L.N. 81 of 2002

FOOD, DRUGS AND DRINKING WATER ACT (CAP. 231)

Contaminants in Food Regulations 2002

IN exercise of the powers conferred by article 12 of the Food, Drugs and Drinking Water Act, the Minister of Health, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and commencement

1. The title of these regulations is the Contaminants in Foods Regulations, 2002, and shall come into force on the 30th April, 2002, provided that these Regulations shall not apply to products placed on the market before that date.

Scope and Applicability.

2.1 These Regulations concern contaminants contained in food.

2.2 These Regulations shall not apply to contaminants which are the subject of more specific rules.

Definitions.

3.1 In these regulations, unless the context otherwise requires, the following definitions shall apply:

"contaminant" means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this definition.

General Provisions.

4.1 Food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market.

4.2 Contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all the stages referred to in paragraph 3.1.

Specific Provisions.

5.1 The maximum levels for certain contaminants in foodstuffs indicated in the Schedule to these Regulations may not be exceeded. Where applicable, the maximum levels specified apply to the edible part of the foodstuffs mentioned.

5.2 The official sampling methods and performance criteria for methods of analysis shall be those laid down by the Schedule.

5.3 In the case of products, other than those mentioned under regulation 7.1, which are dried, diluted, processed or composed of more than one ingredient, the maximum level applicable shall be that laid down in the Schedule, taking into account respectively:

(a) changes of the concentration of the contaminant caused by drying or dilution processes,

(b) changes of the concentration of the contaminant caused by processing,

(c) the relative proportions of the ingredients in the product and

(d) the analytical limit of quantification

The first subparagraph shall apply in so far as no specific maximum levels are fixed for these dried, diluted, processed or compound products.

5.4 The maximum levels specified in the Schedule shall apply also to food intended for infants and young children, taking into account respectively, the changes of the concentration of the contaminant caused by drying, dilution or processing and the relative concentrations of the ingredients in the product.

5.5 Without prejudice to regulations 6.1 and 7.3, it is prohibited to use products as food ingredients for the production of compound foodstuffs which do not comply with the maximum levels set in the Schedule.

Nitrates

6.1 The Superintendent of Public Health, after consultation with the Director responsible for Plant Health and the Head of the Directorate responsible for foodstuffs within the Malta Standards Authority, may, where justified, authorise for a transitional period the placing on the market of fresh lettuces and fresh spinach, grown and intended for consumption in Malta, with nitrate levels higher than those set as maximum levels in the Schedule provided that codes of good agricultural practice are applied to achieve gradual progress towards the levels laid down in these Regulations.

Aflatoxins.

7.1 The maximum limits of aflatoxins applicable to the products, as laid down in points 2(1) and 2(4) of the Schedule shall also be

applicable to processed products thereof in so far as no specific maximum limits are fixed for such processed products.

7.2 With regard to aflatoxins in products mentioned in the first entry of point 2 of the Schedule, it is prohibited:

(a) to mix products complying with the maximum levels laid down in the Schedule with products exceeding these maximum levels or to mix products to be subjected to a sorting technique or physical treatment with products intended for direct human consumption or as an ingredient in foodstuffs,

(b) to use products which do not comply with the maximum levels laid down in point 2 of the Schedule as an ingredient for the manufacture of other foodstuffs,

(c) to detoxify products by chemical treatments.

7.3 Groundnuts, nuts and dried fruit not complying with the maximum levels of aflatoxins laid down in the first entry of point 2 of the Schedule and cereals not complying with the maximum levels laid down in the fourth entry of point 2 can be placed on the market provided that these products:

(a) are not intended for direct human consumption or used as an ingredient in foodstuffs,

(b) comply with the maximum levels laid down in the second entry of point 2 of the Schedule for groundnuts and the third entry of point 2 of the Schedule for nuts and dried fruit,

(c) are subjected to a secondary treatment involving sorting or other physical treatments and that after this treatment the maximum limits laid down in the first and fourth entries of point 2 of the Schedule are not exceeded, and this treatment does not result in other harmful residues,

(d) are labelled clearly showing their destination, and bearing the indication "product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs".

Arsenic

8.1 The general and specific limits for arsenic given in Part 6 of the Schedule shall not apply to:

(a) fish, edible seaweed, or any product containing fish or edible seaweed, where arsenic is naturally present at levels above 1 mg/kg in that fish or seaweed;

(b) any food other than a specified food, fish or edible seaweed which contains arsenic in excess of 1 mg/kg provided that such excess is a result of a specified food as an ingredient, and the increase in the arsenic is proportional to the amount of the specified food used;

(c) hops or hop concentrates intended for use in commercial brewing;

(d) any food for which the maximum arsenic limit is prescribed by any other provisions.

9.1 Lead in excess of 1 mg/kg may be present in: Lead

(i) a food containing two or more ingredients, provided

(a) not less than 10 % by weight of the food consists of an ingredient for which a higher quantity of lead is permitted, and

(b) the limits specified in the Schedule would not be exceeded if the ingredients were sold separately;

(ii) an additive premix consisting of a mixture of two or more substances for use as an ingredient in the preparation of food, which is in a container labelled with a conspicuous, clear and legible statement to the effect that it is an additive premix and is not intended for retail sale, provided the limits specified in the Schedule would not be exceeded if the ingredients were sold separately.

Schedule

Maximum Levels for Certain Contaminants in Foodstuffs

1. Nitrates

Product	Maximum level (mg NO_3/kg)		Sampling method	Reference analysis method
Fresh spinach [1] (*Spinacia oleracea*)	Harvested 1/11 to 31/3 1/4 to 31/10	 3000 2500	Directive 79/700/EEC	
Preserved, deep-frozen or frozen spinach		2000	Directive 79/700/EEC	
Fresh lettuce (*Lactuca sativa L.*) (protected and open-grown lettuce)	Harvested 1/10 to 31/3 1/4 to 30/9 with the exception of open-grown lettuce harvested from 1/5 to 31/8	 4500 3500 2500	Directive 79/700/EEC: However, the minimum number of units per laboratory sample is 10	

2. Mycotoxins

Product	Maximum level			Sampling method	Performance criteria for methods of analysis
	B_1	$B_1+B_2+G_1+G_2$	M_1		
Groundnuts, nuts and dried fruit and processed products of these, intended for direct human consumption or as an ingredient in foodstuffs	2 [2]	4 [2]	-	Directive 98/53/EC	Directive 98/53/EC

[1] The maximum levels for fresh spinach do not apply to fresh spinach to be subjected to processing and which is directly transported in bulk from field to processing plant

[2] The maximum limits apply to the edible part of groundnuts, nuts and dried fruits. If 'nuts in shell' are analysed, it is assumed when calculating the aflatoxin content that all the contamination is on the edible part.

Groundnuts to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	8 [2]	15 [2]	-	Directive 98/53/EC	Directive 98/53/EC
Nuts and dried fruit to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	5 [2]	10 [2]	-	Directive 98/53/EC	Directive 98/53/EC
Cereals (including buckwheat, *Fagopyrum* sp.) and processed products of these intended for direct human consumption or as an ingredient in foodstuffs	2	4	-	Directive 98/53/EC	Directive 98/53/EC
Cereals (including buckwheat, *Fagopyrum* sp.) to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs	2	4	-	Directive 98/53/EC	Directive 98/53/EC
Raw milk, milk for the manufacture of milk-based products and heat-treated milk	-	-	0.05	Directive 98/53/EC	Directive 98/53/EC

3. Heavy metals

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
1. LEAD (Pb)			

Cow's milk (Raw milk, milk for the manufacture of milk-based products and heat-treated milk)	0.02	Directive 2001/22/EC	Directive 2001/22/EC
Condensed milk (including evaporated milk)	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Sugars with a sulphated ash content not exceeding 0.25 per cent of the dry matter	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Sugars with a sulphated ash content exceeding 0.25 per cent of the dry matter but not exceeding 1.0 per cent of the dry matter	1.0	Directive 2001/22/EC	Directive 2001/22/EC
Sugars with a sulphated ash content exceeding 1.0 per cent of the dry matter but not for further refining	5.0	Directive 2001/22/EC	Directive 2001/22/EC
Sugars with a sulphated ash content exceeding 1.0 per cent of the dry matter for further refining	16.0	Directive 2001/22/EC	Directive 2001/22/EC
Cocoa powder	2.0 (calculated on the dry fat-free substance)	Directive 2001/22/EC	Directive 2001/22/EC
Tea	5.0	Directive 2001/22/EC	Directive 2001/22/EC
Infant formulae and follow-on formulae	0.02	Directive 2001/22/EC	Directive 2001/22/EC
Other infant foods (foods which are specially prepared for infants and young children and are described expressly or by implication as such, except infant formulae and follow-on formulae, rusks and dried, dehydrated or concentrated infant foods)	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Rusks	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Meat of bovine animals, sheep, pig and poultry	0.1	Directive 2001/22/EC	Directive 2001/22/EC
Edible offal of cattle, sheep, pig and poultry	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Corned beef	2.0	Directive 2001/22/EC	Directive 2001/22/EC

Game, game pâte	10.0 (excluding discrete particles of shot)	Directive 2001/22/EC	Directive 2001/22/EC
Muscle meat of fish, excluding fish species listed in the entry below	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Muscle meat of wedge sole (*Dicologoglossa cuneata*), eel (*Anguilla anguilla*), spotted seabass (*Dicentrarchus punctatus*), horse mackarel or scad (*Trachurus trachurus*), grey mullet (*Mugil labrosus labrosus*), common two-banded seabream (*Diplodus vulgaris*), grunt (*Pomadasys bennetí*), European pilchard or sardine (*Sardina pilchardus*)	0.4	Directive 2001/22/EC	Directive 2001/22/EC
Dried fish	5.0	Directive 2001/22/EC	Directive 2001/22/EC
Crustaceans, excluding brown meat of crab	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Bivalve molluscs	1.0	Directive 2001/22/EC	Directive 2001/22/EC
Other shellfish	10.0	Directive 2001/22/EC	Directive 2001/22/EC
Cephalopods (without viscera)	1.0	Directive 2001/22/EC	Directive 2001/22/EC
Cereals (including buckwheat), legumes and pulses	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Vegetables, excluding brassica, leafy vegetables, fresh herbs and all fungi. For potatoes, the maximum level applies to peeled potatoes	0.1	Directive 2001/22/EC	Directive 2001/22/EC
Brassica, leafy vegetables and all cultivated fungi	0.3	Directive 2001/22/EC	Directive 2001/22/EC
Fruits, excluding berries and small fruits	0.1	Directive 2001/22/EC	Directive 2001/22/EC
Berries and small fruits	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Dried or dehydrated fruit or vegetables	2.0	Directive 2001/22/EC	Directive 2001/22/EC
Dried herbs, spices (including ground spices and curry powder) and mustard (including prepared mustard)	10.0	Directive 2001/22/EC	Directive 2001/22/EC

Pickles and sauces	2.0	Directive 2001/22/EC	Directive 2001/22/EC
Tomato purée, paste or powder, the total solids content of which is not less than 15 per cent but less than 25 per cent	2.0	Directive 2001/22/EC	Directive 2001/22/EC
Tomato purée, paste or powder, the total solids content of which is not less than 25 per cent	3.0	Directive 2001/22/EC	Directive 2001/22/EC
Glacé angelica	2.0	Directive 2001/22/EC	Directive 2001/22/EC
Hydrolysed protein	2.0	Directive 2001/22/EC	Directive 2001/22/EC
Yeast, yeast products, excluding yeast extracts	5.0 (calculated on the dry matter)	Directive 2001/22/EC	Directive 2001/22/EC
Yeast extracts	2.0	Directive 2001/22/EC	Directive 2001/22/EC
Hops	10.0	Directive 2001/22/EC	Directive 2001/22/EC
Fats and oils, including milk fat	0.1	Directive 2001/22/EC	Directive 2001/22/EC
Fruit juices, concentrated fruit juices (for direct consumption) and fruit nectars	0.05	Directive 2001/22/EC	Directive 2001/22/EC
Soft drinks for consumption without dilution	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Non-alcoholic beverages, ready to drink, not otherwise specified	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Wines (including sparkling wines and excluding liqueur wines), aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails, and ciders, perry and fruit wines. Maximum level applies to products produced from the 2001 fruit harvest onwards	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Beer	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Brandy, geneva, gin, rum, whisky, vodka	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Water ices or other similar frozen confections	0.2	Directive 2001/22/EC	Directive 2001/22/EC

Ice cream or other similar frozen confections (excluding water ices and similar frozen confections)	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Flavourings	10.0	Directive 2001/22/EC	Directive 2001/22/EC
Chemicals for use in or with foodstuffs and not otherwise specified	10.0	Directive 2001/22/EC	Directive 2001/22/EC
Other foodstuffs, without prejudice to regulation 9.1	1.0	Directive 2001/22/EC	Directive 2001/22/EC
2. CADMIUM			
Meat of bovine animals, sheep, pig and poultry, excluding offal	0.05	Directive 2001/22/EC	Directive 2001/22/EC
Horsemeat	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Liver of cattle, sheep, pig and poultry	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Kidney of cattle, sheep, pig and poultry	1.0	Directive 2001/22/EC	Directive 2001/22/EC
Muscle meat of fish, excluding fish species listed in the entry below	0.05	Directive 2001/22/EC	Directive 2001/22/EC
Muscle meat of wedge sole (*Dicologoglossa cuneata*), eel (*Anguilla anguilla*), European anchovy (*Engraulis encrasicholus*), louvar or luvar (*Luvarus imperialis*), horse mackarel or scad (*Trachurus trachurus*), grey mullet (*Mugil labrosus labrosus*), common two-banded seabream (*Diplodus vulgaris*), European pilchard or sardine (*Sardina pilchardus*)	0.1	Directive 2001/22/EC	Directive 2001/22/EC
Crustaceans, excluding brown meat of crab	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Bivalve molluscs	1.0	Directive 2001/22/EC	Directive 2001/22/EC
Cephalopods (without viscera)	1.0	Directive 2001/22/EC	Directive 2001/22/EC
Cereals, excluding bran, germ, wheat grain and rice	0.1	Directive 2001/22/EC	Directive 2001/22/EC
Bran, germ, wheat grain and rice	0.2	Directive 2001/22/EC	Directive 2001/22/EC

Soybeans	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Vegetables and fruits, excluding leafy vegetables, fresh herbs, all fungi, stem vegetables, root vegetables and potatoes	0.05	Directive 2001/22/EC	Directive 2001/22/EC
Leafy vegetables, fresh herbs, celeriac and all cultivated fungi	0.2	Directive 2001/22/EC	Directive 2001/22/EC
Stem vegetables, root vegetables and potatoes (peeled), excluding celeriac	0.1	Directive 2001/22/EC	Directive 2001/22/EC
3. MERCURY			
Fishery products, except those in the entry below	0.5	Directive 2001/22/EC	Directive 2001/22/EC
Anglerfish (*Lophius* spp.) Atlantic catfish (*Anarhichas lupus*) Bass (*Dicentrarchus labrax*) Blue ling (*Molva dipterygia*) Bonito (*Sarda* spp.) Eel (*Anguilla* spp.) Halibut (*Hippoglossus hippoglossus*) Little tuna (*Euthynnus* spp.) Marlin (*Makaira* spp.) Pike (*Esox lucius*) Plain bonito (*Orcynopsis unicolor*) Portuguese dogfish (*Centroscymnes coelolepis*) Rays (*Raja* spp.) Redfish (*Sebastes marinus*, *S. mentella*, *S. viviparus*) Sail fish (*Istiophorus platypterus*) Scabbard fish (*Lepidopus caudatus*, *Aphanopus carbo*) Shark (all species) Snake mackerel (*Lepidocybium flavobrunneum*, *Ruvettus pretiosus*, *Gempylus serpens*) Sturgeon (*Acipenser* spp.) Swordfish (*Xiphias gladius*) Tuna (*Thunnus* spp.)	1.0	Directive 2001/22/EC	Directive 2001/22/EC

4. 3-MONOCHLOROPROPANE-1,2-DIOL(3-MCPD)			
Hydrolysed vegetable protein	0.02	Directive 2001/22/EC	Directive 2001/22/EC
Soy sauce [1]	0.02	Directive 2001/22/EC	Directive 2001/22/EC
5. TIN			
Canned foods	200		
6. ARSENIC			
Non-alcoholic beverages, ready to drink and not otherwise specified in this Schedule	0.1		
Alcoholic beverages, not otherwise specified in this Schedule	0.2		
Black beer, and mixtures of black beer and rum	0.5		
Soft drinks intended for consumption after dilution, and undiluted fruit juices (including concentrates)	0.5		
Ice cream, frozen confections and other similar commodities	0.5		
Onions, dehydrated	2.0		
Hops, dried, other than those intended for use in commercial brewing	2.0		
Liquorice (dried extract)	2.0		
Gelatine	2.0		
Yeast and yeast products other than brewers' yeast intended for manufacture of yeast products	2.0 (calculated on dry matter)		
Brewers' yeast intended for use by manufacturers in the manufacture of yeast products	5.0 (calculated on dry matter)		
Chicory (dried and roasted)	4.0		
Herbs (dried)	5.0		
Finings and clearing agents	5.0		
Hops and concentrates other than those intended for use in	5.0		

[1] Maximum level is given for the liquid product containing 40% dry matter, corresponding to a maximum level of 0.05 mg/kg in the dry matter. The level needs to be adjusted proportionally according to the dry matter content of the products.

commercial brewing			
Spices, including mustard	5.0 (calculated on dry matter)		
Flavourings	3.0		
Chemicals for use in or with foodstuffs and not otherwise specified	2.0		
Other foodstuffs, without prejudice to regulation 8.1	1.0		