which have always been present in the diet. The Guideline Levels remain applicable for one year following a nuclear accident. By an accident is meant a situation where the uncontrolled release of radionuclides to the environment results in the contamination of food offered in international trade.

As the proposed levels have extensive conservative assumptions built-in, there is no need to add contributions between dose per unit intake groups, and each of the three groups should be treated independently. However, the activity of the accidentally contaminating radionuclides within a dose per unit intake group should be added together if more than one radionuclide is present. Thus the 100 Bq/kg level for the 10^{-8} Sv/Bq dose per unit intake group is the total of all contaminants assigned to that group. For example, following a power reactor accident, ^{134}Cs and ^{137}Cs could be contaminants of food, and the 1000 Bq/kg refers to the summed activity of both these radionuclides.

These levels are intended to be applied to food prepared for consumption. They would be unnecessarily restrictive if applied to dried or concentrated foods prior to dilution or reconstitution.

Both FAO and WHO have called attention in the expert meeting reports to special consideration which might apply to certain classes of food which are consumed in small quantities, such as spices. Some of the foods grown in the areas affected by the Chernobyl accident fall-out contained very high levels of radionuclides following the accident. Because they represent a very small percentage of total diets and hence would be very small additions to the total dose, application of the Guideline Levels to products of this type may be unnecessarily restrictive. FAO and WHO are aware that policies vary at present in different countries regarding such classes of food.

See Annex 1 for “Derivation of the Codex Guidelines in Foods Following Accidental Nuclear Contamination.”

ANNEX 1

DERIVATION OF THE CODEX GUIDELINES IN FOODS FOLLOWING ACCIDENTAL NUCLEAR CONTAMINATION

The approach taken by WHO and FAO in recommending the Guideline Levels to the Codex Alimentarius Commission assumes a reference level of dose (5 mSv), a total average food consumption rate, a dose per unit intake factor for various radionuclides and a pattern of food consumption, and calculates the levels by the following formula:

$$\text{Level} = \frac{\text{RLD}}{\text{m x d}}$$

where: RLD = Reference Level of Dose (Sv)
m = mass of food consumed (kg)
d = dose per unit intake factor (Sv/Bq)

Controlling radionuclide contamination of foods moving in international trade requires simple, uniform and easily applied values. This approach is one that can be uniformly applied by government authorities and yet one that achieves a level of public health protection to individuals that is considered more than adequate in the event of a nuclear accident.

In making these joint FAO/WHO recommendations the following assumptions were made in calculating the levels:

1. 5 mSv was adopted as the reference level of dose for an accident. This value, for most radionuclides, is the committed effective dose equivalent resulting from ingestion in the first year after an accident. Owing to the extremely conservative assumptions adopted, it is most unlikely that the application of the following levels will result in a dose to an individual greater than a small fraction of 1 mSv.

2. 550 kg of food is consumed in a year, all of which is contaminated.

3. Dose per unit intake factors for the radionuclides of concern (^{131}I, ^{137}Cs, ^{134}Cs ^{90}Sr, ^{239}Pu) can be conveniently divided into three classes and applied to the general population:
   (a) those with a dose per unit intake of 10^{-6} Sv/Bq such as ^{239}Pu and other actinides;
   (b) those with a dose per unit intake factor of 10^{-7} Sv/Bq such as ^{90}Sr and other beta emitters; and
   (c) those with a dose per unit intake factor of 10^{-8} Sv/Bq such as ^{134}Cs, ^{137}Cs, ^{131}I.

For infant foods and milk a dose per unit intake factor of 10^{-5} Sv/Bq was used instead of the 10^{-6} Sv/Bq value and ^{131}I was assigned to the 10^{-7} Sv/Bq class of radionuclides.

Applying these assumptions to the above formula, the level for the general population for the radionuclides in the 10^{-8} Sv/Bq group is:

$$\frac{5 \text{ x } 10^{-3}}{550 \text{ x } 10^{-8}} = 909 \text{ Bq/kg}$$

which can then be rounded 1000 Bq/kg. For the actinides this value of 10 Bq/kg, as the dose per unit intake factor is 100 times larger, and for the radionuclides in the 10^{-7} Sv/Bq class (such as ^{90}Sr), it is 100 Bq/kg.

It is recognized that the sensitivity of infants may pose a problem if the dose conversion factor for the general population were applied to them indiscriminately. WHO, in its document Derived Intervention Levels for Radionuclides in Food, [1] proposed separate guidelines for infants. The values were based on an infant consumption of milk of 275 L/y and the specific dose conversion factors for infants for ^{90}Sr, ^{131}I, ^{137}Cs.

The resulting WHO Guideline values were:

^{90}Sr	160 Bq/L
^{131}I*	1600 Bq/L
^{137}Cs	1800 Bq/L

[1] DERIVED INTERVENTION LEVELS FOR RADIONUCLIDES IN FOOD. Guidelines for application after widespread radioactive contamination resulting from a major radiation accident. WHO, Geneva, 1988.

* The value for ^{131}I was based on a dose of 50 mSv to the thyroid and a mean life of ingested ^{131}I of 11.5 days.

However, the dose per unit intake factors for infants ingesting alpha-emitting actinides have recently been revised upward and as a prudent measure, a dose per unit intake factor of 10^{-5} Sv/Bq for these radionuclides was applied to infants consuming milk and infant foods.

To reflect the infants' sensitivity, ^{131}I was assigned a dose per unit intake factor of 10^{-7} Sv/Bq, putting it in the same class as ^{90}Sr.

For infant foods and milk the application of these dose per unit intake factors result in a level of 1 Bq/kg for the alpha emitters of the actinide series and any other radionuclide with a dose unit intake factor of 10^{-5} Sv/Bq, and 100 Bq/kg for ^{90}Sr and ^{131}I or any other radionuclides assigned a dose per unit intake of 10^{-7} Sv/Bq.

By infant foods is meant a food prepared specifically for consumption by infants in the first year of life. Such foods are packaged and identified as being for this purpose.

Annex 2

SAMPLING PLAN FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING

INTRODUCTION

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

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

A. Definitions

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

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

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

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

Aggregate sample: the combined total of all the incremental samples taken from the lot or sublot. The aggregate sample has to be at least as large as the 20 kg laboratory sample.

Laboratory sample: smallest quantity of peanuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.

Test portion: portion of the comminuted laboratory sample. The entire 20 kg laboratory sample should be comminuted in a mill. A portion of the comminuted 20 kg sample is randomly removed for the extraction of the aflatoxin for chemical analysis. Based upon grinder capacity, the 20 kg aggregate sample can be divided into several equal sized samples, if all results are averaged.

B. Sampling

<u>Material to be Sampled</u>

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

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

Table 1: Subdivision of Large Lots into Sublots for Sampling

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

Number of Incremental Samples for Lots of Less than 15 Tonnes

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

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

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

Incremental Sample Selection

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

7. Since there is no way to know if the contaminated peanut kernels are uniformly dispersed through out the lot, it is essential that the aggregate sample be the accumulation of many small portions or increments of the product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

Static Lots

8. A static lot can be defined as a large mass of peanuts contained either in a single large container such as a wagon, truck, or railcar or in many small containers such as sacks or boxes and the peanuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because the container may not allow access to all peanuts.

9. Taking a aggregate sample from a static lot usually requires the use of probing devices to select product from the lot. The probing devices used should be specially designed for the type of container. The probe should (1) be long enough to reach all product, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small increments of product taken from many different locations throughout the lot.

10. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows :

Equation 1 : SF = (LT x IS)/(AS x IP). The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

11. True random sampling can be more nearly achieved when selecting an aggregate sample from a moving stream of peanuts as the lot is transferred, for example, by a conveyor belt from one location to another. When sampling from a moving stream, take small increments of product from the entire length of the moving stream; composite the peanuts to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample, then blend and subdivide the aggregate sample to obtain the desired size laboratory sample.

12. Automatic sampling equipment such as cross-cut samplers are commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic equipment is not available, a person can be assigned to manually pass a cup though the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, small increments of peanuts should be collected and composited at frequent and uniform intervals throughout the entire time peanuts flow past the sampling point.

13. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about three times the largest dimensions of the items in the lot.

14. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is :

Equation 2 : S = (D x LT) / (T x V). D is the width of the diverter cup opening (in cm), LT is the lot size (in kg), T is interval or time between cup movement through the stream (in seconds), and V is cup velocity (in cm/sec).

15. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup is :

Equation 3 : SF = (S x V) / (D x MR).

16. Equation 2 can also be used to compute other terms of interest such as the time between cuts (T). For example, the required time (T) between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 30,000 kg lot where the diverter cup width is 5.08 cm (2 inches), and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,

T = (5.08 cm x 30,000 kg)/(20 kg x 30 cm/sec) = 254 sec

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

Weight of the Incremental Sample

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

Packaging and transmission of samples

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

Sealing and labelling of samples

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

C. Sample Preparation

Precautions

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

Homogenisation – Grinding

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

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

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

Test portion

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

D. Analytical Methods

Background

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

Performance Criteria for Methods of Analysis

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

Criterion	Concentration Range	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	-
Recovery-Aflatoxins Total	1 - 15 μg/kg	70 to 110 %	
	> 15 μg/kg	80 to 110 %	
Precision RSD_R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD_r may be calculated as 0.66 times Precision RSD_R at the concentration of interest			

- The detection limits of the methods used are not stated as the precision values are given at the concentrations of interest;
- The precision values are calculated from the Horwitz equation, i.e.:

$$RSD_R = 2^{(1-0.5\log C)}$$

where:

* RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions [$(s_R / \bar{x}) \times 100$]
* C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)

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

1.09 Copper

Reference to JECFA: 10 (1966), 14 (1970), 26 (1982)
Toxicological guidance PMTDI 0.05-0.5 mg/kg bw (1982)
Residue definition: Copper, total
Synonyms: Cu

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Edible fats and oils, refined (not covered by other standards)	0.1		ML	Adopted	CS 19-1981, Rev.2-1999		Edible fats and oils not covered by individual standards. This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.	
	Edible fats and oils, virgin and cold pressed (not covered by other standards)	0.4		ML	Adopted	CS 19-1981, Rev.2-1999		This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.	
	Margarine	0.1		ML	Adopted	CS 32-1981, Rev.1-1989			
	Minarine	0.1		ML	Adopted	CS 135-1981, Rev.1-1989			
	Named animal fats	0.4		ML	Adopted	CS 211-1999	FO	Lard, rendered pork fat, premier jus and edible tallow. This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.	1)
OC 0172	Vegetable oils, Crude	0.4		ML	Adopted	CS 210-1999, Rev.1-2001	FO	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	
OR 0172	Vegetable oils, Edible	0.1		ML	Adopted	CS 210-1999	FO-03	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	1)
	Natural mineral waters	1	mg/l	ML	Adopted	CS 108-1981, Rev.1-1997			

Copper is a naturally occurring element, which sometimes is naturally found in its metallic form, but usually in the form of insoluble or soluble salts. In the soil and in plants and animal tissues it is normally always present in small quantities. Copper is an essential element, but toxic concentrations could be reached by environmental contamination or by specific conditions in connection with uses of copper compounds.

The 26th CCFAC (1994) expressed the view that the MLs for copper in fats and oils, as contained in document CX/FAC 94/11, were not related to safety, but were proposed as quality characteristics to prevent lipid oxidation. These MLs should therefore not be considered as contaminant MLs in the context of the activities of the CCFAC. The CCFAC decided to leave the establishment of such levels to the CCFO (ALINORM 95/12, para. 86-91) . The MLs have accordingly been characterised as quality characteristics in CS 19-1981. This notion however has not yet been expressed in all relevant commodity standards in which MLs for copper are established.

1) The revised Standards for oils and fats contain the following wording for the mentioned contaminant MLs: "The products covered by the provisions of this Standard shall comply with MLs being established by the CAC but in the meantime the following limits will apply."

1.10 Iron

Reference to JECFA: 27 (1983)
Toxicological guidance: PMTDI 0.8 mg/kg bw (1983, Group PMTDI, applies to iron from all sources except for iron oxides used as colouring agent, suplemental iron taken during pregnancy and lactation, and supplemental iron for specific clinical requirements))
Residue definition: Iron, total
Synonyms: Fe

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
	Edible fats and oils, refined (not covered by other standards)	2.5		ML	Adopted	CS 19-1981, Rev.2-1999		This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.	
	Edible fats and oils, virgin and cold pressed	5		ML	Adopted	CS 19-1981, Rev.2-1999		This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.	
	Margarine	1.5		ML	Adopted	CS 32-1981, Rev.1-1989			
	Minarine	1.5		ML	Adopted	CS 135-1981, Rev.1-1989			
OC 0172	Vegetable oils, Crude	5		ML	Adopted	CS 210-1999, Rev.1-2001	FO	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	
OR 0172	Vegetable oils, Edible	2.5		ML	Adopted	CS 210-1999, Rev.1-2001	FO	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.	

Iron is a naturally occurring element, which is not naturally found in its metallic form, but usually in the form of insoluble or soluble salts. In the soil and in plants and animal tissues it is normally always present in small quantities. Iron is an essential element, but toxic concentrations could be reached by environmental contamination or by specific conditions in connection with uses of iron compounds.

The 26th CCFAC (1994) expressed the view that the MLs for iron in fats and oils, as contained in document CX/FAC 94/11, were not related to safety, but were proposed as quality characteristics to prevent lipid oxidation. These MLs should therefore not be considered as contaminant MLs in the context of the activities of the CCFAC. The CCFAC decided to leave the establishment of such levels to the CCFO (ALINORM 95/12, para. 86-91) . The MLs have accordingly been characterised as quality characteristics in CS 19-1981. This notion however has not yet been expressed in all relevant commodity standards in which MLs for iron are established.

1.18 Zinc

Reference to JECFA: 10 (1966), 26 (1982)
Toxicological guidance PMTDI 0.3-1 mg/kg bw (1982)
Residue definition: Zinc, total
Synonyms: Zn

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Step	Reference	Ref to CC	Notes/Remarks for Codex Alimentarius	Notes for CCFAC
No ML									

Zinc is a naturally occurring element, which naturally is never found in its metallic form, but which occurs usually in the form of insoluble or soluble salts. In the soil and in plants and animal tissues it is normally always present in small quantities. Zinc is an essential element, but toxic concentrations could be reached by environmental contamination or by specific conditions in connection with uses of zinc compounds.

The MLs for zinc should probably not be considered as contaminant MLs in the context of the activities of the CCFAC. The MLs should accordingly be characterised as quality characteristics. This notion however has not yet been expressed in the commodity standards in which MLs for zinc are established.