

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 14b**

**CX/FAC 03/18**

**ENGLISH ONLY**

**ANGLAIS SEULEMENT**

**INGLÉS SOLAMENTE**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

**Thirty-fifth Session**

**Arusha, Tanzania, 17-21 March 2003**

### **SCHEDULE 1 OF THE PROPOSED DRAFT CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD**

The 34<sup>th</sup> CCFAC agreed that the Netherlands should update and present Schedule 1 to the Codex General Standard for Contaminants and Toxins in Foods for consideration at each meeting (ALINORM 03/12, para. 104).

## **CODEX ALIMENTARIUS - GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD SCHEDULE I - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOOD**

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### **Introduction**

Schedule I of the Codex General Standard for Contaminants and Toxins in Food (GSCTF) is the list of Codex Standards for individual contaminants and toxins in foods and feeds. It contains all the provisions for food and feed contaminants adopted by the Codex Alimentarius Commission.

Schedule I is not yet (officially) published in the format mentioned in Annex III of the Preamble to the GSCTF. Schedule I can only be officially published containing adopted standards. Since it is a dynamic document that needs to be changed regularly on the basis of progress in Codex Committees, it is considered necessary to present to all delegates a working document in the format of Schedule I, updated annually, on the development and progress of standards in CCFAC and other Codex Committees. This working document shall contain all existing and proposed Codex Standards for contaminants and toxins in foods and feeds, with notes and references regarding relevant Codex decisions and information sources. In this way also the obligations of Annex IV of the GSCTF can be met. Schedule I as presented here is thus a working document provided to the Committee for information purposes; it is a second draft and no guarantees can be given regarding the exact validity of the contents. It is hoped that with the aid of suggestions for improved texts by the participants of the CCFAC and other interested parties, it will become a valuable informatory document to the discussions of the CCFAC. The annually redrafted Schedule I will provide an overview of the situation regarding contaminants to the CCFAC, albeit an unofficial document. Schedule I is a substance-based presentation and for full understanding of the background can only be read in conjunction with the GSCTF and its annexes.

Schedule II is not yet published. It is intended to provide a product-based presentation of the Codex contaminant standards and could be made available when these data are assembled in a suitable database format.

The working document of Schedule I is due to time constraints not yet complete and for the main part only elaborated regarding the essential standard aspects; it could in future also contain more explanatory notes and a more or less elaborate general introduction per substance. Some examples are more fully elaborated with explanatory notes, references etc.; the content provided is characterized in the index of contaminants. References to Codes of Practice being developed or established are (or should be) made.

### **Information contained**

The following information will be contained in the working document of Schedule I, according to the agreed format (Annex III of the GSCTF).

- Name of the contaminant, Codex number and short monograph (synonym; TDI; ref JECFA; definition)
- In the form of a table:
  - ? Commodity
  - ? Product code
  - ? Maximum or Guideline Level in mg/kg or other appropriate expression
  - ? Suffix to specify the application of the ML/GL
  - ? Type of standard (ML or GL)
  - ? Step or other indication of status (adopted by CAC)
  - ? Reference to official documents, relevant Codex Committee meetings with decisions etc.
- Notes and remarks to the table, including short summaries of decisions, requests for information etc.
- An Index of contaminants in Code order and in alphabetic order will be provided.
- Explanatory notes to the terms used.

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**INDEX OF CONTAMINANTS IN CODE ORDER**

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1.9	copper	short concept
1.10	iron	short concept
1.11	lead	short concept
1.13	mercury	concept with notes
1.16	tin	short concept
1.18	zinc	short concept
3.1.5	monochloromethane (vinylchloride)	short concept
3.4	polychlorobiphenyls	
3.8	chlorinated dibenzodioxins and dibenzofurans	short concept
3.10.1	1,3-dichloro-2-propanol	short concept
3.10.2	3-chloro-1,2-propanediol	(combined)
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5.2	ochratoxins	concept with notes
5.3.1	T-2 and HT-2-toxin	short concept
5.3.8	deoxynivalenol	short concept
5.4.1	fumonisin	short concept
5.4.3	zearalenone	concept with notes
5.6.1	patulin	concept with notes
8.	radionuclides	short concept

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**INDEX OF CONTAMINANTS IN ALPHABETIC ORDER**

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## CODEX ALIMENTARIUS - GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD SCHEDULE I - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOOD

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### EXPLANATORY NOTES

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Code nr.:	The codes for food commodities are according to the food and feed categorization system adopted in the GSCTF, as mentioned in Annex V. The food/feed categorization system also specifies the (part of the) commodity as it should be analysed and to which the ML applies, unless a specific commodity definition is provided annex to the ML The codes for substances are derived from the coding system mentioned in Annex IV of the GSCTF.
Definition:	Definition of the contaminant in the form to which the ML applies or which may or should be analysed in commodities.
Reference: (ref.)	references, e.g. to JECFA or CCFAC meetings in which the contaminant was discussed, characterised by the year in which the meeting took place and/or the number of the meeting.
Step:	Step in the Codex Procedure for developing standards; see the Codex Procedural Manual. The term CXL is used for a definitive Codex Standard.
suffix:	Note accompanying a 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.
synonym:	symbols, synonyms, abbreviations, scientific descriptions and identification codes used to define the contaminant.
Toxicology:	Toxicological advice about the maximum acceptable or tolerable intake level of the contaminant for humans, expressed in milligrammes (mg) or microgrammes (mcg or µg) per kg body weight (bw).
Type:	Refers to type of maximum level, e.g. ML or GL. See the definitions in the preamble of the GSCTF

### Qualification of MLs

(*)	At or about the limit of determination
C	In canned products only
F	Fat soluble contaminant (Further provisions about the application of the ML may be necessary)
R	Under review
T	Temporary

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**1.3 Arsenic**

Synonym: As  
 Toxicology: PTWI 15 mcg/kg bw for inorganic arsenic  
 Reference: JECFA 1983, 1988  
 Definition: arsenic, total (As-tot) when not otherwise mentioned; or inorganic arsenic (As-in), or other specification

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Cereals*					CPL 94		* Development of MLs discontinued
	Pulses*					CPL 94		* "
	Legumes*					CPL 94		* "
	Edible fats and oils	0.1		ML	CXL			
	Fruit juices and nectars	0.2		ML	CXL			
	Cocoa butters		*	ML	CXL		CS 86-1981 *	* ML of 0.5 mg/kg deleted in R2001
	Chocolate (except..)	0.5		ML	CXL		CS 87-1981	
	Chocolate, unsweetened	1		ML	CXL		CS 87-1981	
	Dry cocoa products		*				CS 105-1981*	* ML of 1 mg/kg deleted in R2001
	Cocoa products, other		*				CS141-1983*	*ML of 1 mg/kg deleted in R2001
	Composite and filled chocolate	1		ML	CXL		CS142-1983	
	Cocoa butter confectionery	0.5	*	ML	CXL		CS 147-1985	* ML of 0.5 mg/kg deleted in R2001
	Vinegar	1	*	ML	CXL		162-87*	* regional European Standard
	Mayonnaise	0.3	*	ML	CXL		CS 168-1987*	* regional European Standard
	Natural mineral water	0.01#		ML	CXL		108-81, rev.1	# changed from 0.05 mg/l in amend.2001

**Notes and remarks**

**General**

A position document CX/FAC 99/22 on arsenic was last discussed in CCFAC 1999; see ALINORM 99/12A, para. 137.

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**1.6 Cadmium**

Synonym: Cd  
 Toxicology: PTWI 7 mcg/kg bw  
 Reference: JECFA 1988, 2000 (55),  
 Definition: cadmium, total

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Cereals*	0.1		ML	CXL	CPL, FAC 01	CAC/GL 39-2001	* excl. bran, germ, wheat grain, rice
	Pulses*	0.1		ML	CXL	CPL, FAC 01	CAC/GL 39-2001	* does not include peanut
	Legumes*	0.1		ML	CXL	CPL, FAC 01	CAC/GL 39-2001	* excl. soybean
	Fruit	0.05		ML	3	FAC 02		# See Alinorm 03/3, para. 20
	Vegetables, excl. tomatoes and *	0.05		ML	3	FAC 02		* see other mentioned vegetables
	Leafy vegetables, fresh herbs,	0.2		ML	3	FAC 02		
	Fungi, celeriac	0.2		ML	3	FAC 02		
	Potatoes*, stem & root vegetables**	0.1		ML	3	FAC 02		* peeled ** excl. celeriac
	Wheat grain*	0.2		ML	3	FAC 02		* incl. bran and germ
	Milled rice	0.2		ML	3	FAC 02		
	Soybean and peanuts	0.2		ML	3	FAC 02		
	Meat of cattle, poultry, pig, sheep	0.05		ML	3	FAC 02		
	Meat of horse	0.2		ML	3	FAC 02		
	Liver of cattle, poultry, pig, sheep		1)	ML		FAC 02		
	Kidney of cattle, poultry, pig, sheep		1)	ML		FAC 02		
	Crustaceans		1)	ML		FAC 02		
	Molluscs	1.0		ML	3	FAC 02		

Natural mineral water

0.003 \*

ML

CXL

CS 108-1981 \* mg/l

**Notes and remarks****General**

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 were discussed in the CCFAC and progress is mentioned in the CCFAC Reports.

- 1) The proposed MLs for crustaceans (at 0.5 mg/kg, excl. lobster & brown meat from crab), liver of cattle, poultry, pig and sheep (at 0.5 mg/kg), kidney of cattle, poultry, pig and sheep (at 1.0 mg/kg) were discontinued as these food groups were minor contributors to exposure from cadmium.



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**1.9 Copper**

Synonym: Cu  
 Toxicology: PMADI 0.5 mg/kg bw; daily dietary requirement 0.05 mg/kg  
 Reference: JECFA 1973, 1982  
 Definition: copper, total

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Edible fats and oils, virgin and cold pressed	0.4	1)	ML	CXL		CS 19-1981*	*Rev. 2-1999
	Edible fats and oils, refined	0.1	1)	ML	CXL		CS 19-1981*	*Rev. 2-1999
	Margarine	0.1		ML	CXL		CS 32-1981*	*Rev. 1 -1989
	Minarine	0.1		ML	CXL		CS 135-1981*	*Rev. 1 -1989
	Fruit juices and nectars	5	2)	ML	CXL		CS 164-1989*	*and CS 161-1989
	Vegetable juices	5	2)	ML	CXL		CS 179-1991	
	Cocoa butters						CS 86-1981*	*ML of 0.4 mg/kg deleted in R 2001
	Chocolate (except..)	15		ML	CXL		CS 87-1981	
	Chocolate, unsweetened	30		ML	CXL		CS 87-1981	
	Cocoa powders, dry cocoa-sugar mixt. <sup>s</sup>		*				CS 105-1981*	ML of 50 mg/kg deleted in R 2001
	Cocoa products, other		*				CS141-1983*	MLs of 30-50 mg/kg deleted in R2001
	Composite and filled chocolate	20			CXL		CS142-1983	
	Vinegar	10	3)	ML	CXL		CS 162-1987*	* regional European Standard
	Mayonnaise	2.0		ML	CXL		CS 168-1987*	* regional European Standard
	Natural mineral water	1	*	ML	CXL		CS 108-1981	* mg/l

**Notes**

1) This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.

2) and ML for sum of copper, zinc and iron 20 mg/kg.

3) sum of copper and zinc

### **Remarks**

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.

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**1.10 Iron**

Synonym: Fe  
 Toxicology: PMTDI 0.8 mg/kg bw, except for iron from oxides; recommended daily dietary requirement 10/20 mg (men/women)  
 Reference: JECFA 1969, 1983  
 Definition: iron, total

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Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Edible fats and oils, virgin and cold pressed	5.0	1) 2)	ML	CXL		CS 19-1981*	*Rev. 2-1999
	Edible fats and oils, refined	2.5	1) 2)	ML	CXL		CS 19-1981*	*Rev. 2-1999
	Margarine	1.5		ML	CXL		CS 32-1981*	*Rev. 1 -1989
	Minarine	1.5		ML	CXL		CS 135-1981*	*Rev. 1 -1989
	Fruit juices and nectars	15	1)	ML	CXL		CS 164-1989*	and CS 161-1989
	Vegetable juices	5	1)	ML	CXL		CS 179-1991	
	Cocoa butters	2.0		ML	CXL		CS 86-1981	
	Vinegar	10		ML	CXL		CS 162-1987*	* regional European Standard

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**Notes**

1) and ML for sum of copper, zinc and iron: 20 mg/kg.

2) This ML is mentioned to be a quality characteristic, for voluntary application by commercial partners and not for application by governments.

**Remarks**

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.

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**1.11 Lead**

Synonym: Pb  
 Toxicology: PTWI 25 mcg/kg bw per week  
 Reference: JECFA 1972, 1978, 1987, 1993  
 Definition: lead, total

Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
FC1 FP9 FS12 FB18	Fruit, except...	0.1		ML	CXL	FAC 00	CS 230-2001	
FT26 F130	Small fruit and berries	0.2		ML	CXL	FAC 00	CS 230-2001	
VA 35 VO50 VC45 VR75	Vegetables, except ...* #	0.1		ML	CXL	FAC 00	CS 230-2001	* see other mentioned vegetables and product codes # includes potatoes as peeled p.
VB 40	Brassica, except kale	0.3		ML	CXL	FAC 00	CS 230-2001	
VL 53	Leafy vegetables, except spinach	0.3		ML	CXL	FAC 00	CS 230-2001	
C 81	Cereal grains	0.2		ML	CXL	FAC 00	CS 230-2001	
VD 70	Pulses	0.2		ML	CXL	FAC 00	CS 230-2001	
VP 60	Legume vegetables	0.2		ML	CXL	FAC 00	CS 230-2001	
MM97 PM100	Meat of cattle, pig, sheep, poultry	0.1		ML	CXL	FAC 00	CS 230-2001	
MF 97 PF 111	Fat from meat, poultry	0.1		ML	CXL	FAC 00	CS 230-2001	
MO 97	Edible offal of cattle, pig, poultry	0.5		ML	CXL	FAC 00	CS 230-2001	
ML 107	Milk* 1) 2)	0.02	R	ML	CXL	FAC 00	CS 230-2001	* also sec. milk products, as consumed.
FM 183	milk fat 2) 5)	0.1	R	ML	CXL	FAC 00	CS 230-2001	
FF 269	wine 3)	0.20		ML	CXL	FAC 00	CS 230-2001	
LM unspec.	Infant formulae	0.02		ML	CXL	FAC 00	CS 230-2001	

WF115 VD120)	Fish * #	0.2		ML	6	FAC 02		* as fish muscle # comments asked
WS 125	)							
WC 143	Crustaceans		4)			FAC 02		
IM 151	Molluscs		4)			FAC 02		
JF 175	Fruit juices*	0.05		ML	CXL	FAC 01		* ready to drink; includes nectars
	Fruit juices and nectars	0.3*		ML	CXL		CS various	* mentioned to be under review
	Vegetable juices	0.3*		ML	CXL		CS various	* mentioned to be under review
	Chocolate (except..)	1		ML	CXL		CS 87-1981	
	Chocolate, unsweetened	2		ML	CXL		CS 87-1981	
	Dry cocoa products		*				CS 105-1981*	* ML of 2 mg/kg deleted in R2001
	Cocoa products, other		*				CS141-1983*	*ML of 2 mg/kg deleted in R2001
	Composite and filled chocolate	1		ML	CXL		CS142-1983	
	Cocoa butter confectionery	1	*	ML	CXL		CS 147-1985	* ML of 0.5 mg/kg deleted in R2001
	Vinegar	1	*	ML	CXL		162-87*	* regional European Standard
	Mayonnaise	0.3	*	ML	CXL		CS 168-1987*	* regional European Standard
	Natural mineral water	0.01	*	ML	CXL		CS 108-1981	* mg/l

### Notes and remarks

Further notes and MLs to be incorporated (e.g. situation regarding lead MLs in commodity standards not fully covered here yet)

The CAC agreed (ALINORM 01/41, para. 124) that the CCFAC should develop a Code of Practice on the prevention and reduction of lead contamination in food and recommended that the FAO Guidelines on lead-soldered cans could be useful in this regard. A first draft of this Code of Practice (CX/FAC 03/28) is to be discussed by the 2003 CCFAC.

- 1) For dairy products, an appropriate concentration factor should apply.
- 2) 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.
- 3) 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).
- 4) The 34th CCFAC decided to discontinue the elaboration of MLs for lead in crustaceans and bivalve molluscs (previously proposed to be 0.5 resp. 1.0 mg/kg, at step 6), because they did not significantly contribute to the total dietary lead exposure.
- 5) The 34th CCFAC (2002) decided that the ML of 0.05 mg/kg in butter (as contained in CS A-1 1971, Rev. 1-1999) should be deleted

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**1.13 Mercury**

Synonym: Hg  
 Toxicology: PTWI 5 mcg/kg bw total mercury, of which no more than 3.3 mcg/kg bw as methylmercury  
 Reference: JECFA 1972, 1978, 1988, 1999  
 Definition: Specified per product and per standard as total mercury (tm) or methylmercury (mm)

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Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
WF 115, except.) WD 120, except.) WS 125, except.)	Fish, except predatory fish	0.5	mm	GL	CXL	CCFFP CCFAC *	CAC/GL 7-91	(1) (3); *: 92, 94, 00
WS 131, 132 WF 865	Predatory fish, such as shark, tuna, swordfish, pike and others (2)	1.0	mm	GL	CXL	CCFFP	CAC/GL 7-91	(1), (2) (3)
DW	Natural mineral water	0.001 mg/l	tm	ML	CXL	CCNMW	C-STAN 108-81* * Rev. 1 -1997	

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**Notes and remarks**

General: Mercury is a naturally occurring element which can be present in foodstuffs by natural causes; elevated levels can occur due to e.g. environmental contamination by industrial or other uses of mercury. No CCFAC position document available. See also remark 4.

- (1) The Guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.  
 (2) The CGLs for methylmercury in fish were adopted by the CAC-19 in 1991, 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.

- (3) 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 mm. It was decided to defer any decision on the question of GLs based on mm or tm until JECFA had performed the risk assessment. The 53rd JECFA (1999) maintained the existing PTWI for mm and recommended that mm 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 mm concentrations in fish or on fish consumption are being considered. The 32nd CCFAC(2000) took note of these recommendations.
- (4) 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.



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1. 16 Tin

Synonym:	Sn
Toxicology:	PTWI 14 mg/kg bw per week for inorganic tin
Reference:	JECFA 1988, 2000 (55)
Definition:	tin, total (Sn-tot) when not otherwise mentioned; or inorganic tin (Sn-in), or other specification

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Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Liquid canned foods	200	C	ML	3	FAC 99-02		1) 2)
	Solid canned foods	250	C	ML	3	FAC 99-02		1) 2)
	Fruit juices and nectars, except...	200	R C	ML	CXL		CS 164-1989	
	Apple, grape, blackcurrant, small fr. j/n	150	R C	ML	CXL		CS various	
	Vegetable juices	200	R C	ML	CXL		CS 179-1991	
	Various fruit and vegetable products	250	R C	ML	CXL		CS various	
	Meat and meat products	200	R C	ML	CXL		CS various	
	Meat and meat products	50	R	ML	CXL		CS various	
	Soups and broths	150	R	ML	CXL		CS 117-1981 (R95)	

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**Notes and remarks**

The present discussion paper on tin (CX/FAC 03/29) is a revision of the position paper first discussed in CCFAC 1997 and contains all relevant information and references.

- 1) The 23rd CAC (1999) held the proposed draft MLs at step 5, pending the evaluation by JECFA in 2000. The 55th JECFA 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.
- 2) Following a discussion in the 34th CCFAC (2002), the proposed MLs were returned to step 3. Information is requested on acute toxicity, tin levels in liquid and solid canned foods and to technological aspects in regard to the use of lacquered and non-lacquered cans (CL 2002/10-FAC).

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**1.18 Zinc**

Synonym: Zn  
 Toxicology: PMTDI 1 mg/kg bw; estimated daily dietary requirement 15-22 mg/person  
 Reference: JECFA 1973, 1982  
 Definition: zinc, total

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Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Fruit juices and nectars	5	1)	ML	CXL		CS 164-1989*	*and CS 161-1989
	Vegetable juices	5	1)	ML	CXL		CS 179-1991	
	Vinegar	10	2)	ML	CXL		CS 162-1987*	* regional European Standard

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**Notes**

- 1) and ML for sum of copper, zinc and iron: 20 mg/kg.  
 2) sum of copper and zinc

**Remarks**

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.

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**3.1.5 Monochloroethene**

Synonym: Vinyl chloride (monomer), abbreviated VC or VCM, chloroethylene  
 Toxicology:  
 Reference: IARC Vol. 19, 377-438 (1979)  
 Definition: vinylchloride monomer

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<b>Commodity/Product Code</b>	<b>Product Name</b>	<b>Level mg/kg</b>	<b>Suffix</b>	<b>Type</b>	<b>Step/ Status</b>	<b>Committee</b>	<b>Reference, Standard</b>	<b>Notes, remarks</b>
	Food	0.01		GL	CXL	FAC 86-91	CAC/GL 006-1991	1)

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**Notes and remarks**

Vinylchloride monomer is the main starting substance for the manufacture of polymers which are used as resins, o.a. as packaging material for o.a. 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.

1) The GL in food packaging material is 1.0 mg/kg.

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**3.8 Dioxins**

Synonym:	chlorinated dibenzodioxins and -furans
Toxicology:	PTMI 70 pg TEQ/kg bw/month (including dioxin like PCBs)
Reference:	JECFA 57, 2001
Definition:	dioxins, total TEQ according to agreed procedure (to be further defined when MLs are developed)

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Commodity/Product Code	Product Name	Level mg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
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**Notes and remarks**

The term dioxins refers to a group of polychlorinated planar aromatic compounds which differ from each other in the amount and the position of the chlorine atoms. 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 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 individual toxic effects of the congeners in a mixture can thus be calculated to common toxic equivalents (TEQs) and are added to obtain the total toxic dioxin potency of a mixture. It has been shown that also some PCB-congeners (those with a planar "dioxin-like" structure) have effects on the Ah receptor and thus 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 34th CCFAC. A revision of this document was requested, with also data on dioxin levels in food and feed; the latest version is CX/FAC 03/32, to be discussed by the 2003 CCFAC. The 34th CCFAC agreed that it should not draft MLs for dioxins at the time.

A proposed draft Code of Practice for source directed measures to reduce dioxin and dioxin like PCB contamination of foods has been prepared (latest version CX/FAC 03/33, to be discussed by the 2003 CCFAC).

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**3.10 Chloropropanols**

Synonym: 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)  
 Toxicology: PMTDI 2 mcg/kg bw for 3-MCPD. No safe limit could be established for 1,3-DCP, because of the nature of the toxicity.  
 Reference: JECFA 57 (2001)  
 Definition: to be decided when MLs are proposed. Reporting of levels of individual compounds is desirable.

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<b>Commodity/Product Code</b>	<b>Product Name</b>	<b>Level mg/kg</b>	<b>Suffix</b>	<b>Type</b>	<b>Step/ Status</b>	<b>Committee</b>	<b>Reference, Standard</b>	<b>Notes, remarks</b>
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**Notes and remarks**

Chloropropanols can be formed in foods as a result of processing and storage conditions. 3-MCPD has been shown to be a precursor for 1,3-DCP-formation. High levels of chloropropanols (up to 100 mg/kg and more) have especially been found in products like soy sauces and hydrolysed vegetable proteins. There is an obvious connection with the production method and the levels of chloropropanols in these products are shown to be declining in the last decade. These compounds have also been found however in many other foods, including baked goods, bread, cooked/cured meat/fish and malt ingredients. 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. The setting of MLs for chloropropanols in foodstuffs was asked to be considered at the 35th session of the CCFAC. The last version of the position paper is CX/FAC 02/28.

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**4.9.1 Acrylonitrile**

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

Toxicology:

Reference: IARC Vol. 71, 43-108.

Definition: acrylonitrile (monomer)

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<b>Commodity/Product Code</b>	<b>Product Name</b>	<b>Level mg/kg</b>	<b>Suffix</b>	<b>Type</b>	<b>Step/ Status</b>	<b>Committee</b>	<b>Reference, Standard</b>	<b>Notes, remarks</b>
	Food	0.02		GL	CXL	FAC 86-91	CAC/GL 006-1991	

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**Notes and remarks**

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 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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**5.1 Aflatoxins**

Synonym: Abbreviations used are AFB, AFG, AFM, with numbers, to designate specific compounds; AF-tot for the total (see def.).  
 Toxicology: Aflatoxins are carcinogenic for animals and probably also for humans. Exposure should be restricted to a minimum, without threatening an adequate food supply. The carcinogenic potency has been assessed by the JECFA .  
 Reference: JECFA 1987, 1997, 2001  
 Definition: Depending on the commodity, the contaminant is defined as aflatoxins total (B1 +B2 + G1 + G2), or (in milk) as the metabolite AFM1.

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<b>Commodity/Product Code</b>	<b>Product Name</b>	<b>Level mcg/kg</b>	<b>Suffix</b>	<b>Type</b>	<b>Step/ Status</b>	<b>Committee</b>	<b>Reference, Standard</b>	<b>Notes, remarks</b>
SO 703	Peanuts, raw Peanuts, processed	15	AF-tot	ML	CXL	FAC 88-98	CS 209-1999	1) 1)
TN 675	Tree nuts					FAC 02		Discussion Paper CX/FAC 03/23; 2)
DF 297	Figs, dried					FAC 94		Information was asked by the 1994 FAC
GC 81 GC 645	Cereals Corn (maize)					FAC 88-91		3)
ML 106	Milk	0.5	AFM1	ML	CXL	FAC 88-01	CS 232-2001	4)
	Animal Feedingstuffs					FAC 87-94	RCP 045-1997	5)

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## Notes and remarks

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 homogenous 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.

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 usually 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 mcg/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 mcg/kg as a ML for AF-total in peanuts), decided to propose 15 mcg/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 will be considered by the 2003 CCFAC.
2. A Code of Practice for the reduction of aflatoxin contamination in tree nuts is being developed (last version CX/FAC 03/24).
3. Corn was included in a Technical Consultation on sampling plans for aflatoxins in commodities. See FAO Food and nutrition Paper 55 (Rome, 1993).
4. 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 mcg/kg and 0.5 mcg/kg. At the request of the 32nd CCFAC (2000), the 56th JECFA (2001) evaluated the exposures and cancer risks associated with these 2 options and concluded that the additional risks for liver cancer for the higher ML are very small. As a result, 0.5 mcg/kg was forwarded as proposed ML at step 8 by the 2001 CCFAC. The 2001 CAC adopted this proposed 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 3.
5. 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.

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## 5.2 Ochratoxins

Synonym:	Ochratoxins include a number of related mycotoxins (A, B, C and their esters and metabolites), the most important one being ochratoxin A, abbreviated here as OTA.
Toxicology:	PTWI 100 ng/kg bw for OTA
Reference:	JECFA 37 (1990), 44 (1995), 56 (2001), [2004]
Definition:	ochratoxin A (OTA)

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Commodity/Product Code	Commodity/Product Name	Level mcg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
GC 640, 650, 654	Wheat, barley, rye	5	*	ML	8 1)	FAC 91-02		* includes derived products

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### Notes and remarks

#### General

Ochratoxin A 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, 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- $\alpha$  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 ochratoxin 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 is being developed (last version in Appendix XII of ALINORM 03/12, to be discussed by the 2003 CCFAC in step 6).

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.

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5.3.1 T-2 and HT-2 toxin

Synonym:

Toxicology: PMTDI 0.06 mcg/kg bw, group PMTDI for the sum of T-2 and HT-2 toxin

Reference: JECFA 56 (2001)

Definition: sum of T-2 and HT-2 toxin

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Commodity/Product Code	Product Name	Level mcg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
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**Notes and remarks**

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 is 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 protect 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.

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, diarrhoea, 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 of mycotoxin contamination in cereals, which is being developed (last version in Appendix XII of ALINORM 03/12, to be discussed by the 2003 CCFAC in step 6).

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).

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5. 3. 8 Deoxynivalenol

Synonym: Vomitoxin. Deoxynivalenol is abbreviated as DON  
 Toxicology: PMTDI 1 mcg/kg bw  
 Reference: JECFA 56 (2001)  
 Definition: deoxynivalenol

Commodity/Product Code	Product Name	Level mcg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
GC 81	raw cereal grains subject to sorting etc.	[2000]		ML	1)	FAC 01-02		1) proposed in CX/FAC 03/35
	Cereal grain and cereal products*	[500]		ML	1)	FAC 01-02		* for direct human consumption, except Infant food
	Cereal-based infant foods	[100]		ML	1)	FAC 01-02		

**Notes and remarks**

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 protect 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 regional diets.

The situation regarding deoxynivalenol has been reviewed in a discussion paper (last version CX/FAC 03/35).

DON is incorporated with a specific Annex for trichothecenes in the Code of Practice for the prevention of mycotoxin contamination in cereals, which is being developed (last version in Appendix XII of ALINORM 03/12, to be discussed by the 2003 CCFAC in step 6).

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5. 4. 1 Fumonisin s

Synonym:	Several related compounds have been described, notably fumonisin B1, B2 and B3 (abbreviation: FB1 etc.)
Toxicology:	PMTDI 2 mcg/kg bw, group PMTDI for the sum of FB1, B2 and B3
Reference:	JECFA 56 (2001)
Definition:	[sum of FB1, FB2and FB3]

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Commodity/Product Code	Product Name	Level mcg/kg	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
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**Notes and remarks**

Fumonisin s 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*). Fomonisin s 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 fumonisin s in corn and corn-based products is well documented; sporadic natural occurrence in sorghum, rice and navy beans has been reported. Fumonisin s 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. National estimates for the mean or median intake were generally much lower than the PMTDI. Fumonisin s 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 protect 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. Fumonisin s 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. All estimates of the intake via the human diet were well below the PMTDI (the highest being 0.2 mcg/kg bw).

A position paper has been prepared for fumonisin s (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.

Fumonisin is incorporated with a specific Annex in the Code of Practice for the prevention of mycotoxin contamination in cereals, which is being developed (last version in Appendix XII of ALINORM 03/12, to be discussed by the 2003 CCFAC in step 6).

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### 5.4.3 Zearalenone

Synonym:	Zearalenone is the most important of a group of related mycotoxins and relevant metabolites. It is abbreviated here as ZEN. A metabolite of ZEN, Zeranol (ZAL) is used as veterinary drug.
Toxicology:	PMTDI 0.5 mcg/kg bw
Reference:	JECFA 53 (1999)
Definition:	Zearalenone for residues of the mycotoxin in plant products; zeranol for residues of the veterinary drug in animal products.

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Commodity/Product Code	Product Name	Level	Suffix	Type	Step/ Status	Committee	Reference, Standard	Notes, remarks
	Cattle liver	10	ZAL	ML*	CXL	RVDF		* based on use as veterinary drug
	Cattle muscle	2	ZAL	ML*	CXL	RVDF		

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### Notes and remarks

#### General

Zearalenone 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 promoters, 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, a Codex ML was not necessary for the time being.

ZEN is incorporated with a specific Annex in the Code of Practice for the prevention of mycotoxin contamination in cereals, which is being developed (last version in Appendix XII of ALINORM 03/12, to be discussed by the 2003 CCFAC in step 6).

- 1) 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 +  $\alpha$ - and  $\beta$ -ZEL against ZAL. A ratio of 5 or more probably indicates only contamination by mycotoxins.

**CODEX ALIMENTARIUS - GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD  
SCHEDULE 1 - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOOD**

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**5.6.1 Patulin**

Synonym:

Toxicology: PMTDI 0.4 mcg/kg bw

Reference: JECFA 37 (1990); 44 (1995)

Definition: patulin

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<b>Commodity/Product Code</b>	<b>Product Name</b>	<b>Level mcg/kg</b>	<b>Suffix</b>	<b>Type</b>	<b>Step/ Status</b>	<b>Committee</b>	<b>Reference, Standard</b>	<b>Notes, remarks</b>
JF 226	Apple juice*	50		ML	8	FAC 97-02		1); 2); * includes apple juice as ingredient in other beverages

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**Notes and remarks**

Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera *Aspergillus*, *Penicillium* and *Byssoschlamys*. 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.

The situation regarding patulin has been reviewed in a position paper (last version CX/FAC 99/16).

1. A Code of Practice for the prevention of patulin contamination in apple juice and apple juice ingredients in other beverages is being developed (last version CX/FAC 02/20, to be discussed at step 6 in the 2003 CCFAC).
2. As an alternative ML, a level of 25 mcg/kg has been discussed within the CCFAC and the CAC. Because consensus could not be reached, the 2001 CAC returned the draft ML of 50 mcg/kg to step 6 for further consideration by the CCFAC. The 2002 CCFAC forwarded this draft ML for adoption at step 8 to the CAC. The possible reduction of the ML from 50 to 25 mcg/kg will be reconsidered by the CCFAC once the Code of Practice has been implemented (i.e., after 4 years). More data are requested on the level of patulin in apple juice and apple juice ingredients for other beverages.



**CODEX ALIMENTARIUS - GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD**  
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**8 Radionuclides**

**CAC/GL 5-1989**

**Guideline levels for radionuclides in foods following accidental nuclear contamination**  
**For use in international trade**

<b>Foods destined for general consumption</b>		
<b>Dose per unit intake factor in Sv/Bq</b>	<b>Representative radionuclides</b>	<b>Level in Bq/kg</b>
$10^{-6}$	241-Am, 239-Pu	10
$10^{-7}$	90-Sr	100
$10^{-8}$	131-I, 134-Cs, 137-Cs	1000

<b>Milk and infant foods</b>		
<b>Dose per unit intake factor in Sv/Bq</b>	<b>Representative radionuclides</b>	<b>Level in Bq/kg</b>
$10^{-5}$	241-Am, 239-Pu	1
$10^{-7}$	131-I, 90-Sr	100
$10^{-8}$	134-Cs, 137-Cs	1000

**Notes**

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