



Food Safety and Standards
Authority of India

**[FOOD SAFETY AND STANDARDS
(CONTAMINANTS, TOXINS AND
RESIDUES) REGULATION, 2011 AND
FAQ]**

INTRODUCTION:

The Food Safety and Standards (Contaminants, Toxin and Residues) Regulation, 2011 came into force on 5th August, 2011 and deals with the compliance of various Contaminants, toxins and Residues Standards prescribed in food. The salient features of these regulations are : It provides detailed standards of various contaminants, naturally occurring toxic substances and residues of insecticides in different food articles.

The regulation is divided into two chapters. Chapter 1 deals with the implementation period and definitions of crop contaminants. Chapter 2 provides maximum limits of various metal contaminants, crop contaminants, residues of insecticides, antibiotic and pharmacologically active substances in different foods.

Features of the Regulation:

Chapter 1.

The first part of the chapter prescribes the date on which these regulations came into force and the definition of crop contaminant.

Chapter 2:

This chapter is broadly classified into three sub-regulations, i.e, Regulation 2.1 Metal Contaminants, Regulation 2.2 Crop Contaminants and naturally occurring toxic substances and Regulation 2.3 Residues. As per the maximum limits specified therein, the Food Business Operator should comply with the limits for their food products for which they have been granted license/ registration as mentioned in this regulation. In addition the standards laid down in Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 shall also be adhered to.

Regulation 2.1 Metal Contaminants. It prescribes the limits (parts per million by weight) of various metals in different articles of food in quantities not in excess of, as specified in the table of this regulation. The various types of metal contaminants covered in this regulation are lead, Copper, Arsenic, Tin , Zinc, Cadmium, Mercury, Methyl Mercury, Chromium and Nickel.

The regulation also states that chemicals described in monographs of the Indian Pharmacopoeia when used in foods, shall not contain metal contaminants beyond the limits as specified in appropriate monographs of Indian Pharmacopoeia.

Regulation 2.2 Crop Contaminants and naturally occurring toxic substances: Prescribes the maximum limits in $\mu\text{g}/\text{Kg}$ of crop contaminants like Aflatoxin, Aflatoxin M₁, Patulin and Ochratoxin A, in different articles of food. It also prescribes the maximum limit of contaminants naturally occurring in any article of food like Agaric acid, Hydrocyanic acid, Hypericine and Saffrole.

Regulation 2.3 Residues: This regulation specifies that no insecticides shall be used directly in any article of food unless as specified in regulation 2.3.1 (2) of this Regulation, which prescribes the tolerance limits of different insecticide in different foods.

Also for the purposes of this Regulation, the expression "insecticide" shall have meaning as assigned to it in the Insecticide Act, 1968 (46 of 1968), unless otherwise stated. It also states that maximum levels are expressed in mg/kg on a whole product basis and that the term "all foods" mentioned in the table in regulation 2.3.1 refers to raw agricultural products moving in commerce.

It is also mentioned that nothing in this Regulation will apply to fumigants which are registered and recommended for use in food articles by Registration Committee, constituted under Insecticides Act, 1968. This Regulation prescribes the tolerance limit for a total of 149 Insecticides which includes insecticides like Carbaryl, D.D.T, Endosulfan A and B, Melathion etc.

Regulation 2.3.2 prescribes the maximum tolerance limit of antibiotics in shrimps, prawns and any other variety of fish and fishery products. Mainly four types of antibiotics i.e Tetracycline, Oxytetracycline, Trimethoprim and Oxolinic acid are covered in this regulation. In addition it also includes the list of antibiotics and other pharmacologically active substances which are prohibited for use in seafood processing units including shrimps, prawns or any other variety of fish and fishery products. Some of the prohibited antibiotics and other pharmacologically active substances are all Nitrofurans including, Furalfadone, Furazolidone, Chloramphenicol and Nalidixic acid etc.

Frequently Asked Questions (FAQs)

Q1. What are contaminants in food and crop contaminants?

Ans. As per the definition laid in Food Safety and Standards Act, 2006 a "contaminant" means any substance, whether or not added to food, but which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry or veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination and does not include insect fragments, rodent hairs and other extraneous matter;

"Crop contaminant" means any substance not intentionally added to food, but which gets added to articles of food in the process of their production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging transport or holding of articles of such food as a result of environmental contamination.

Q2. What are commonly found metal contaminants in food products?

Ans. Following are the commonly occurring metal contaminants found in Food products Lead, copper, Arsenic, Tin, zinc, Cadmium Mercury, chromium, Nickel and their limits in ppm across different food products is prescribed in Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011.

Q3. What does the Indian Law say about metal contamination?

Ans. The Food Safety and Standards (Contaminants, Toxin and Residues) Regulation, 2011 prescribes that the chemicals as described in the monograph of Indian Pharmacopoeia when used in food shall not contain metal contaminants beyond the limit prescribed therein. The regulation also prescribes the quantity in ppm per weight of various metal contaminants across different articles of food.

Q4. How many insecticides have been covered under this regulation whose tolerance limit has been prescribed?

Ans. a total of 149 insecticides have been covered in this regulation whose tolerance limit have been prescribed.

Q5. What are the commonly found crop contaminants covered in this regulation?

Ans. The commonly occurring crop contaminants covered in this regulation are Aflatoxin, Aflatoxi M₁, Patulin and Ochrtoxin.

Q6 What practice can be followed to control mycotoxin contaminations in raw agricultural produce?

Ans. Codex alimentarius has developed code of practice for prevention and reduction of mycotoxin contamination in cereals which can be referred on the Codex Alimentarius website with the reference code as CAC/RCP 51-2003. It recommended practices based on good agricultural practices (GAP) and good manufacturing practices (GMP) at levels of pre-harvest, Harvest, storage, Transport and Storage and it also provides a complementary management system to consider in the future.

Q7. What are naturally occurring toxic substances?

Ans. The toxic substances which may occur naturally in any article of food are referred to as naturally occurring toxic substances (NOTS) for eg. Agaric acid, Hydrocyanic acid, Hypericine, Saffrole.

Q8. what is an ADI?

Ans. ADI is referred to as Acceptable Daily Intake, It is a measure of the amount of a specific substance (originally applied for a food additive, later also for a residue of a veterinary drug or pesticide) in food or drinking water that can be ingested (orally) on a daily basis over a lifetime without an appreciable health risk. ADIs are expressed usually in milligrams (of the substance) per kilograms of body weight per day. ADI is a safety touchstone for regulating pesticide in foods. Problem posed by pesticide led to the global scientific community developing the concept of ADI. Regulators across the world make sure that pesticide exposure of the population never exceeds the ADI.

Q9. How are MRLs/MLs estimated?

Pesticide residues on crops are monitored through the use of Maximum Residue Limits (MRL), which are based on the analysis of the quantity of a given chemical remaining on food product samples. The MRL is usually determined by repeated (on the order of 10) of field trials, where the crop has been treated according to Good Agricultural Practice (GAP) and an appropriate pre harvest interval or withholding period has elapsed. Regulating pesticides on the ground revolves around a regulatory yardstick called the MRL- or Maximum Residue Limit- of a pesticide in a food commodity. It is legally enforceable standard.

Q10. What is PPM?

Ans. Parts per million also can be expressed as milligrams per litre (mg/L). This measurement is the mass of a chemical or contaminate per unit volume of water. Most contaminants are expressed as parts per million (ppm). This means that the concentration of a particular substance is very low even though the regulatory agency may consider it a significant amount. One ppm is 1 part in 1 million or the value is equivalent to the absolute fractional amount multiplied by one million. A better way to think of ppm is to visualize putting four drops of ink in a 55-gallon barrel of water and mixing it thoroughly. This procedure would produce an ink concentration of 1 ppm.

Q11. Are there any national standards regulating antibiotics in honey?

Ans. The imports and domestic consumption of honey is managed by FSSAI. FSSAI has issued an advisory on banning use of antibiotics in honey which can be referred on www.fssai.gov.in. The BIS has a norm for extracted honey under IS 4941:1994. Brands wishing to obtain the ISI mark (also known as standards mark that suggests conformity to BIS rules) have to follow it. There is also the honey grading and marking rules, 2008 under Agriculture Produce (Grading and Marking) Act, 1937 which is implemented by the Union ministry of agriculture.

Q12. What it is the source of antibiotics in honey?

Ans. Antibiotic traces in honey come from the bees that are treated with antibiotics. Beekeepers largely use these antibiotics to cure bacterial diseases, but some also use them to promote growth and production.

Today honey is produced in an environment polluted by different sources of contamination. Environmental sources of this contamination include pesticide, heavy metals, bacteria and radioactivity. Contamination also comes from beekeeping practice (apiculture): acaricides used to control parasitic mites, bee repellents used during harvesting season, pesticide for wax moth etc. Antibiotics like oxytetracyclin, for instance are used to treat disease such as European foulbrood disease.

Q13. Why are antibiotics used in foods?

Ans. Antibiotics are used for treating diseases. Typically, the kind of antibiotics used in farm animals are the same as or closely related to those used in humans.

Q14. How does India regulate antibiotics in food?

Ans. In India, antibiotics are used widely in food animals as growth promoters and to prevent and treat infections. Non-therapeutic usage of antibiotics has been especially common in poultry production and fisheries and now, in bee keeping. However, under the Food Safety and Standards act, 2006, currently there are no regulatory provisions regarding the use of antibiotics in livestock. The Regulation regulates use of antibiotics in fisheries under regulation 4.4.2; Antibiotics and other pharmacologically active substances of this regulation. The regulation gives a list of antibiotics and other pharmacologically active substances that are prohibited in any unit processing sea foods.

Q15. Are there any limits for antibiotics in this regulation? Which are the prohibited antibiotics?

Ans. The tolerance limits for antibiotics Tetracycline, Oxytetracycline, Trimethoprim and Oxolinic acid have been prescribed for sea foods including shrimps, prawns or any other variety of fish and fishery products. A total of 28 antibiotics and other Pharmacologically Active Substances are prohibited in any unit processing sea foods including shrimps, prawns or any other variety of fish and fishery products. The list of 28 prohibited antibiotics can be obtained in regulation 2.3.2 of Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011.