



FSSAI ISSUES REGULATIONS SPECIFYING PERMISSIBLE LIMITS OF TOXINS IN FOOD

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The FSSAI has issued a draft notification to amend the Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011. The proposed amendment specifies the permissible levels of toxic metal contaminants including lead, arsenic, tin and cadmium in food items by introducing the following entries against each metal toxin/contaminant proposed to be regulated under the said regulations:

- Lead Various fruits and vegetables (including assorted subtropical, bulb, leafy and legume vegetables), pulses, canned fruits and vegetables, jam, mango chutney, table olives, pickled cucumber, processed tomato concentrates, fruit juices, cereal grains, meat of cattle, sheep and pig (including fat from such meat)
- Arsenic Margarine, minarine, named animal fats, mineral water, fish and crustaceans, molluscs, salt, vegetable oil, olive oil, edible fats and oils
- Tin Canned fruits, canned vegetables, pickled cucumber, mango chutney, table olives, processed tomato concentrates, luncheoned meat canned fish products and cooked cured chopped meat products, including ham, pork shoulder and beef
- Cadmium Fruity, leafy & legume vegetables, potatoes, wheat, rice, cereal grains, pulses, salt and mineral water
- Mercury Natural mineral water, salt, food grade, non-predatory fish, crustaceans, cephalopods, mollusks and predatory fish such as tuna, sword fish and all fishery products
- Chromium All fishery products

This amendment comes with a view towards fixing the standards in processed foods with presence of heavy metal contaminants in them, especially in the backdrop of findings of lead beyond permissible limits in the instant noodles Maggi, owned by Nestle Group.

PSA view: In light of the hue and cry over hygiene levels pertaining to food processing and the monitoring of contaminants in food products in the Indian market, this draft notification is a much awaited step by the FSSAI towards harmonizing the Indian food safety standards with the international standards, like Codex.

FSSAI proposes rules on health supplements and nutraceuticals

The FSSAI has recently issued a draft of Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary uses, Foods for Special Medical Purposes, Functional Foods, and Novel Foods) Regulations, 2015 ("Draft Regulations"). These Draft Regulations have defined and classified Nutraceuticals, Foods for Special Dietary Use, Foods for Special Medical Purposes, Foods containing Probiotic Ingredients, Foods containing prebiotic ingredients, Specialty Foods containing ingredients based on Ayurveda, Unani and Siddha and Traditional Health Systems of India and Novel Foods on the basis of essential composition, labeling, usage of additives, contaminants and toxins, besides claims on health and nutritional values. The Draft Regulations further mandate manufacturers to label such foods as "food or health supplement" and to prominently display on such labels, the phrase "not for medicinal use", and specify the quantity one must intake and that the product does not intend to cure any disease etc. These labeling requirements are in addition to the existing requirements under Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

PSA view: While separating items like health supplements and nutraceuticals from medicines in terms of classification may make it easier for the FSSAI to regulate the manufacture, processing and sale of such foods, the additional labeling requirements may complicate compliance for food business operators who now have to comply with specific packaging and labeling requirements for different food categories in addition to the existing requirements under the Food Safety and Standards (Packaging and Labeling) Regulations, 2011. IPC makes ADR reporting easy

IPC has made a strategic move to promote involvement of the healthcare professionals in strengthening the Pharmacovigilance Programme of India. IPC has recently released suspected adverse drug reaction ("ADR") reporting forms for voluntary reporting of adverse drug reactions by healthcare professionals. With this form, all healthcare professionals including clinicians, dentists, pharmacists and nurses can report ADRs to IPC. The form empowers healthcare professionals to notify IPC which acts as the national coordination centre for the PvPI programme of India on any suspected cases of ADRs. With this form, healthcare professionals can report adverse reactions due to herbal products as well as non-serious reactions too. The form so collected shall be periodically forwarded to the global pharmacovigilance database managed by WHO Uppsala Monitoring Centre in Sweden.

PSA view: It is high time that a mechanism is devised wherein pharma covigilance is made mandatory on drug manufacturers and doctors. The form is indeed a laudable step and a welcome move as far as patient safety and drug monitoring is concerned.

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