Annex: Contaminants Reference Table

(CODEX ML, Guidance value and Predictive values for commodities)

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1.1 Codex maximum permitted limit (Codex ML) for Contaminants in Food and Feed

		Arsenic (As -total)	Lead[d] (Pb)	Cadmium[d] (Cd)	Mercury (Hg-Tot)	Melamine	Radionuclides	Aflatoxins[d]
	Toxicological guidance value	3 mcg/Kg BW/day	25 mcg/kg BW (PTMI[a])	25 mcg/kg BW (PTMI[a])	4 mcg/kg BW (PTWI[b])	0.2 mg/kg BW (TDI[c])	*Guideline level*[3]	
A	**Milks**[1]	*	0.02 mg/kg	*	*			0.5 mcg/kg (M1)
Ai	**Skimmed milk powder (Concentration factor =10.6**)**	*	0.212 mg/kg	*	*			5.3 mcg/kg (M1)
B	**Legumes and seeds** Soyabeans and products, chickpeas, and other pulses	*	0.1 mg/kg	0.1 mg/kg	*			*
	Peanut	*	0.1 mg/kg	0.1 mg/kg	*			Processed further -15 mcg/kg (B, G, M) Ready to eat -10 mcg/kg (B, G, M)
C	**Fats and oils**	0.1 mg/kg	0.08 mg/kg	*	*			*

D	**Cereals, roots, tubers, and derived products**	*	0.2 mg/kg	0.1 mg/kg	*			*
	Cereal based foods for infants and young children	*	*	*	*			200 mcg/kg (Deoxynivalenol)
	Infant formula, formula for special medical purposes intended for infants and follow-up formula (as consumed) [2]	*	0.01 mg/kg	*	*	**Powder infant formula** 1mg/kg **Liquid infant formula** 0.15 mg/kg	**Infants' foods** *Pu-238, Pu-239, Pu-240, Am 241*…….1Bq/kg S*r-90, Ru-106, I-129, I-131, U-235*…100 Bq/kg *S-35, Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192, H-3, C-14, Tc-99*.....1000Bq/kg	
	Food (other than infant formula)	*	*	*	*	2.5 mg/Kg (*unintentional and unavoidable presence*)	**Foods other than infants' foods** Pu-238, Pu-239, Pu-240, Am-241-…....10Bq/kg Sr-90, Ru-106, I-129, I-131, U-235..100 Bq/kg S-35, Co-60, Sr-89, Ru-103, Cs-134, Cs-137, Ce-144, Ir-192...1000Bq/kg H-3, C-14, Tc-99....10000Bq/kg	

	Flour, meal, semolina, and flakes derived from wheat, maize, or barley	*	*	*	*	1000 mcg/kg (Deoxynivalenol)
	Cereal grains (wheat, maize, and barley) destined for further processing	*	*	0.1 mg/kg	*	2000 mcg/kg (Deoxynivalenol)
	Raw maize grain	*	*	*	*	4000 mcg/kg (Fumonisins B1+B2)
	Maize flower and maize meal	*	*	*	*	2000 mcg/kg (FumonisinsB1+B)
	Wheat, barley, rye	*	*	0.2 mg/kg	*	5 mcg/kg (Ochratoxin A)
	Rice	Polished -0.2 mg/kg Husked - 0.35 mg/kg	1 mg/kg	Polished - 0.4 mg/Kg	*	
E	**Carbohydrates** Plant starch, Lactose, Maltodextrin and Sucrose (sugar)	*	*	*	*	
F	**Vitamin & minerals premix** (Considering single dose oral drug)	1.5 mcg/g	0.5 mcg/g	0.5 mcg/g	3 mcg/g	
G	**Salt, food grade**	0.5 mg/kg	1 mg/kg	0.5 mg/Kg	0.1 mg/kg	

**Minimum level is assured by GMP/GAP, [a] PTMI Provisional Tolerable Monthly Intake, [b] PTWI Provisional Tolerable Weekly Intake, [c] TDI Tolerable Daily intake,[d] The Codex ML are under review for certain commodities*

*** Concentration factor (Theoretical): Skimmed milk (water= 90.9 %, Total solid= 9.1%, total fat= 0.18%), Skimmed milk powder (water= 3.16 %, total solid= 96.84%).*

*So, 96.84 g Dry milk solid -=- 100 g Skimmed powder; 9.1 g dry milk solid-=- (100/96.84) *9.1= 9.4 g SMP.*

100 g milk when dehydrated (theoretically, with no loss) gives 9.4 g SMP & 100 g milk is dehydrated (100/9.4) = 10.6 times, So Concentration factor= 10.6

[1] Liquid milk for consumption or for further processing. A concentration factor applies to partially or wholly dehydrated milk (concentration factor comes from producer)

[2] RUTF is categorized as a food for special medical purposes (FSMP) and can be applicable for therapeutic milk,

[3] Apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency and for reconstituted or prepared food not for concentrated and dried foods.

1.2 Codex guidelines on biological & processing contaminants

1	*GE (Glycidyl Esters) in Fats and oils*	Minimum level must be ensured by suitable processing measures, *under review*	Evaluations of the joint FAO/WHO expert Committee on Food Additives (JECFA: Glycidyl esters: report: TRS 1002- JECFA 83/74
2	*Dioxins and polychlorinated biphenyls (PCBs)*	PTMI 70 pg/kg bw/month Codex code of practice for reduction	Related Code of Practice: Code of Practice for the Prevention and Reduction of Dioxin and Dioxin-like PCB Contamination in Food and Feeds (CAC/RCP 62-2006); Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)
3	*3 MCPD & 3 MCPD esters in fats and oils*	Provisional maximum tolerable daily intake 4 mcg/kg BW	Evaluations of the joint FAO/WHO expert Committee on Food Additives (JECFA): 3-monochloro-1,2-propanediol (3-MCPD) esters: report: TRS 1002- JECFA 83/104
4	*Tropane alkaloids (Combined hyoscyamine/scopolamine) in Soyabean and soya products*	Max 10 mcg/kg (Max 30 mcg/kg in emergency) in Super cereal+ LNS	FAO/WHO expert meeting on tropane alkaloids, executive summary, 2020. Tropane alkaloids applies for formula with soy-based ingredients.

1.3 Codex maximum Limit (ML) for most common Pesticide residue in commodities

Ingredients/Commodity	**Carbamates**			**Organochlorine**		**Organophosphorus**				**Pyrethroid**	
	Aldicarb	*Carbaryl*	*Carbofuran*	*DDT*	*Chlordane*	*Malathion*	*Parathion*	*Diazinon*	*Chlorpyrifos*	*Permethrin*	*Deltamethrin*
Milk & dairy products	0.01 mg/kg	0.05 mg/kg		0.02 mg/kg				0.02 mg/kg			0.05 mg/kg
Legumes and seeds						2 mg/kg	0.1 mg/kg	5 mg/kg		0.1 mg/kg	
Soyabean	0.02 mg/kg	0.2 mg/kg				2 mg/kg			0.1 mg/kg	0.05 mg/kg	
Peanut	0.02 mg/kg									0.1 mg/kg	
Cereals, roots, tubers, and derived products				0.1 mg/kg			0.2 mg/kg			2 mg/kg	2 mg/kg
Barley, wheat	0.02 mg/kg	0.2 mg/kg			0.02 mg/kg	10 mg/kg			0.5 mg/kg		
wheat flour						0.2 mg/kg			0.1 mg/kg	0.5 mg/kg	0.3 mg/kg

Maize	0.05mg/kg	0.02 mg/kg	0.05 mg/kg		0.02 mg/kg	0.05 mg/kg		0.02 mg/kg	0.05 mg/kg		
Sorghum	0.1 mg/kg	10 mg/kg	0.1 mg/kg		0.02 mg/kg	3 mg/kg			0.5 mg/kg		
Polished rice		1 mg/kg	0.1 mg/kg		0.02 mg/kg				0.5 mg/kg		
Oats, Rye					0.02 mg/kg						
Soya oil		0.2 mg/kg			0.02 mg/kg				0.03 mg/kg		
Sugar cane			0.1 mg/kg								

1.4 Maximum and Indicative limit values for contaminants in RUTF

Contaminants		**Maximum Limit Values**	**Calculated Indicative Limit values***
	Arsenic		<82 mcg/kg
	Cadmium		<22 mcg/kg
	Lead		<0.04 mg/kg
	Mercury		<16 mcg/kg
Pesticides	Carbamates	<10 ppb	
	Organochlorine	<10 ppb	
	Organophosphorus	<10 ppb	
	Pyrethroid	<10 ppb	
Biological contaminants	Total aflatoxins	<10 ppb	
	Combined hyoscyamine/scopolamine	<10 ppb	

Processing contaminants	3-MCPD		<109 mcg/kg**
	GE (Glycidyl Esters)		<11 mcg/kg
Radionuclides	Cs134 & Cs137	<370 bq/kg	

***** *These values are indicative only and shall be used as a target for maximum level in RUTF, not as standard limits. The manufacturer shall implement a close monitoring of the ingredients to try to minimise contaminations and reduce the level below the indicative limit values. Where contaminant levels are detected above the indicative limit value in finished product RUTF, a risk assessment shall be conducted by the manufacturer and provided to UNICEF to inform a risk/benefit decision.*

***This indicative limit value is calculated when considering a maximum tolerable intake (e.g., for 3-MCPD, PMTDI 4 mcg/kg bw/day), for a 5kg child receiving 2 sachets of RUTF per day (based on MSF protocols: ITFC: 170kcal/kg/day in transition phase = 1.7 RUTF sachets /ATFC: 2 sachets for children 5-9.9 kg)*

Applicable references

1. *Expert advice on appropriate criteria and limits for contaminants in Ready to Use Therapeutic Foods, 2018*
2. *USP (232) Elemental Impurities- Limits/chemical test, in drug substance*
3. *Evaluation of certain food additives and contaminants, Joint FAO/WHO Expert Committee on food additives, WHO Technical Report Series 947*
4. *Vitamin with minerals powder USP 42-NF 37 monograph (2019)*
5. *CXC 193-1995: General Standard for Contaminants and Toxins in Food and Feed.*
6. *CXG 33-1999 Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs*
7. *CXS 228-2001 General Methods of Analysis for Contaminants*

FOR MORE INFORMATION

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