

# Food Safety and Standards Act, 2006 and Regulations thereunder

In order to regulate food industry, including dairy industry, and also with a view to address food safety and quality comprehensively and holistically, the Government of India has enforced the new Food Safety and Standards Act 2006 and the Regulations, thereunder, with effect from August 2011. In fact, it has been a long journey for the country, and specifically for the domestic food industry, to witness this change in the national food laws with a much deliberated shift in its focus from 'prevention of food adulteration' to 'ensuring food safety' in the interest of all stakeholders.

The new food laws provide for a scientific risk-based approach in dealing with food safety, and a rational approach in dealing with issues of compliance by the food industry. The dairy sector as such is dealt with more comprehensively by the Food Safety and Standards Act 2006 and the Regulations thereunder, given the extensiveness of the provisions relating to milk and milk products/dairy businesses in these Regulations. This highlights the importance of milk and milk products as food, and also prominence of the dairy sector in the country.

In order to achieve the common goal of ensuring safety and quality of our food products, all stakeholders (including regulators, industry and other concerned agencies) need to continue working in tandem towards development of an enabling food safety regulatory environment and effective implementation of the same. The new food safety regulatory environment should be taken as an opportunity by the cooperative dairy sector to further streamline its operations and continue ensuring quality and safety of its dairy products in the market. Nevertheless, the dairy industry also needs to come forward in identifying valid issues confronting it for their meaningful resolution by the regulators.

A brief summary<sup>1</sup> of the Act and Regulations, thereunder, is provided below:

## **A. Food Safety and Standards Act, 2006**

### **Objectives of the Act**

As provided in the preamble of the Act, its main objectives are to: a) have a single law relating to food, b) establish the Food Safety and Standards Authority of India, c) lay down science based standards for articles of food,

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<sup>1</sup> This summary is intended to provide an overview and hence is by no means complete. For detailed information on the provisions, please refer to the relevant Act and Regulations.

d) effectively regulate food processing industry, and e) ensure availability of safe and wholesome food for human consumption.

### **Scope of the Act**

All types of foods intended for human consumption, including a) primary foods, b) unprocessed/semi-processed/processed food, c) genetically engineered foods, d) organic foods, e) substances and water used in food preparation, f) packaged drinking water etc. fall under the purview of the Act. It, however, excludes animal feeds, live animals and plants prior to harvesting from its scope. The provisions of the Act also do not apply to any farmer or farming operations or crops or livestock, and supplies used or produced in farming or products of crops produced by a farmer at farm level.

### **Elements of the Act**

Details of key provisions are as under:

- **Definitions:** The Act defines food, primary food, infant food, misbranded food, substandard food, unsafe food, food additive, ingredient, food safety, food safety audit, food safety management system, hazard etc. Likewise, definitions of pesticide residue and residues of veterinary drugs, and foods for special dietary uses, functional foods, nutraceuticals, health supplements, genetically engineered or modified foods and organic foods also appear in the Act.

*‘Primary food’* and *‘water’* used in the preparation of food are included in the definition of *‘food’*. However, *‘primary food’* (a produce of agriculture or horticulture or animal husbandry and dairying etc. in its natural form) is considered as an article of food for the purpose of this Act **only** when it is in the hands of a person other than farmer.

- **Enforcement of the Act:** The Food Safety Authority of India and the State Food Safety Authorities are responsible for enforcement of the Act. The State Authority comprises a Commissioner of Food Safety, Designated Officer for each district and Food Safety Officer for each specified local area. The Commissioner is primarily responsible for state level implementation of food safety standards and other requirements laid down under the Act and the regulations established thereunder.

Some specific functions of the Commissioner include - to carry out survey of food manufacturing /processing units in the State to find out compliance by such units of the food article standards; prohibiting in the interest of public health, manufacture/storage/distribution/sale of any article of food in the State or any part of the State for a period of up to 1 year.

The Act also provides for FSSAI recognised organisations/agencies carrying out food safety audit of food businesses and checking compliance with food safety management systems required under the Act or the regulations made thereunder.

- **Penalties:** The Act provides for graded penalties for food business operator (FBO) where offences like manufacturing, storing or selling misbranded or substandard food is punishable with a fine, and more serious offences with imprisonment. The Act also makes provision for monetary compensation by the concerned FBO in case of injury or death of the consumer as a result of consuming unsafe food. The Act, notably, also provides for a penalty provision (monetary) for Food Safety Officer for acting against an FBO on a false premise.
- **Responsibilities and liabilities of food business operators:** An FBO (i.e. anyone owning or carrying out a business relating to food) is required to obtain appropriate license from the Designated Officer under the Act. However, it exempts petty manufacturers and tiny food businesses from such a requirement and, instead, they are required to register themselves with appropriate authorities and comply with all provisions related to safe and wholesome food for human consumption.

The Act requires every FBO to ensure that the articles of food satisfy the requirements of this Act, and the regulations made, thereunder, at all stages of production, processing, import, distribution and sale within the business under its control. Therefore, the responsibilities of ensuring safety of food would be that of the FBOs.

Liabilities of manufacturers, packers, wholesalers, distributors and sellers in respect of violations under the Act are also mentioned. Notably, among various liabilities specified, wholesalers and sellers are also made liable under the Act for supplying or selling the article of food after the date of its expiry and handling/storing articles of food in unhygienic conditions.

The Act has a provision for food recall procedures. If a FBO has reasons to believe that a food item is not in compliance with the specified standards, he has to initiate procedures to withdraw the food in question and inform the competent authority.

- **Safety standards for food articles:** The Act prohibits use of food additives and processing aids in, and insecticides on, articles of foods unless they are in accordance with specified regulations.

Likewise, it also specifies that no article of food shall contain any contaminant, naturally occurring toxic substances or toxins, hormones, heavy metals, insecticide and pesticide residues, veterinary drug residues, antibiotic residues, solvent residues, pharmacologically active

substances, and microbiological counts in excess of tolerance limits as specified by Regulations under this Act.

The Act also prohibits manufacture, distribution, sale or import of any novel food, genetically modified articles of food, irradiated food, organic food, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods etc. except under the provisions of the Act and Regulations made, thereunder.

The Act makes it mandatory to label all packaged foods in a specified manner. It also specifies requirements for import of food articles into India, and also provides for laying down of standards by the Food Authority for import of food articles.

## **B. Regulations under Food Safety and Standards Act, 2006**

Several Regulations have been notified under the Act and enforced with effect from August 2011. These include:

### **Food Safety & Standards (Licensing & Registration of Food Businesses) Regulations, 2011:**

The regulation details requirements for the registration or license to operate a food business:

- All the FBOs have to get registered or obtain a license to operate food business.
- Petty FBOs shall register themselves with the registering authority as notifying by the state government. However a producer of milk who is registered member of a dairy cooperative society and supplies or sells the entire milk to the society is exempted from the provision of registration.
- Dairy units, including milk chilling units, are required to obtain licence/registration from different licensing/registration authorities on the basis of the following criteria:

Central Licensing Authority	State Licensing Authority	State Registration Authority
<ul style="list-style-type: none"><li>• Units handling more than 50,000 litres of liquid milk/day or 2,500 tonnes of milk solids per annum;</li><li>• Units operating business in more than one state; and/or,</li><li>• Units engaged in food imports.</li></ul>	Units handling more than 500 litres of milk up to 50,000 litres of milk/day	Units handling up to 500 litres of milk/day

- The Regulations provide the list of documents to be submitted for new application for license to Central/State Licensing Authority. Important among these are:
  - Name and list of equipment and machinery along with installed capacity.
  - Food Safety Management System Plan or Certificate, if any.
  - Analysis report (chemical & bacteriological) of water to be used as ingredient in food from a recognised/ public health laboratory to confirm its potability.
  - Recall plan wherever applicable, with details to whom the product is distributed (traceability).
  - NOCs from municipality or local body and from State Pollution Control Board.
- The Regulations also specify conditions of license. FBOs shall ensure that these conditions are complied with all times during course of its food business. The critical conditions among these are:
  - Maintain sanitary and hygienic standards and workers' hygiene as specified in Schedule – 4.
  - Inform Authorities about any change or modifications in activities/infrastructure of the FBO.
  - Ensure testing of relevant chemical and/or microbiological contaminants in food products in accordance with these regulations as frequently as required on the basis of historical data and risk assessment through NABL accredited/FSSAI notified labs at least once in six months.
  - Ensure that the required temperature shall be maintained throughout the supply chain from the place of procurement or sourcing till it reaches the end consumer including chilling, transportation, storage etc.
- These Regulations specify the general hygienic and sanitary practices to be followed by FBOs. These are the basic compulsory requirements for ensuring safety of food manufactured in any premises. FBOs are also required to continuously try to improve the sanitary and hygienic conditions at the premises with a goal of attaining HACCP standards.

The general requirements specified pertain to infrastructure facility, food operations and controls, sanitation and maintenance of establishment, personal hygiene etc. Specific hygienic and sanitary practices to be followed by FBOs engaged in manufacture, processing, storing and selling of milk and milk products are also included in the Regulations.

Dairy businesses shall ensure compliance with all conditions of license and safety, sanitary and hygienic requirements. Licensed dairy businesses are inspected by the authority or its agencies periodically. The

validity period of license/ registration is between 1 to 5 years as chosen by the FBO.

### **Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011**

The Regulations provide identity (compositional and quality) and food safety (chemical and bacteriological) standards of milk and different milk products, and also specify list of food additives permitted for use in various milk products. The salient features are as follows:

- These Regulations include definitions of milk and its various variants (mixed milk, full cream milk, standardised milk, toned milk, double toned milk, skimmed milk), recombined milk, milk products, and heat treatments used in dairy processing (pasteurisation and sterilisation).

The definition of milk is as under:

*“Milk is the normal mammary secretion derived from complete milking of healthy milch animal without either addition thereto or extraction therefrom unless otherwise provided in these Regulations. It shall be free from colostrum. ....”.*

As per this definition, milk sold as ‘buffalo’ or ‘cow’ or ‘mixed’ milk **cannot** be standardised to their respective minimum requirements of fat and solids-not fat content, as specified in these Regulations, by adjustment (extraction/addition) of milk solids.

Mechanical extraction of fat is allowed for ‘skimmed milk’ and adjustment of milk solids is allowed in full cream milk, standardised milk, toned milk and double toned milk, as provided for in their definitions.

- The compositional standards of around 50 types of dairy products are provided in these Regulations. The listed dairy products include milk, fermented milks (*dahi*, yoghurt), milkfat products (cream, ghee, butteroil), concentrated and dried milks, cheeses, dairy based desserts/confections (includes ice cream, milk lollies etc.), whey products, edible casein products, indigenous milk products (*khoa*, *shrikhand*, *paneer*) etc. These product standards are being reviewed by the Authority for harmonisation, as appropriate, with respective Codex standards where available.
- The permissible limits of different food additives for use in defined milk products are specified in the Regulations (Appendix A Tables 14 and 15). Appendix A, Table 3 provides list of additives for use in some proprietary dairy products. Only those additives listed in these Tables can be used in respective milk products at the levels specified therein.

The different classes of food additives permitted for use are: stabilizers and emulsifiers, thickener and modifying agents, flavours, colours (natural & synthetic), acidity regulators, preservatives, anticaking agents, acidifying agents, antioxidants etc. All these food additive provisions are being reviewed by the Authority for their harmonisation, as appropriate, with the related Codex provisions.

- Appendix B, Table 2 provides the microbiological standards for milk products. The sampling plans and the reference test methods are also mentioned. The specified microbiological standards include both hygiene (total plate count, coliform count, *E. coli*, yeast and mold count etc.) and food safety parameters (*Salmonella*, *Staphylococcus aureus*, spore count (aerobic and anaerobic), *Listeria monocytogenes* etc.

### **Food Safety and Standards (Contaminants, Toxins & Residues) Regulations, 2011**

The Regulations specify maximum limits/ maximum residue limits of various contaminants, toxins etc. in food products including milk and milk products.

- These Regulations prescribe maximum limits of 8 metal contaminants i.e. lead, copper, arsenic, tin, zinc, cadmium, mercury and methyl-mercury in food products, including dairy products.

Though the limit for lead in milk is not specifically mentioned in these Regulations, but the limit of 2.5 ppm for lead specified for 'Foods not specified' applies by default to milk also. This limit is 125 times less stringent than the Codex specified limit of 0.02 ppm for lead in milk.

- Maximum residue limits of the crop contaminants and naturally toxic substances, including aflatoxin in all articles of food and aflatoxin M<sub>1</sub> in milk are also specified in these Regulations. The limit for Aflatoxin M<sub>1</sub> in milk is 0.5 µg/kg or parts per billion (ppb) which is the same as specified in the relevant Codex standard.
- These Regulations also prohibit use of any insecticide directly on articles of food and further prescribe tolerance limits for residues of insecticides. For milk and milk products, residue limits of 26 insecticides are specified.
- The Regulations do not specify limits for residues of antibiotics and other pharmacologically active substances in milk and milk products.

A summary of the contaminant limits in these Regulations is provided in the Annex.

The limits/residue limits for the above chemical contaminants are being reviewed by the Authority for their possible harmonization with corresponding limits in the Codex Alimentarius.

### **Food Safety and Standards (Prohibition and Restrictions on Sale) Regulations, 2011**

These Regulations provide for certain restrictions and prohibition on sales or use/storage for sale of some food products. Important restrictions in respect of dairy products are as under:

- Cream which has not been prepared exclusively from milk or which contains less than 25 % of milk fat.
- Milk which contains any added water.
- Ghee which contains any added matter not exclusively derived from milk fat.
- Skimmed milk as milk.
- *Dahi* or curd not prepared from boiled, pasteurised or sterilised milk.
- Milk or a milk product specified in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 containing a substance not found in milk, except as provided in the regulations.
- Admixtures of butter and *ghee*.
- The sale of ghee having less Reichert Value (RM) and a different standard for Butyro-refractometer reading at 40<sup>o</sup> C than that specified for the area except under 'AGMARK' seal.

Additionally, the Regulations also mention that:

- No person shall sell or have in his possession for the purpose of sale or for use as an ingredient in the preparation of an article of food for sale a mixture of *ghee* or butter and any substance
  - prepared in imitation of or as a substitute for *ghee* or butter, or
  - consisting of or containing any oil or fat which does not conform to the definition of *ghee*.
- All types of i) infant milk foods including the cereal based weaning food and follow up formula, ii) condensed milks sweetened and iii) milk powders shall not be sold except under Indian Standards Certification Mark.

- No person shall store, expose for sale or permit the sale of any insecticide in the same premises where articles of food are stored, manufactured or exposed for sale.

### **Food Safety & Standards (Packaging & Labelling) Regulations, 2011**

These Regulations deal with the general packaging and labelling requirements for food products and also specify some product specific requirements for their packaging and labelling. Those relevant for dairy products are briefly presented below:

#### a) Packaging requirements:

- Containers made of aluminium, plastic material and tin used in packaging or storing of dairy products shall conform to the listed Indian Standards Specifications.
- Wrapping or packaging may not be re-used for dairy products, except where containers are of a type which may be re-used after thorough cleaning and disinfecting.
- Tin and plastic containers once used, shall not be re-used for packaging of *ghee*.

#### b) Labelling requirements:

- Every prepackaged food shall carry a label containing information on- name of the food, list of ingredients, nutritional information (including some claims related to type of fatty acids and nutrient enrichment), veg or non-veg identification, food additives declarations, name and complete address of the manufacturer, net quantity, lot/batch identification, date of manufacture/packing, best before and use by date with any associated storage conditions, country of origin for imported food, and instructions for use – in a manner as specified in these Regulations. Some notable provisions include:
  - When milk products derived solely from milk are used as ingredients in any food, the class title 'milk solids' can be used in the list of ingredients for all such milk products.
  - Added water is required to be declared in the list of ingredients except in cases where water forms part of an ingredient, such as, brine, syrup or broth, used in the compound food and so declared in the list of ingredients.
  - Nutritional information required to be declared on the label is in respect of energy and amounts of protein, carbohydrate (specifying quantity of sugar) and fat; any other nutrient for which a nutrition or health claim is made; and nutrients (minerals, proteins,

vitamins, metals or their compounds, amino acids or enzymes) used for the purpose of enrichment.

- The Regulations specify stringent labelling provisions in respect of infant milk substitute and infant foods. The label of these foods shall have certain mandatory statements and warnings as under:
  - a statement “MOTHER’S MILK IS BEST FOR YOUR BABY” in capital letters
  - a statement that Infant milk substitute should be used only on the advice of a health worker as to the need for its use and the proper method of its use.
  - a warning that Infant milk substitute or infant food is not the sole source of nutrition of an infant
  - Warning/caution-Careful and hygienic preparation of infant food/infant milk substitute is most essential for health.  
etc.
- Product specific labelling requirements in respect of some dairy products are also provided in these Regulations. The following additional label declarations are specified:
  - For condensed milk (unsweetened)

CONDENSED MILK UNSWEETENED (Evaporated Milk) (This tin contains the equivalent) of (x)..... litres of toned mik
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- For condensed milk (sweetened)

CONDENSED MILK SWEETENED This tin contains the equivalent) of (x)..... litres of toned mik with sugar added
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- For condensed skimmed milk (unsweetened)

CONDENSED SKIMMED MILK UNSWEETENED (Evaporated Milk) This tin contains the equivalent) of (x)..... litres of skimmed mik
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- For condensed skimmed milk (sweetened)

CONDENSED SKIMMED MILK SWEETENED This tin contains the equivalent) of (x)..... litres of skimmed mik with sugar added
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- For condensed skimmed milk (unsweetened)

CONDENSED SKIMMED MILK UNSWEETENED  
(Evaporated Milk) (This tin contains the equivalent) of (x).....  
litres of skimmed milk

- For condensed milk (sweetened and flavoured)

This has been flavoured with .....  
NOT TO BE USED FOR INFANTS BELOW SIX MONTHS

- For condensed milk/condensed skimmed milk (unsweetened) sterilized by Ultra High Temperature (UHT) treatment

This has been sterilized by UHT process

- For milk powder

MILK POWDER  
This tin contains the equivalent) of (x)..... litres of toned milk

- For milk powder containing lecithin

MILK POWDER IN THIS PACKAGE CONTAINS LECITHIN

- For partly skimmed milk powder

PARTLY SKIMMED MILK POWDER  
This tin contains the equivalent) of (x)..... litres of partly  
skimmed milk having ..... per cent milk fat

- For skimmed milk powder

SKIMMED MILK POWDER  
This tin contains the equivalent) of (x)..... litres of skimmed  
milk

- For malted milk food containing added natural colouring matter except caramel

MALTED MILK FOOD IN THIS PACKAGE CONTAINS  
PERMITTED NATURAL COLOURING MATTER

- For cheese (hard), surface treated with Natamycin

SURFACE TREATED WITH NATAMYCIN
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- For low fat *paneer* and *chhana*

LOW FAT PANEER/CHHANA
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- In addition to the above, dairy products permitted to contain artificial sweeteners are also required to mention on their label the following declaration

- |       |                                                                                    |
|-------|------------------------------------------------------------------------------------|
| (i)   | This contains ..... (Name of the artificial sweetener)                             |
| (ii)  | Not recommended for children                                                       |
| (iii) | (a) * Quantity of sugar added ..... gm/100gm<br>(b) No sugar added in this product |
| (iv)  | * Not for Phenylketonurics (if Aspartame is added)                                 |

\* To strike out whatever is not applicable.

Note: The above declarations are required to be completed by inserting at (x) or blank spaces, where indicated, the appropriate number or words.

### **Food Safety and Standards (Laboratory and Sampling Analysis) Regulations, 2011**

- These Regulations specify the 'Notified Laboratories' for analysis of samples of imported foods and 'Referral Laboratories' for analysis of samples of articles of foods under the provisions of the Act and their respective areas of jurisdiction.

The Centre for Analysis and Learning in Livestock and Food (CALF) of the NDDB has been notified by FSSAI as a referral laboratory for analysis of milk and milk products.

The Regulations also specify the quantity of sample of food items including the milk and milk products to be sent to the laboratories for analysis and the type and quantity of preservatives to be used in the food samples.

**ANNEX****STANDARDS FOR MILK AND MILK PRODUCTS ESTABLISHED UNDER  
THE FOOD SAFETY AND STANDARDS (CONTAMINANTS, TOXINS AND  
RESIDUES) REGULATIONS, 2011 IN INDIA****A. Tolerance limits for residues of pesticides in milk (unless otherwise mentioned)**

<b>S. no.</b>	<b>Pesticide</b>	<b>Tolerance Limit in milk, mg/kg (mg/kg=ppm)</b>	<b>Remark</b>
1.	2, 4- D	0.05	MMP
2.	Aldrin and dieldrin	0.15	Fat Basis, MMP, applies to aldrin and dieldrin singly or in combination, expressed as dieldrin
3.	Benomyl	0.10	Fat Basis, MMP
4.	Carbendazim	0.10	Fat Basis, MMP
5.	Carbofuran	0.05	Fat Basis, MMP, Sum of carbofuran and 3-hydroxy carbofuran expressed as carbofuran
6.	Chlordane	0.05	Fat Basis, MMP, Cis- & trans-chlordane
7.	Chlorfenvinphos	0.20	Fat Basis, MMP, Applies to alpha and beta isomers
8.	Chlorpyrifos	0.01	Fat Basis, MMP
9.	Cypermethrin	0.01	Fat Basis, MMP, Sum of isomers
10.	DDT	1.25	Fat Basis, MMP, Applies to DDT, DDD and DDE, singly or in combination
11.	Edifenphos	0.01	Fat Basis, MMP
12.	Ethion	0.50	Fat Basis, MMP, Applies to ethion and its oxygen analogue expressed as ethion
13.	Fenitrothion	0.05	Fat Basis, MMP
14.	Fenthion	0.05	Fat Basis, MMP, Sum of fenthion, its oxygen analogue & their sulphoxides, & sulphones, expressed as fenthion

S. no.	Pesticide	Tolerance Limit in milk, mg/kg (mg/kg=ppm)	Remark
15.	Fenvalerate	0.01	Fat Basis, MMP
16.	Heptachlor	0.15	Fat Basis, MMP, Applies to heptachlor & its epoxide expressed as heptachlor
17.	Hexachlorocyclohexane (HCH) (alpha)	0.02	--
18.	Hexachlorocyclohexane (beta)	0.02	--
19.	Hexachlorocyclohexane (gamma i.e. lindane)	0.01	--
		0.20	Fat Basis, MP
		0.20	Milk products with less than 2% fat
20.	Hexachlorocyclohexane (delta)	0.02	--
21.	Monocrotophos	0.02	MMP
22.	Paraquat	0.01	Paraquat Dichloride expressed as paraquat cations
23.	Phorate	0.05	Fat Basis, MMP, Sum of phorate, its oxygen analogue & their sulphoxide & sulphones expressed as phorate
24.	Phenthoate	0.01	Fat Basis, MMP
25.	Pirimiphos-methyl	0.05	Fat Basis, MMP
26.	Trichlorfon	0.05	--

MMP = Applies to milk and milk products

#### B. Maximum limits for toxic metals

Metal	Maximum Limit, mg/kg (mg/kg=ppm)	Remark
Arsenic	0.1	For milks
	1.1	Foods not specified (Applies for milk Products also)
	0.05	For infant milk substitutes and infant foods
	0.5	For ice cream, ice lollies and similar frozen confections

<b>Metal</b>	<b>Maximum Limit, mg/kg (mg/kg=ppm)</b>	<b>Remark</b>
Cadmium	1.5	Other foods <i>(Applies for milk and milk Products also)</i>
	0.1	For infant milk substitutes and infant foods
Copper	30	Foods not specified <i>(Applies for milk and milk Products also)</i>
	15 but not less than 2.8	For infant milk substitutes and infant foods
Lead	2.5	Foods not specified <i>(Applies for milk and milk Products also)</i>
	0.2	For infant milk substitutes and infant foods
	1.0	For ice cream, iced lollies and similar frozen confections
Mercury	1.0	Other foods <i>(Applies for milk and milk Products also)</i>
Methyl-mercury (calculated as the element)	0.25	All foods <i>(Applies for milk and milk Products also)</i>
Tin	5.0	For infant milk substitutes and infant foods
	250	Foods not specified <i>(Applies for milk and milk Products also)</i>
Zinc	50 but not less than 25	For infant milk substitutes and infant foods
	50	Foods not specified <i>(Applies for milk and milk Products also)</i>

### C. Maximum limits of crop contaminant

<b>Contaminant</b>	<b>Maximum Limit, µg/kg (µg/kg = ppb)</b>	<b>Remark</b>
Aflatoxin	30	In all articles of food
Aflatoxin M <sub>1</sub>	0.5	For milk