

Melamine Concerns Prompt Tighter Regulations Worldwide

The recent discovery of melamine tainted milk powder and dairy products produced in China has raised public concern worldwide. A number of countries worldwide have either banned or are stepping up monitoring of China-sourced dairy products over fears they could contain milk contaminated with the chemical. Recent regulatory developments are summarized below:

United States: FDA issued the Interim Safety and Risk Assessment of Melamine and its Analogues in Food for Humans which concludes the following:

- No amount of melamine is considered safe in infant formula at this point.
- For all other foods, only amounts less than 2.5 ppm do not raise public health concerns.
- Link to: [FDA Report](#).

Canada: Health Canada has set the following interim standards for melamine in products containing milk and milk-derived ingredients:

- A maximum of 1 ppm for infant formula and sole source nutrition products, including meal replacement products.
- A maximum of 2.5 ppm for other food products containing milk and milk-derived ingredients.
- Link to: [Health Canada](#).

Hong Kong: Amendment to Harmful Substances in Food Regulation (Cap. 132 AF) sets forth the following:

- Any food intended to be consumed principally by children under the age of 36 months and any food intended to be consumed principally by pregnant or lactating women shall not contain melamine in excess of 1 mg/kg.
- For other foods, melamine level shall not exceed 2.5 mg/kg.
- Link to: [Hong Kong Amendment](#).

China: New national standard GB/T 22388-2008 sets forth the following:

- Limit of 1 mg/kg for infant formulas
- Limit of 2.5 mg/kg for other dairy products and foods that contain more than 15% milk.
- Melamine determination methods set in the standard are HPLC, GC-MS or GC-MS/MS, and LC-MS/MS, with quantification limits of 2mg/kg, 0.05 mg/kg, and 0.01mg/kg respectively. The standard applies to the quantitative measurement of melamine level in raw milk, dairy products and products with milk content.

European Union: Commission Decision 2008/798/EC (published October 14, 2008, and repealing Decision 2008/757/EC) contains the following specific measures:

- The import and sale of all infant formula and follow-on formula from China is prohibited.
- All composite products from China that contain milk **at any level** must be detained at import and tested to ensure they do not contain melamine at a concentration greater than 2.5mg/kg.

- Composite feed that contains milk from China is also covered under the terms of the Decision. This requirement will ensure that non-compliant food product is not diverted for animal feed use.
- High protein-content products other than milk-containing products may be controlled if Member States suspect they could be contaminated with melamine; however this is not an obligation of Member States.
- All imports must come via a designated point of control where the checks are to be carried out.
- Importers of milk-containing products from China must give prior notification of the importation of the product to the authority at the designated point of control.
- Member States are required to check product already on the market on a random basis to ensure that it does not contain melamine.
- Any product found to contain melamine at a concentration greater than 2.5mg/kg will be destroyed.
- The importer shall bear the costs incurred as part of the import controls. The food business operator responsible for a product found to be non-complaint shall bear the costs of controls on, and destruction of, that product.
- Link to: [European Commission Decision](#).

Australia and New Zealand: Food Standards Australia New Zealand (FSANZ) has made the following determinations:

- A maximum level of 1 mg/kg for melamine in infant formula is considered appropriate.
- A maximum level of 2.5 mg/kg for melamine in dairy-based foods and foods containing dairy-based ingredients is appropriate and acceptable.
- A level of melamine above 2.5 mg/kg of food is indicative of food adulteration.
- For infant formula, even at relatively low levels of adulteration, an infant will quickly exceed the Tolerable Daily Intake for melamine, if consuming formula only.
- Foods with low levels of dairy-based ingredients, such as candies and biscuits, are likely to be infrequently consumed and in small amounts so they are not considered to be a high-risk food for potential dietary exposure to melamine even if the dairy ingredient has been adulterated.
- Link to: [Food Standards Australia New Zealand](#).

To assist manufacturers, distributors and retailers, STR is pleased to offer melamine testing of raw materials, intermediate and finished products. Our hazard prevention program includes comprehensive design evaluation, safety testing, audit, inspection and responsible sourcing services. For more information, contact us at info@STRQuality.com.