Food Safety and Standards Authority of India

Advisory No.: 2/FSSAI/2008

ADVISORY TO THE STATE HEALTH AUTHORITIES ON MONITORING MELAMINE CONTAMINATION OF FOODS

Background

Melamine has been detected at high levels in several foods and feeds in many countries. In most of the cases the adulterated foods or its ingredients have been traced to China.

In September this year, there were extensive media reports about thousands of infants in China being affected due to melamine contamination of baby foods. At least four babies have died and around 1 lakh have become sick after consuming powdered milk baby food laced with melamine. According to the reports the milk used to make the baby food was adulterated with melamine to enhance its apparent protein content. Products of dozens of Chinese companies have been reported to contain high levels of melamine.

Several countries have subsequently reported presence of melamine in the food products entering their markets. It remains a possibility that melamine contaminated food is present also in the Indian market.

In view of the above, it is necessary that special attention is paid by the State Food Authorities to protect Indian consumers from the adverse health effects associated with consumption of melamine contaminated / adulterated food.

This advisory is being issued to provide the State Food Authorities with available relevant information on the significance and sources of melamine contamination of food and to facilitate appropriate preventive actions on their part to address this current food safety situation on urgent basis.

Melamine

Melamine is an organic base and is only slightly soluble in water. It contains 66 % nitrogen. It has a variety of non-food uses. Some such uses are in making the following products:

- Amino resins and plastics
- Melamine foam, a polymeric cleaning product
- Fabrics
- Glues

- Flame retardants
- Major component of pigment yellow 150 (colorant for inks and plastics)
- Nitrogenous fertilizers
- Melamine derivatives of arsenical drugs - Treatment of African sleeping sickness (trypanosomiasis)

Melamine is also a minor metabolite of the pesticide cyromazine, and is formed in the body of mammals who ingest cyromazine. Cyromazine is also reported to be converted into melamine in plants.

Melamine and its structural analogues – ammeline, ammelide and cyanuric acid – can contaminate foods due to widespread use of melamine in plastics and as an adulterant to increase the nitrogen content in foods.

Harmful Effects

- Laboratory studies have shown calculi (stone) formation, inflammatory reactions and hyperplasia (excessive formation of cells) in the urinary bladder in rats and mice experimentally fed with melamine through diet.

- The harmful effect of melamine is considered to increase in combination with its analogues, particularly cyanuric acid.

- The deaths of four infants and sickness of thousands infants in China on consumption of melamine laced baby food have been attributed to formation of kidney stones and acute renal failure.

Toxicological Reference Values and Food Legislation

- The United States Food and Drug Authority (FDA) derived a Tolerable Daily Intake (TDI) of 0.63 mg/kg body weight for melamine and its structural analogues (ammeline, ammelide and cyanuric acid). Considering that half (1.5 kg) of the 3 kg food consumed by a person weighing 60 kg is contaminated with melamine, and keeping an additional safety factor of 10 on the TDI due to the reported increased toxicity of melamine in presence of cyanuric acid, the US-FDA has calculated that any food (other than infant formula) should not contain more that 2.5 ppm melamine and its analogues to be within the above TDI.

- In 2007, the European Food Safety Authority (EFSA) made a provisional recommendation to apply a TDI of 0.5 mg/kg body weight for total melamine and its analogues (ammeline, ammelide and cyanuric acid).

- In Europe, melamine is approved for use as a monomer and as an additive in plastics with a specific migration limit of 30 mg/kg food (Commission Directive EC No 2002/72 related to materials and articles intended to come into contact with foodstuffs from 6 August 2002).

- It is considered that infant formula should not contain melamine more than 1 ppm and other foods not more than 2.5 ppm.

Presence of Melamine in Foods

Contamination

Melamine can enter the food chain through the following possible routes:

- Use of the pesticide cyromazine on crops.

- Use of nitrogenous fertilizers (if containing melamine as a source of nitrogen) for growing food crops.

- Consumption of cyromazine / melamine contaminated crops / crop residues by food producing animals. Cyromazine is metabolized into melamine in the animal's body and, therefore, could be present as contaminant in the animal origin food.

- Leaching of melamine from plastics used in food equipment, containers or packaging materials that come in contact with food, especially acidic foods at high temperatures.

Levels of melamine in foods through these contaminating sources are considered low and not a concern to human health.

Adulteration

Foods may be adulterated with melamine to make the protein content of the food appear higher for economic gains. It has been claimed that levels below 2.5 ppm melamine in foods is not deemed to indicate adulteration.

Specific Actions to be taken by State Food Authorities

In view of the seriousness of the matter, the State Food Authorities are advised to take special care and actions to ensure that food products containing melamine are not present in the market to protect consumer's health. Following specific actions must be taken with immediate effect:

1. Set up special Inspection Teams of inspectors responsible for monitoring melamine in foods in the market and food manufacturing facilities. Both imported products as well as domestically produced products should be covered in monitoring.

2. Testing food material for presence of melamine. Samples of milk and dairy products should be collected regularly from the market and manufacturing facilities and tested for presence and levels of melamine.

   Melamine content of more than 1 ppm in infant formula and more than 2.5 ppm in other foods should be viewed with suspicion of adulteration and such foods should not be allowed to be sold.

3. All Chinese made dairy products should be withdrawn from the market. All other Chinese made food products, or food products containing ingredients imported from China, should be tested for melamine. If tested to contain more than 2.5 ppm of melamine, the food should be withdrawn from the market.

4. Consumers should be advised to avoid consuming Chinese origin dairy foods, or foods containing Chinese origin ingredients.

5. Request consumers to report any instance of sale of Chinese origin milk products in India, immediately to an identified officer. Such products should be removed from the shelf immediately.

The State Food Authorities will keep the FSSAI informed of the status by submitting fortnightly report for the next four months initially. Any significant result of monitoring should be informed to the FSSAI immediately.

Analytical Methods

1. The analytical methods based on GC/MS, ELISA, HPLC/UV, LC/MS and LC/MS-MS for detecting and quantifying melamine in different food matrices are provided in the Appendix 1.

2. The detailed procedure for testing melamine in infant foods using LC/MS-MS is provided in Appendix 2.

3. Appendix 3 provides procedure to detect non-protein nitrogen rich substances added in milk/milk products.